

**TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH
CHAPTER 681. MEDICAL MARIJUANA CONTROL PROGRAM**

RULEMAKING ACTION:

Notice of proposed PERMANENT rulemaking.

PROPOSED RULES:

- Subchapter 1. General Provisions [AMENDED]
 - 310:681-1-1. Purpose [AMENDED]
 - 310:681-1-2. Regulatory program established [AMENDED]
 - 310:681-1-3. Limitations of licenses [AMENDED]
 - 310:681-1-4. Definitions [AMENDED]
 - 310:681-1-5. Criminal history screening [AMENDED]
 - 310:681-1-6. Proof of residency [AMENDED]
 - 310:681-1-7. Proof of identify [AMENDED]
 - 310:681-1-8. Applicant photograph [AMENDED]
 - 310:681-1-9. Recommending physician registration [AMENDED]
 - 310:681-1-9.1.Recommending physician standards [AMENDED]
- Subchapter 2. Medical Marijuana Licenses [AMENDED]
 - 310:681-2-1. Application for patient license [AMENDED]
 - 310:681-2-2. Application for patient license for persons under age eighteen (18) [AMENDED]
 - 310:681-2-3. Application for caregiver’s license [AMENDED]
 - 310:681-2-3.1. Withdrawal of a caregiver’s authorization [AMENDED]
 - 310:681-2-4. Application for temporary patient license [AMENDED]
 - 310:681-2-5. Term and renewal of medical marijuana license [AMENDED]
 - 310:681-2-8. Possession limits [NEW]
 - 310:681-2-9. Prohibited Acts and penalties [NEW]
 - 310:681-2-10. Confidential patient information [NEW]
- Subchapter 3. Transportation License [AMENDED]
 - 310:681-3-1. License for transportation of medical marijuana [AMENDED]
 - 310:681-3-2. Requirements for transportation of marijuana [AMENDED]
 - 310:681-3-3. Transporter agent license [NEW]
 - 310:681-3-4. Employer deactivation of transporter agent license [NEW]
 - 310:681-3-5. Information contained on a transporter agent license [NEW]
 - 310:681-3-6. Inventory manifests [NEW]
- Subchapter 4. Medical Research License [AMENDED]
 - 310:681-4-1. License required [NEW]
 - 310:681-4-1.1. Responsibilities of the license holder [NEW]
 - 310:681-4-2. Licenses [NEW]
 - 310:681-4-3. Applications [NEW]
 - 310:681-4-4. Inspections [NEW]
 - 310:681-4-5. Inventory tracking, records, and reports [NEW]
 - 310:681-4-6. Penalties [NEW]
- Subchapter 5. Commercial Establishments [AMENDED]
 - 310:681-5-1. License required [AMENDED]
 - 310:681-5-1.1. Responsibilities of the license holder [AMENDED]
 - 310:681-5-2. Licenses [AMENDED]
 - 310:681-5-3. Applications [AMENDED]
 - 310:681-5-3.1. Proof of residency for commercial licensees [NEW]
 - 310:681-5-3.2. Persons prohibited from holding a commercial license [NEW]
 - 310:681-5-4. Inspections [AMENDED]
 - 310:681-5-6. Inventory tracking, records, reports, and audits [AMENDED]

310:681-5-6.1. Penalties [AMENDED]
 310:681-5-8. Composition of medical marijuana industry expert board/food safety standards board [AMENDED]
 310:681-5-8.1. Food safety standards for processors [AMENDED]
 310:681-5-9. Standards for handling and processing medical marijuana and medical marijuana products [AMENDED]
 310:681-5-10. Medical marijuana waste disposal [AMENDED]
 310:681-5-12. Marijuana transaction limitations [AMENDED]
 310:681-5-17. Entry to commercial establishments [AMENDED]
 310:681-5-18. Prohibited acts [AMENDED]
 Subchapter 6. Commercial Facilities [AMENDED]
 310:681-6-1. General security requirements for commercial establishment [AMENDED]
 310:681-6-2. Construction of premises [AMENDED]
 Subchapter 7. Packaging and Labeling [AMENDED]
 310:681-7-1. Labeling [AMENDED]
 310:681-7-2. Prohibited products [AMENDED]
 310:681-7-3. Advertising [NEW]
 Subchapter 8. Laboratory Testing
 310:681-8-1. Testing standards and thresholds [NEW]
 310:681-8-2. General operating requirements and procedures [NEW]
 310:681-8-3. Sampling requirements and procedures [NEW]
 310:681-8-4. Laboratory quality assurance and quality control [NEW]
 310:681-8-5. Quality assurance laboratory [NEW]
 Subchapter 9. Waste Disposal Facilities [NEW]
 310:681-9-1. License or permit required [NEW]
 310:681-9-1.1. Responsibilities of the license or permit holder [NEW]
 310:681-9-2. Licenses and permits [NEW]
 310:681-9-3. License applications [NEW]
 310:681-9-4. Permit applications [NEW]
 310:681-9-5. Inspections [NEW]
 310:681-9-6. Security requirements [NEW]
 310:681-9-7. Audits and inventory [NEW]
 310:681-9-8. Penalties [NEW]
 310:681-9-9. Waste disposal [NEW]
 Subchapter 10. Receivership [NEW]
 310:681-10-1. Certificate of Authority [NEW]
 310:681-10-2. Term and renewal of Certificate of Authority [NEW]
 310:681-10-3. Responsibilities of the Certificate of Authority holder [NEW]
 310:681-10-4. Revocation of Certificate of Authority [NEW]
 Appendix A: Testing Thresholds [NEW]
 Appendix B: Lab Quality Control Results [NEW]

SUMMARY:

The proposed new and amended rules contain emergency rules that the Oklahoma State Department of Health proposes to adopt as permanent rules. The proposed rulemaking would make permanent the 2019 emergency rules at OAC 310:681 which the Department adopted to fulfill requirements and to provide procedures and processes necessary to implement legislative changes mandated by SB162, HB2612, HB2601, SB882, HB2613, SB 532, and SB1030, as codified under 63 O.S. §§ 420 *et seq.*, 63 O.S. §§ 427.1 *et seq.*, 63 O.S. §§ 427a *et seq.* Patient license changes include the removal of board certification as a requirement for physicians recommending medical marijuana, as well as the addition of physicians licensed by the Board of Podiatric Medical Examiners as physicians that can provide recommendations. The requirement that patients smile with their mouth closed in their picture has

been removed. The processing time for patient licenses changed from 14 calendar days to 14 business days, and a reduced application fee for 100% disabled veterans has been established. Medical marijuana business changes that are addressed in the proposed permanent rules include adding a definition for business licensee to be consistent with 63 O.S. §427.14, the increased application processing timeline, renewal application process, new residency documentation requirements, and approved waste disposal method to destroy root balls, stems, fan leaves, and seeds. Additionally, medical marijuana businesses will need to provide a certificate of compliance with zoning classifications, municipal ordinances, and all applicable safety, electrical, fire, plumbing, waste, construction, and building specification codes. The definition of school is modified to now include preschools for the purposes of the 1,000 feet requirement for dispensaries. The proposed rules establish new business compliance components that include the authority for certain business types to sell to other business types, the requirement to participate in a seed-to-sale inventory tracking system, to test harvest and product batches, and to comply with new packaging and labeling requirements. The proposed permanent rules address several new license categories: transporter, transporter agent, short-term patient, research facility, education facility, testing laboratory, and waste disposal facility (including waste disposal permits). The rule proposals include provisions for testing laboratory operating requirements and sampling requirements. It also modifies testing requirements and testing thresholds and provides provisions regarding remediation of medical marijuana and medical marijuana products. The proposed rules also include provisions related to a quality assurance laboratory for oversight of licensed testing laboratories and inventory management for current and new license.

AUTHORITY:

Commissioner of Health, Title 63 O.S. § 1-104, Title 63 O.S. §§ 420 *et seq.*, Title 63 O.S. §§ 427.1 *et seq.*, 63 O.S. §§ 427a *et seq.*

COMMENT PERIOD:

February 3, 2020, through March 7, 2020. Interested persons may informally discuss the proposed rules with the contact person identified below; or may, through March 7, 2020, submit written comment to the contact person identified below, or may, at the hearing, ask to present written or oral views.

Pursuant to 75 O.S. § 303(A), the public hearing for the proposed rulemaking in this chapter shall be on March 5, 2020, at the Oklahoma State Department of Health, 1000 Northeast Tenth Street, Oklahoma City, OK 73117-1207, in room 1102 from 9AM to noon. The alternate date and time in the event of an office closure due to inclement weather is March 9, 2020, in room 1102, from 9AM to noon. Those wishing to present oral comments should be present at that time to register to speak. The hearing will close at the conclusion of those registering to speak. Interested persons may attend for the purpose of submitting data, views or concerns, orally or in writing, about the rule proposal described and summarized in this Notice.

REQUESTS FOR COMMENTS FROM BUSINESS ENTITIES:

Business entities affected by these proposed rules are requested to provide the agency with information, in dollar amounts if possible, on the increase in the level of direct costs such as fees, and indirect costs such as reporting, recordkeeping, equipment, construction, labor, professional services, revenue loss, or other costs expected to be incurred by a particular entity due to compliance with the proposed rule. Business entities may submit this information in writing through March 7, 2020, to the contact person identified below.

COPIES OF PROPOSED RULES:

The proposed rules may be obtained for review from the contact person identified below or via the agency website at www.ok.gov/health.

RULE IMPACT STATEMENT:

Pursuant to 75 O.S., § 303(D), a rule impact statement is available through the contact person identified below or via the agency website at www.ok.gov/health.

CONTACT PERSONS:

Audrey C. Talley, Agency Rules Liaison, Oklahoma State Department of Health, 1000 N. E. 10th Street, Oklahoma City, OK 73117-1207; phone (405) 271-9444 ext. 56535, e-mail AudreyT@health.ok.gov.

RULE IMPACT STATEMENT

TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH CHAPTER 681. MEDICAL MARIJUANA CONTROL PROGRAM

1. **DESCRIPTION:**

The proposed new and amended rules contain emergency rules that the Oklahoma State Department of Health proposes to adopt as permanent rules. The proposed rulemaking would make permanent the 2019 emergency rules at OAC 310:681 which the Department adopted to fulfill requirements and to provide procedures and processes necessary to implement legislative changes mandated by SB162, HB2612, HB2601, SB882, HB2613, SB 532, and SB1030, as codified under 63 O.S. §§ 420 *et seq.*, 63 O.S. §§ 427.1 *et seq.*, 63 O.S. §§ 427a *et seq.* Patient license changes include the removal of board certification as a requirement for physicians recommending medical marijuana, as well as the addition of physicians licensed by the Board of Podiatric Medical Examiners as physicians that can provide recommendations. The requirement that patients smile with their mouth closed in their picture has been removed. The processing time for patient licenses changed from 14 calendar days to 14 business days, and a reduced application fee for 100% disabled veterans has been established. Medical marijuana business changes that are addressed in the proposed permanent rules include adding a definition for business licensee to be consistent with 63 O.S. §427.14, the increased application processing timeline, renewal application process, new residency documentation requirements, and approved waste disposal method to destroy root balls, stems, fan leaves, and seeds. Additionally, medical marijuana businesses will need to provide a certificate of compliance with zoning classifications, municipal ordinances, and all applicable safety, electrical, fire, plumbing, waste, construction, and building specification codes. The definition of school is modified to now include preschools for the purposes of the 1,000 feet requirement for dispensaries. The proposed rules establish new business compliance components that include the authority for certain business types to sell to other business types, the requirement to participate in a seed-to-sale inventory tracking system, to test harvest and product batches, and to comply with new packaging and labeling requirements. The proposed permanent rules address several new license categories: transporter, transporter agent, short-term patient, research facility, education facility, testing laboratory, and waste disposal facility (including waste disposal permits). The rule proposals include provisions for testing laboratory operating requirements and sampling requirements. It also modifies testing requirements and testing thresholds and provides provisions regarding remediation of medical marijuana and medical marijuana products. The proposed rules also include provisions related to a quality assurance laboratory for oversight of licensed testing laboratories and inventory management for current and new license.

The Title of Chapter 681 is changed to Medical Marijuana Regulations.

310:681-1-4. Definitions: Adds definitions for:

Advertising

Authority or OMMA

Business License to be consistent with a license received by a medical marijuana business as defined in 63 O.S. § 427.14

Caregiver

Child-Resistant as defined in 63 O.S. § 427.18

Dispose or Disposal

Education facility

Entrance to a private or public school

Flower

Flowering

Harvest Batch

Immature plant
 Indirect Beneficial Owner
 Medical Marijuana Business as defined in 63 O.S. § 427.14
 Medical marijuana research
 Municipality
 Officer of a corporate entity or Principal officer
 Owner to be consistent with 63 O.S. § 427.2
 Pesticide
 Political Subdivision
 Preschool
 Production batch
 Public institution
 Public money
 Registered to conduct business
 Research project
 Research facility
 Shipping container
 Strain
 Quality Assurance Laboratory
 Terpenoids
 Testing Laboratory
 THC Transporter
 Transporter Agent
 Useable medical marijuana
 Waste disposal facility
 Waste disposal facility license
 Waste disposal facility permit;
Changes definitions for:
 Commercial Establishment to Commercial Licensee to include any licensee except patient, caregiver and transportation agent licensees
 Dispense to be consistent with 63 O.S. § 427.2;
Modifies definitions for:
 Cannabinoid
 Clone to be consistent with 63 O.S. § 427.2
 Commercial License to include any licenses except patient, caregiver and transportation agent licenses
 Dispensary to make clear a dispensary can also sell, transfer and transport to other dispensaries and research and education facilities
 Entity to include an individual
 Grower to clarify a grower can sell, transfer and transport to a dispensary, processor, grower, research facility, education facility or testing laboratory
 Marijuana to be consistent with 63 O.S. § 427.2
 Medical Marijuana Concentrate to be consistent with 63 O.S. § 427.2
 Medical marijuana waste to be consistent with 63 O.S. § 427.2
 Oklahoma resident to reflect the requirements of 63 O.S. § 427.14(H)
 Oklahoma Uniform Symbol or Universal Symbol to clarify that the universal symbol must be printed in a color designated by the Department
 Package to make clear that packaging does not include carry-out bags or similar containers
 Physician to be consistent with 63 O.S. §§ 420 *et seq.* and 63 O.S. § 427.10
 Private School to make consistent with the term School as defined under 63 O.S. § 427.2

Processor
Transportation license;
Removes definition for:
Batch

310:681-1-5. Criminal history screening: Adds additional individuals required to undergo background screening to be consistent with 63 O.S. § 427.1 *et seq.*

310:681-1-6. Proof of residency: Adds “current Oklahoma” to the proof of residency requirement

310:681-1-7. Proof of identity: Clarifies the proof identity requirements for commercial and non-commercial license applicants.

310:681-1-8. Applicant photograph: Removes requirement that an applicant’s must smile with their mouth closed.

310:681-1-9. Recommending physician registration: Removes board certification requirement.

310:681-1-9.1. Recommending physician standards: Adds requirement the physician shall not be located at the same physical address of a dispensary to be consistent with 63 O.S. § 427.10 (D).

310:681-2-1. Application for patient license: removes references to board certification; provides discounted rate for a one hundred percent disabled veteran at twenty dollars and provides them with an approved alternative method of application submission; and establishes a new short term, sixty (60) day patient license with an established fee of \$100 or a reduced fee of twenty dollars for patients that can prove they are insured by Medicaid or Medicare or are a one hundred percent (100%) disabled veteran.

310:681-2-2. Application for patient license for persons under age eighteen (18): establishes that the short term license is also available to minors under the same requirements to adult patients.

310:681-2-3. Application for caregiver’s license: clarifies that caregivers may exercise the same rights as the medical marijuana patient license holder, except they may not use medical marijuana or medical marijuana product obtained on behalf of the medical marijuana patient license holder and may only exercise cultivation rights on behalf of up to five (5) patients; and a caregiver shall immediately notify the Department if marijuana patient license holder for whom he or she is designated caregiver is deceased.

310:681-2-5. Term and renewal of medical marijuana license: establishes a process for physician termination of a license; establishes that patient and caregiver licenses may be subject to nonrenewal for failure to comply with applicable Statutes or the Rules; and clarifies records and information regarding surrender of patient licenses are confidential.

310:681-2-8. Possession Limits: Adds possession limits from 63 O.S. § 420.

310:681-2-9. Prohibited acts and penalties: Establishes prohibited acts by a patient licensee or a caregiver and sets forth fines and penalties

310:681-2-10. Confidential Patient Information: Clarifies Department records with patient information are confidential.

Subchapter 3: Changes title of Subchapter 3 from “Transportation License” to “Transporter License.”

310:681-3-1. License for transportation of medical marijuana: Establishes the transporter license and the application requirements for a commercial transporter license as a standalone business.

310:681-3-2. Requirements for transportation of marijuana: adds requirements for vehicles used to transport medical marijuana and medical marijuana products; adds record retention requirements; establishes penalties for violation of applicable Oklahoma statutes and rules; and establishes penalties for when a transporter agent fails to carry a copy of the commercial transporter license and transporter agent license during transport in violation of the law.

310:681-3-3. Transporter agent license: establishes a transporter agent license and the application requirements and process; the new agent license requires an annual fee of one hundred dollars; establishes that all transport of medical marijuana must be done by a transporter agent; clarifies that transporter agent license does not extend beyond the expiration, surrender or revocation of the

employing transporter license; establishes requirements for renewal of transporter agent license; and establishes that transporter agent licenses may be subject to nonrenewal for failure to comply with Oklahoma law.

310:681-3-4. Employer deactivation of transporter agent license: establishes process for notifying the Department for deactivation of transporter agent license when the agent ceases to work for a business.

310:681-3-5. Information contained on a transporter agent license: establishes the minimum information that will be displayed on a transporter agent license is outlined; and requires transporter agent to carry the transporter agent license and a copy of employer license at all times.

310:681-3-6. Inventory manifests: establishes requirements for inventory manifests and outlines all information that must be documented for all transport; and establishes process and documentation requirements for refusal to accept delivery of medical marijuana and/or medical marijuana products.

Subchapter 4: Changes title of Subchapter 4 to “Research Facilities and Education Facilities”

310:681-4-1. License required: establishes license for research facilities and education facilities and outlines acceptable purposes in accordance with 63 O.S. §§ 427.19 and 427.20.

310:681-4-1.1 Responsibilities of the license holder: establishes the responsibilities of research and education facility license holders.

310:681-4-2. Licenses: establishes timeframe for, location of, and renewal of research and education facility licenses; liquidation of products, changes in information, transfer of license, and surrender; establishes that research and education facility licenses may be subject to nonrenewal for failure to comply with applicable Statutes and Rules; and clarifies what documents must be provided to the Department for change requests that affect the licensee’s qualifications for licensure.

310:681-4-6. Penalties: establishes administrative fines and penalties for violations against research and education facility licensees.

Subchapter 5: Changes title of Subchapter 5 to “Medical Marijuana Businesses” in accordance with 63 O.S. §427.14.

310:681-5-1.1. Responsibilities of license holder: adds requirement that licensee must ensure all information and records provided online to the OMMA are complete, accurate and updated.

310:681-5-2. Licenses: requires renewal denial by the Department to be provided in writing; change in information is required to be submitted in advance and approved prior to changes that effect licensure; unless authorized by the Department, licensees are limited to one location change request and one ownership change request per year of licensure; establishes requirements and processes for liquidation of products for a license that has not been renewed, revoked, suspended or surrendered; establishes that a business license may be subject to nonrenewal for failure to comply with applicable statutes and rules; and clarifies what documents must be provided to the Department for change requests that affect the licensee’s qualifications for licensure.

310:681-5-3. Applications: adds documentation required in accordance with 63 O.S. §§ 427 and 427.14, including a certificate of compliance, documents establishing proof of residency, sales tax permit (if applicable), and accreditation documentation (if applicable); and establishes process for rejection and resubmission.

310:681-5-3.1 Proof of residency for commercial licensees: proof of current two years presiding residency or previous five year continuous residency is defined; and the process and documents required are provided.

310:681-5-3.2. Persons prohibited from holding a commercial license: establishes persons prohibited from holding a license; and clarifies the prohibitions listed in that section apply to renewals.

310:681-5-4. Inspections: establishes the Department’s inspection authority over all medical marijuana commercial licensee’s and details the Department’s inspection authority in accordance with 63 O.S. §§ 427.4 and 427.6; and added language requiring Department to conduct one on-site inspection of a testing laboratory applicant prior to initial licensure and annually thereafter.

310:681-5-6. Inventory tracking, records, reports and audits: adds requirement that private patient information shall not be retained by a medical marijuana business for more than 60 days; and establishes requirement for seed-to-sale tracking system when applicable.

310:681-5-8.1. Food Safety Standards for Processors: removes required testing procedures to Subchapter 8.

310:681-5-10. Medical marijuana waste disposal: adds ability for licensees to dispose of root balls, stems, fan leaves, seeds, and stalks by burning, incineration, burying, mulching, composting and other techniques approved by Department of Environmental Quality.

310:681-5-17. Entry to commercial establishments: modifies language to allow non-licensed minors to enter a licensed premise when accompanied by their parent or legal guardian.

310:681-5-18. Prohibited acts: removes prohibition of consumption of medical marijuana products on the premise in accordance with 63 O.S. § 427.8 (C); prohibits physicians from being located at the same physical address of a dispensary; prohibits licensee from falsifying or misrepresenting documents or other information submitted to the Department; prohibits licensee from threatening or harming patients, medical practitioners, or employee of the Department; prohibits licensee from using extraction equipment or processes that utilize butane, propane, carbon dioxide, or other hazardous material; and prohibits licensee from purchasing or obtaining medical marijuana or medical marijuana products.

310:681-7-1. Labeling and Packaging: adds requirements regarding non-acceptance, documentation, general requirements, and label requirements.

310:681-7-3. Advertising: adds new restrictions on advertising, including a prohibition on advertising depicting a child consuming marijuana or being especially appealing to children

310:681-8-1. Testing standards and thresholds: new section that establishes testing requirements and thresholds for both processors and growers; establishes that only laboratories issued licenses by the Department may conduct testing; modifies language to make clear that harvest and production batches may not exceed 10 pounds; establishes requirement that dispensaries must ensure that the medical marijuana and medical marijuana products being purchased and sold have passed all tests; this includes obtaining and maintaining copies of the certificate of analysis; growers and processors are required to provide copies of the certificate of analysis to the Dispensary upon request; establishes a 90-day grace period for changes to Subsection (h) that require a change in methodology, proficient testing enrollment or accreditation; moves the testing thresholds for microbiological testing, mycotoxins, residual solvents and chemical residue, and metals to Appendix A; changes the pesticide thresholds to 0.05 ppm; establishes requirement to test for water activity and moisture content and establishes processes and procedures for remediation and retesting.

310:681-8-2. General operating requirements and procedures: establishes general operating requirements and procedures for licensed laboratories; changes “testing personnel” to “analysts”; and modifies the limit of detection requirements for equipment.

310:681-8-3. Sampling requirements and procedures: establishes sampling requirements and procedures; revises sample size requirements and establishes sample collection processes; establishes requirement that any reference laboratories must be identified on the certificate of analysis; establishes requirement that certificates of analysis contain “pass” or “fail” indications and clarifies what tentatively identified compounds must be reported to the Department and requires laboratories to notify Department immediately and provide a copy of the COA.

310:681-8-4 Laboratory quality assurance and control: establishes laboratory quality assurance requirements.

310:681-8-5 Quality Assurance Laboratory: establishes duties and authority of quality assurance laboratory.

New Subchapter 9, “Waste Disposal Facilities”

310:681-9-1. License or permit required: establishes licenses and permits for waste disposal facilities.

310:681-9-1.1. Responsibilities of the license or permit holder: establishes responsibilities of the license or permit holder are the same as marijuana business under OAC 310:681-5-1.1.

310:681-9-2. Licenses and permits: timeframe for, location of, and renewal of waste licenses; liquidation of products, changes in information, transfer of license or permit, surrender of license or permit, revocation of license or permit; establishes that waste disposal licenses and permits may be subject to nonrenewal for failure to comply with applicable statutes and rules; and clarifies what documents must be provided to the Department for change requests that affect the waste disposal licensee's qualifications for licensure.

310:681-9-3. License applications: establish license application process and documentation, application fees and required information.

310:681-9-4. Permit applications: establish permit application process and documentation, application fees and required information.

310:681-9-5. Inspections: establishes and details the Department's inspection authority over waste disposal facilities.

310:681-9-6. Security requirements: establishes security requirements for storage and transportation of waste and requirements for documentation, record keeping and reporting.

310:681-9-7. Audits and inventory: establishes and details the Department's audit authority over waste disposal facilities and record keeping requirements.

310:681-9-8. Penalties: establishes administrative fines and penalties for violations against waste facility licensees.

New Subchapter 10, "Receivership"

310:681-10-1. Certificate of Authority: establishes a Certificate of Authority requirements and supporting documentation.

310:681-10-2. Term and renewal of Certificate of Authority: establishes term of Certificate of Authority.

310:681-10-3. Responsibilities of the Certificate of Authority holder: establishes responsibilities of the Certificate of Authority holder are the same as marijuana business under OAC 310:681-5-1.1.

310:681-10-4. Revocation of Certificate of Authority: establishes revocation reasons for Certificate of Authority.

Appendix A: Charts the thresholds for testing required under Subchapter 8.

Appendix B: Establishes requirements for laboratory quality control (CQC) results.

2. DESCRIPTION OF PERSONS AFFECTED AND COST IMPACT RESPONSE:

The classes of persons potentially affected by the proposed rules include primarily medical marijuana businesses, research and education facilities, and waste disposal facilities involved with the growing, processing, dispensing, transporting, testing, researching, and disposing of medical marijuana and its derived products. Applicants seeking a stand-alone transporter license, laboratory license, research facility license, and education facility license are subject to application fees of \$2,500, as required by the "Unity Bill" codified at 63 O.S. §§ 427.16, 427.17, 427.19, and 427.20. All employees seeking to transport medical marijuana on behalf of a business must obtain a transporter agent license, which is \$100. Waste facilities seeking an application are subject to application fees of \$5,000 and permit fees of \$500 per permit under the Oklahoma Waste Management Act codified at 63 O.S. § 430.

Owners, principal researchers, and principal officers who are associated with entities applying for laboratory license subject to Subchapter 5 (Medical Marijuana Business) and Subchapter 8 (Laboratory Testing), transporter license or transporter agent license subject to Subchapter 3, research facility license or education facility license subject to Subchapter 4, or waste disposal license subject to Subchapter 9 of the proposed rule will experience indirect costs related to fees to undergo a criminal history screening, to obtain registration from the Oklahoma Bureau of Narcotics and Dangerous Drugs, to obtain a certificate of compliance from its political subdivision, to obtain any applicable permits

from various entities such as the Oklahoma Tax Commission, the Department of Agriculture, Department of Environmental Quality, local municipal permits and other permits and licenses that might apply.

The classes of individuals potentially affected by rules pertaining to laboratory testing include owners and operators of licensed growers, processors, dispensaries and laboratories. As required by 63 O.S. § 427.17, all harvest and production batches must be tested and cannot contain more than 10 pounds of medical marijuana or medical marijuana product. 63 O.S. § 427.17 requires harvest or production batches to be tested for microbials, mycotoxins, residual solvents, pesticides, THC and other cannabinoid potency, terpenoid potency and heavy metals that are addressed in these Rules. The Rules require additional testing for water activity to prevent mold in products that are sold to patients. Samples must be provided to a licensed laboratory for testing. 63 O.S. § 427.18 also implemented more stringent packaging and labeling requirements that are addressed in these Rules. Licensed growers, processors and dispensaries would be responsible for direct and indirect compliance costs to ensure all testing, labeling and packing requirements for medical marijuana and medical marijuana products.

3. DESCRIPTION OF PERSONS BENEFITING, VALUE OF BENEFIT AND EXPECTED HEALTH OUTCOMES:

The classes of persons who are likely to benefit from the proposed rules include the population of patients consuming medical marijuana or medical marijuana products for some medical purpose. Subchapter 1 (General Provisions) and Subchapter 2 (Medical Marijuana Licenses) of the proposed rule, establish criteria to receive an adult patient, minor patient, short-term patient, temporary patient, or caregiver license.

Subchapter 5 and 7 contains specific standards which now apply to medical marijuana and medical marijuana products. Consumers of medical marijuana and medical marijuana products are likely to have more specific information on the contents of products they purchase, due to the regulations at 310:681-5-8.1 and 310:681-7. Pursuant to 63 O.S. § 427.18, packaging must also now be child-resistant and have additional labeling requirements designed to protect children. Packaging and labeling standards are anticipated to improve public safety by improving the ability of all entities to monitor the origin of unsafe or contaminated products and help prevent child consumption. New lab testing guidelines are also expected to make product safer. There will be more frequent and extensive testing requirements to help ensure product is safe for consumption. Growers and processors must have every harvest and production batch, which cannot be more than 10 pounds, tested by a licensed laboratory. Per 63 O.S. § 427.17(U), licensed laboratories must be licensed by the OSDH, and there will also be a requirement that licensed laboratory is accredited by an approved accrediting body beginning January 1, 2020. Also, licensed laboratory testing will be monitored by a quality assurance laboratory to ensure compliance with testing requirements.

The proposed permanent rules also address OSDH's broader inspection authority as provided by 63 O.S. § 427.4 and 427.6. OSDH now has inspection authority over all commercial establishments.

Additionally, the proposed permanent rules provide procedures for remediation. Rather than immediately dispose of medical marijuana and medical marijuana products that fail testing, businesses will have the opportunity to safely remediate product in certain circumstance. After remediation, the medical marijuana and medical marijuana product must still pass testing requirements. It is anticipated remediation will benefit medical marijuana businesses, as well as consumers.

4. ECONOMIC IMPACT, COST OF COMPLIANCE AND FEE CHANGES:

The fees for licenses are established in statute. As proposed in rule, the regulatory office for medical marijuana will collect fees from applicants as required in statutes and detailed separately below:

Individual Licenses for Adult Patients and Minor Patients: \$100.00 or \$20.00 for Medicare or Medicaid patients and 100% disabled veterans. (OAC 310:681-2-1, as authorized by 63 O.S. § 420 (D)).

This cost paid by applicants is justified due to authorization in law and assists the regulatory office cover the administrative costs to maintain services.

Short-term Patient License: \$100.00 or \$20.00 for Medicare or Medicaid patients and 100% disabled veterans. (OAC 310:681-2-5, as authorized by 63 O.S. § 420 (E)).

This cost paid by applicants is justified due to authorization in law and assists the regulatory office cover the administrative costs to maintain services.

Caregiver License for Medical Marijuana Patients: \$0 (OAC 310:681-2-3, as authorized by 63 O.S. § 420 (K)).

There is not a cost paid by applicants for a caregiver license.

Retail Dispensary License: \$2,500 for license, penalty of \$5,000 for initial reporting violations, \$1,000 for first offense of unlawful sale or purchase, and \$500.00 per inspection-related violation. (OAC 310:681-5-3 and OAC 310:681-5-6.1, as authorized by 63 O.S. § 427.6).

This cost paid by applicants is justified due to authorization in law and assists the regulatory office cover the administrative costs, such as inspections and staffing.

Grower License: \$2,500 for license, penalty of \$5,000 for initial reporting violations, \$1,000 for first offense of unlawful sale or purchase, and \$500.00 per inspection-related violation. (OAC 310:681-5-3 and OAC 310:681-5-6.1, as authorized by 63 O.S. § 427.6).

This cost paid by applicants is justified due to authorization in law and assists the regulatory office cover the administrative costs, such as inspections and staffing.

Processor License: \$2,500 for license, penalty of \$5,000 for initial reporting violations, \$1,000 for first offense of unlawful sale or purchase, and \$500.00 per inspection-related violation. (OAC 310:681-5-3, OAC 310:681-5-4 and OAC 310:681-5-6.1 as authorized by 63 O.S. § 423 (A) and 427.6)

This cost paid by applicants is justified due to authorization in law and assists the regulatory office cover the administrative costs, such as inspections and staffing.

Research License: \$2,500 for license, penalty of \$5,000 for initial reporting violations, \$1,000 for first offense of unlawful sale or purchase, and \$500.00 per inspection-related violation.

This cost paid by applicants is justified due to authorization in law, and assists the regulatory office cover the administrative costs, such as inspections and staffing.

Education License: \$2,500 for license, penalty of \$1,000 for first offense of unlawful sale or purchase, and \$500.00 per inspection-related violation.

This cost paid by applicants is justified due to authorization in law, and assists the regulatory office cover the administrative costs, such as inspections and staffing.

Transporter License: \$2,500 for stand-alone license, penalty of \$1,000 for first offense of unlawful sale or purchase, and \$500.00 per inspection-related violation. Transportation licenses are also automatically issued to licensed growers, processors, and dispensaries, which require a \$2,500 application fee (63 O.S. § 424 (A)).

This cost paid by applicants is justified due to authorization in law, and assists the regulatory office cover the administrative costs, such as inspections and staffing.

Transporter Agent License: \$100 for transporter agent license. There is a proposed \$50 fine against an agent and \$500 fine against the employer when an agent transports without his or her transporter agent ID and a copy of the employing transporter's license.

This cost paid by applicants is justified due to authorization in law, and assists the regulatory office cover the administrative costs.

Waste Disposal Facility license and permit: \$5,000 for license and \$500.00 for a permit, penalty of \$1,000 for first offense of unlawful sale or purchase, and \$500.00 per inspection-related violation.

This cost paid by applicants is justified due to authorization in law, and assists the regulatory office cover the administrative costs, such as inspections and staffing.

Laboratory license: \$2,500 for license, penalty of \$5,000 for initial reporting violations, \$1,000 for first offense of unlawful sale or purchase, and \$500.00 per inspection-related violation.

This cost paid by applicants is justified due to authorization in law, and assists the regulatory office cover the administrative costs, such as inspections and staffing.

The Department will accept public comments from the persons who may potentially be impacted by costs as a result of compliance with the permanent rule. Members of the general public and law enforcement are anticipated to have the ability to provide complaints and information to the regulatory office, through its website and phone number. The proposed rule involves implementing a statewide system of licensure for medical marijuana patients and commercial entities. As required by 63 O.S. § 420(I), the permanent rules continue to provide for an online licensure verification system to enable timely confirmation of valid medical marijuana licenses. One valid purpose of this verification system will be for local law enforcement authorities to query possible licensees who may be present in their municipality and confirm the authenticity and expiration dates of a given license. Local law enforcement agencies are one of the most common intergovernmental partners expected to run online queries of the verification system, which may assist in gathering information during police stops and other instances. The Department expects costs to be minimal, as there will be no fees for running a query. Political subdivisions are required to issue Certificate of Compliance to applicants seeking a medical marijuana commercial license. This is expected to impact political subdivisions' staffing and administrative costs; this will also impact business owners by \$0-\$2,500.00, depending on the political subdivision's charge. As proposed at OAC 310:681-1-3, licenses issued by the Department will not apply to tribal trust, tribal restricted, or federal lands. The agency has concluded it does not have the legal authority to regulate these separate governmental bodies, but will maintain communication as appropriate, through tribal and other consultations to discuss potential impacts of OAC 310:681 rules.

5. COST AND BENEFITS OF IMPLEMENTATION AND ENFORCEMENT TO THE AGENCY:

The estimated cost to the Department to implement the updated legislation and related rules is \$15,000,000.00. This estimation includes costs related to the addition of new licenses, a Seed to Sale System, and a Surveillance (Oversight) Lab. Due to the unknown volume of licenses, the anticipated costs could vary.

6. IMPACT ON POLITICAL SUBDIVISIONS:

Implementation of the proposed rule will involve some cooperation with partner agencies and political subdivisions, including but not limited to the Oklahoma Tax Commission, Oklahoma Bureau of Narcotics and Dangerous Drugs, Oklahoma Department of Agriculture and Oklahoma Department of

Environmental Quality. The OSDH expects costs of implementation for partner agencies to be limited, as there will be no fees for any cooperative activities.

63 O.S. § 427.14 requires a medical marijuana business to be in good standing with the Oklahoma Tax Commission and Secretary of State. The OSDH currently cooperates with the Oklahoma Tax Commission to exchange relevant information to ensure each agency's duties under 63 O.S. § 426, but to ensure a business is in good standing requires additional cooperation before a business becomes licensed.

Pursuant to 63 O.S. §§ 2-101 & 2-302, all applicants for a commercial license must register with the Oklahoma Bureau of Narcotics and Dangerous Drugs Control (OBNDD) after receiving a license from the Oklahoma Medical Marijuana Authority. The OSDH currently cooperates with the OBNDD to exchange relevant information about holders of commercial medical marijuana licenses to assist with compliance verification. Additionally, the proposed permanent rule at OAC 310:681-5-10 refers to rules issued by the Oklahoma Department of Environmental Quality (DEQ) at OAC 252:205, on the subject of disposal of hazardous waste. The OSDH currently cooperates with the Department of Environmental Quality and OBNDD to ensure each agency's duties under 63 O.S. § 420 *et seq.* can be completed with as minimal burden as possible.

Pursuant to 63 O.S. § 427, an applicant must receive a certificate of compliance from their political subdivision prior to licensure or renewal. The OSDH currently cooperates with political subdivisions to ensure each the statutory requirements can be completed with as minimal burden as possible.

Pursuant to 63 O.S. § 428 *et seq.*, DEQ and OSDH have jurisdiction over medical marijuana waste. Before any applicant can receive a medical marijuana waste license, the proposed permanent rules at OAC 310:681-9-1 require that an applicant must first obtain a permit from DEQ. An applicant may also be required to obtain a permit from the Department of Agriculture. The OSDH currently cooperates with DEQ and the Department of Agriculture to ensure each agency's duties under 63 O.S. § 428 *et seq.* can be completed with as minimal a burden as possible.

Agency partners and other political subdivisions currently have the ability to provide complaints and information to the regulatory office, through its website, phone number and staff contacts. The Department will accept comments regarding other potential impacts on political subdivisions from the rule in writing and by public hearing.

7. ADVERSE EFFECT ON SMALL BUSINESS:

While the impact is not yet known, it is anticipated that the statutorily mandated transporter agent license fees, laboratory and testing costs, and packaging and labeling costs will impact small businesses.

8. EFFORTS TO MINIMIZE COSTS OF RULE:

The use of existing systems, processes, and staff will be utilized to help mitigate additional costs.

Compliance costs have not fully been established. Efforts in planning to avoid costly regulation methods are underway. The Department has established an interim method for monthly reporting through an already held technology system to avoid the immediate cost to the current platform. However, to streamline the reporting, as well as the need to follow up with specific business entities, the Department is planning to integrate the licensing platform for this purpose.

9. EFFECT ON PUBLIC HEALTH AND SAFETY:

These permanent rules seek to fulfill core public health functions of protecting Oklahomans from potential harms through known evidenced-based policies and promising practices, while staying within the limited authority provided by the enabling law. Evidence remains limited on the beneficial uses of cannabis and concern remains on its effects on specific populations. The Department has identified public health concerns with the implementation of a medical marijuana program and will require packaging that is not attractive to minors; contains a label that reads: "Keep out of reach of children;" child resistant packaging; and a label warning that states "Women should not use marijuana or medical marijuana products during pregnancy because of the risk of birth defects." In addition, the Department recognizes a public health concern related to smoke and second hand smoke produced by consumption of some forms of marijuana, and its potential effects.

The Department will accept public comments regarding other potential risks or benefits from the rule in writing and by public hearing.

10. DETRIMENTAL EFFECTS ON PUBLIC HEALTH AND SAFETY WITHOUT ADOPTION:

As noted in the prior sections, assessment of potential effects on public health and safety without adoption is unknown.

The Department accepted public comments regarding the rule in writing and by public hearing, and are documented in the attached rule packet.

11. PREPARATION AND MODIFICATION DATES

This rule impact statement was prepared on December 12, 2019.

**TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH
CHAPTER 681. MEDICAL MARIJUANA CONTROL PROGRAM REGULATIONS**

SUBCHAPTER 1. GENERAL PROVISIONS

310:681-1-1. Purpose [AMENDED]

The purpose of this Chapter is to ensure the health and safety of all Oklahomans and provide reasonable and orderly regulation of medical marijuana as authorized by the lawful passage of State Question 788, codified as 63 O.S. § 420 et seq.; 63 O.S. § 427; the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq.; and the Oklahoma Medical Marijuana Waste Management Act, 63 O.S. § 427a et seq. This regulatory authority shall be known as the "Oklahoma Medical Marijuana Authority" ("OMMA") and shall be a division of the Oklahoma State Department of Health.

310:681-1-2. Regulatory program established [AMENDED]

(a) ~~Pursuant to 63 O.S. § 420A(C), 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 Oklahoma Medical Marijuana Authority website at <http://omma.ok.gov/>.

(d) The Oklahoma State Department of Health is located at 1000 N.E. 10 Street, Oklahoma City, Oklahoma, 73117. ~~All approval and rejection letters shall be sent to the applicant through U.S. Mail.~~

310:681-1-3. Limitations of licenses [AMENDED]

All medical marijuana licenses and rights granted under Oklahoma law and this Chapter and under 63 O.S. § 420A et seq. shall only be valid in the State of Oklahoma, excluding any tribal trust or tribal restricted land or federal lands in the state.

310:681-1-4. Definitions [AMENDED]

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

"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.

"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) ~~"Pending-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. ~~OMMA has 14 days to review the submission of any corrections to a rejected application;~~

(C) "Approved" means the application has been approved and that a license will be issued and mailed to the applicant; and

(D) "Denied" means the applicant does not meet the qualifications under ~~63 O.S. § 420A~~ 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" means a specifically identified quantity of marijuana, no greater than ten (10) pounds, that is uniform in strain, cultivated using the same growing practices, and harvested at the same time at the same location, and dried or cured under uniform conditions; and with regard to medical marijuana concentrate and medical marijuana products, means an identified quantity that is uniform, that is intended to meet specifications for identity, strength, and composition, and that is processed, packaged, and labeled during a specified time period according to a single manufacturing, packaging, and labeling protocol.~~

"Batch number" means a unique numeric or alphanumeric identifier assigned prior to any testing ~~or sale~~ 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 diverse chemical compounds that can act on cannabinoid receptors in cells and alter neurotransmitter release in the brain, including phytocannabinoids that are produced naturally by marijuana and some other plants 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.

"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 C.F.R. 1700.15 (1995) and 16 C.F.R. 1700.20 (1995);

(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 no taller than eight inches and is capable of developing into a new plant and has shown no signs of flowering.~~

~~"Commercial establishment" ("Establishment") or "Commercial licensee" means an individual or entity licensed under this Chapter by~~

~~the Department as a medical marijuana dispensary, grower, processor, or researcher issued a commercial license and does not mean a patient, caregiver, or transporter agent.~~

"Commercial license" means a license issued to a medical marijuana dispensary, grower, processor, or researcher 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 ~~63 O.S. § 420A et seq.~~ 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.

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

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

"Dispensary" or "Commercial Dispensary" means an individual or entity that has been issued a medical marijuana business licensed license by the Department pursuant to ~~63 O.S. § 421A and this Chapter,~~ which allows the dispensary to purchase medical marijuana or medical marijuana products from a ~~licensed processor~~ processor, ~~or~~ grower, or dispensary; ~~and~~ to sell medical marijuana and medical marijuana products only to a ~~qualified~~ licensed patient, to the ~~qualified~~ licensed patient's parent(s) or legal guardian(s) if ~~qualified~~ licensed patient is an minor, and a licensed caregiver; 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 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 a ~~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.

"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 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 and the Oklahoma Administrative Code ("OAC") 310:257-1-3 ("'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 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 ~~commercial~~ business licensed license by the Department pursuant to 63 O.S. § 422A, which allows the grower to grow, harvest, dry, cure, and package, sell, transfer, and transport or contract with a commercial transporter for the transport of medical marijuana in ~~accordance~~ accordance with Oklahoma law and ~~to~~ this Chapter for the purpose of selling to a dispensary, ~~or~~ 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, 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.

"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."

"Inventory tracking system" means a required tracking system that accounts for the entire life span of medical marijuana, from either the seed or immature plant stage until the medical marijuana or

medical marijuana product is consumed, used, disposed of or otherwise destroyed.

"**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. § 422A(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 all parts of a plant of the genus cannabis, whether growing or not; the seeds of a plant of that type; the resin extracted from a part of a plant of that type; and every compound, manufacture, salt, derivative, mixture, or preparation of a plant of that type or of its seeds or resin. "Marijuana" does not include the mature stalks of the plant or fiber produced from the stalks; oil or cake made from the seeds of the plant; or any other compound, manufacture, salt, derivative, mixture, or preparation of the mature stalks, except the resin extracted from the mature stalks, fiber, oil or cake; the sterilized seed of the plant that is incapable of germination; or industrial hemp, from the plant Cannabis sativa L. and any part of such plant, whether growing or not, with a delta-9-tetrahydrocannabinol concentration of not more than three-tenths of one percent (0.3%) on a dry weight basis the same as the term that is defined in 63 O.S. § 2-101.~~

"**Mature plant**" means harvestable female marijuana plant that is flowering.

"**Medicaid**" means the federal 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, ~~and includes medical marijuana concentrate and medical marijuana products.~~

"**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 ~~qualified~~ 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 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 roots, stems, stalks and fan leaves and roots; and any wastewater generated during growing and processing.

"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" shall have the same definition as set forth in the Oklahoma Municipal Code, 11 O.S. § 1-102, and "means any incorporated city or town."

"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" shall have 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 ~~resides in the State of Oklahoma~~ and can provide proof of residency as required by ~~63 O.S. § 420A et seq. and~~ 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 indicating 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.

"Out-of-State ~~state~~ Medical ~~medical~~ Marijuana ~~marijuana~~ Patient ~~patient~~ License ~~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 ~~grower or processor~~ 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 **"~~Qualified Licensed patient~~"** means a person that has been properly issued a medical marijuana license pursuant to ~~63 O.S. § 420A et seq.~~ Oklahoma law and these rules 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, ~~or~~ 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 and ~~meets the definition of "board certified" under rules established by either the Oklahoma Board of Medical Licensure or the Oklahoma Board of Osteopathic Examiners.~~

"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~~ a preschool, 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 ~~or medical marijuana concentrate~~.

"Processor" or "Commercial Processor" means an individual or entity that has been issued a medical marijuana business licensed license by the Department pursuant to 63 O.S. § 423A, which allows the processor to: purchase medical marijuana or medical marijuana products from a grower or processor; process, package, and 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, ~~or~~ processor, or testing laboratory in accordance with Oklahoma law and this Chapter; and may process medical marijuana received from a ~~qualified~~ licensed patient into a medical marijuana concentrate, for a fee.

"Production batch" means

- (A) Any amount of medical marijuana concentrate, not to exceed ten (10) pounds, 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, 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.

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

"Public school" means ~~a~~ a preschool, elementary, middle, or high school established under state law ~~a~~, 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.

"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.

"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. § 420A 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 ~~63 O.S. § 420A et seq.~~ Oklahoma law and this Chapter is rescinded.

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

"Sampler" means a person who is employed by 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.

"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 classification of marijuana or cannabis plants in either pure sativa, indica, afghanica, ruderalis, or hybrid varieties.

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

"Terpenoids" means isoprenes that are the aromatic compounds found in cannabis, including, but not limited to: limonene, myrcene, pinene, linalool, eucalyptol, Δ-terpinene, β-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 tetrahydrocannabinolic 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 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 who are automatic holders of transporter licenses.

"**Transporter Agent**" means an agent, employee, officer, or owner of commercial transporter, grower, processor, or dispensary 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.

"~~Transportation~~ **Transporter license**" means a medical marijuana commercial business license issued by the Department either (A) automatically to commercial licensees growers, processors, and dispensaries upon approval of a commercial business license, or (B) to commercial transporters solely for the transportation, storage, and distribution of medical marijuana and medical marijuana products which allows growers, processors, or dispensaries, or their authorized agent(s), to deliver medical marijuana from their licensed locations to the licensed locations of other growers, processors, or dispensaries.

"**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.

310:681-1-5. Criminal history screening [AMENDED]

(a) **Parties subject to screening.** Prior to issuance of any dispensary, grower, processor, transportation, commercial license or transporter agent license, researcher license authorized by 63 O.S. § 420A et seq. and this Chapter, the following shall undergo an Oklahoma state criminal history background check within thirty (30) days prior to the

application for the license:

- (1) Individual applicants applying on their own behalf;
 - (2) ~~All owners of any applicant for a dispensary, grower, processor, or transportation license;~~ and Individuals applying on behalf of an entity;
 - (3) ~~For research license applicants, all principal investigators involved in the research project.~~ All principal officers of an entity;
 - (4) All owners of an entity;
 - (5) For corporations seeking a business license, all officers, directors, and stockholders; and
 - (6) For public institutions seeking a research facility license, all principal investigators and co-principal investigators.
- (b) **Disqualifying Criminal Conviction.** Any commercial applicant with a disqualifying criminal conviction is not qualified to receive or renew a commercial license.
- (c) **OBNDD Registration.** Any ~~dispensary, grower, processor, or researcher~~ commercial licensee issued a license authorized by this Chapter, that is required under Oklahoma law to obtain an Oklahoma State Bureau of Narcotics and Dangerous Drugs Control ("OBNDD") registration shall do so prior to possessing or handling any marijuana or marijuana product pursuant to 63 O.S. §§ 2-302 & 2-303, 63 O.S. § 2-101, and OAC 475:10-1-10.
- (d) **Fees.** All applicable fees, including those charged by the Oklahoma State Bureau of Investigation vendor or OBNDD, are the responsibility of the applicant.

310:681-1-6. Proof of residency [AMENDED]

- (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) A residential property deed to property in the State of Oklahoma;
 - (6) A current rental agreement for residential property located in the State of Oklahoma; or
 - (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 [AMENDED]

- (a) All Applicants 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;
 - (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;
- (2) Front and back of 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.

310:681-1-8. Applicant photograph [AMENDED]

The digital photograph to be submitted with an application shall:

- (1) Be a clear, color photograph of the head and top of the shoulders;
- (2) Be an image file in a .jpg, .png or .gif digital image format no larger than 3 MB in size;
- (3) Be in one of the following approved formats:
 - (A) A scanned photograph shall be scanned at a resolution of 300 pixels per inch from a 2 x 2 inch image with dimensions in a square aspect ratio (the height must be equal to the width).
 - (B) A captured image must have minimum acceptable pixel dimensions of 600 x 600 pixels and maximum acceptable pixel dimensions of 1200 x 1200 pixels.
- (4) Be taken within the last six (6) months to reflect the applicant's appearance;
- (5) Be taken in front of a plain white or off-white background;
- (6) Be taken in full-face view directly facing the camera at eye level with nothing obscuring the face, such as a hat or eyewear:
 - (A) If a hat or head covering is worn for religious purposes, submit a signed statement that verifies the hat or head covering in the photo is part of recognized, traditional religious attire that is customarily or required to be worn continuously in public.
 - (B) If a hat or head covering is worn for medical purposes, submit a signed doctor's statement verifying the hat or head covering in the photo is used daily for medical purposes.
 - (C) Applicant's full face must be visible and your hat or head covering cannot obscure your hairline or cast shadows on your face.
- (7) Be taken with a neutral facial expression (preferred) or a natural smile ~~with the mouth closed~~, and with both eyes open;
- (8) Not be digitally enhanced or altered to change the appearance in any way; and
- (9) Sufficiently resemble the photograph included in any identification provided for proof of identity or residence.

310:681-1-9. Recommending physician registration [AMENDED]

(a) A physician may file a registration with the Department as a recommending physician on a form prescribed by the Department if the physician holds a valid, unrestricted and existing license to practice in the State of Oklahoma ~~and meets the definition of "board certified" under rule established by either the Oklahoma Board of Medical Licensure or the Oklahoma Board of Osteopathic Examiners.~~

(b) If a physician chooses to register with the Department, a registration must include, at a minimum, all of the following:

(1) The physician's full name, business address, professional email address, telephone numbers and, if the physician owns or is affiliated with a medical practice, the name of the medical practice;

~~(2) The physician's area of board certification and sufficient documentation proving the physician's unexpired board certification;~~

~~(3) (2) The physician's medical license number; and~~

~~(4) (3) A certification by the physician that states that the physician's Oklahoma license to practice medicine is active and in good standing.~~

310:681-1-9.1. Recommending physician standards [AMENDED]

(a) Any Physician, before making a recommendation for medical marijuana under these provisions, shall be in "good standing" with their licensure board. 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 [AMENDED]

(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 ~~Board-Certified~~ 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 ~~or board-certification~~ number including an identification of the physician's license type ~~and area of board certification~~;
- (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. § ~~420A~~ 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. § ~~420A~~ 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.

(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.

310:681-2-2. Application for patient license for persons under age eighteen (18) [AMENDED]

(a) The application for a patient license for persons under the age of eighteen (18) shall be on the Department issued form and shall include at a minimum:

- (1) The first name, middle name, last name and suffix, if applicable, of the applicant and of the applicant's parent(s) or legal guardian(s);
- (2) The mailing address of the applicant and of the applicant's parent(s) or legal guardian(s);
- (3) The date of birth of the applicant and of the applicant's parent(s) or legal guardian(s);
- (4) The telephone number and email address of the applicant and/or the applicant's parent(s) or legal guardian(s);
- (5) If the person submitting the application on behalf of a minor is the minor's legal guardian, a copy of documentation establishing the individual as the minor's legal guardian;
- (6) The signature and attestation by the parent(s) or legal guardian(s) that the information provided in the application is true and correct; and
- (7) 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's parent(s) or legal guardian(s) is an Oklahoma resident as established in OAC 310:681-1-6 (relating to proof of residency).
- (2) Documents establishing proof of identity as set forth in OAC 310:681-1-7 (relating to proof of identity) for the applicant and the applicant's parent(s) or legal guardian(s).

(3) A digital photograph, as established in OAC 310:681-1-8 (relating to applicant photograph), of the applicant and the applicant's parent(s) or legal guardian(s).

(4) Certifications and recommendations from two Oklahoma ~~Board-Certified~~ physicians dated within thirty (30) days of the date of submission of the application to the Department, on the forms provided by the Department, and including the information required under OAC 310:681-2-1(c)(4).

(d) Minor Patient Licenses are valid for a term of two (2) years, or until the minor turns age eighteen (18), whichever occurs first.

(e) Under no circumstances shall a minor patient license holder be authorized to smoke or vaporize any medical marijuana or medical marijuana products, unless both recommending physicians agree it is medically necessary. This Subsection does not prohibit minors from using nebulizers or other aerosolized medical devices.

(f) Payment of the application fee as established in 63 O.S. § ~~420A~~ 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. § ~~420A~~ 420 et seq.

(5) Application fees are nonrefundable.

(g) An applicant who can meet the requirements for a minor patient license as established in OAC 310:681-2-2 but whose physician recommendations for medical marijuana are 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 310:681-2-2(f), in which case applicant shall pay a reduced fee of \$20.00.

310:681-2-3. Application for caregiver's license [AMENDED]

(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 ~~Board Certified~~ 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.

(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.

310:681-2-3.1. Withdrawal of a caregiver's authorization [AMENDED]

(a) A medical marijuana patient license holder may withdraw ~~A~~ a caregiver's license ~~shall be withdrawn for any patient that~~ at any time by ~~provides~~ providing written or electronic notification to the Department, on the Department provided form, and the Department shall immediately withdraw the license ~~of their wish to withdraw the~~ caregiver's authorization. This withdrawal shall not be subject to appeal.

(b) Upon notice from the Department that the caregiver's license has been withdrawn, the caregiver shall immediately return his or her license to the Department.

310:681-2-4. Application for temporary patient license [AMENDED]

(a) Temporary patient license application shall be made on a form provided by the Department and shall include the following:

(1) All information provided for in OAC 310:681-2-1(a) (relating to patient license application);

(2) Electronic copy or digital image in color of applicant's unexpired out-of-state medical marijuana patient license;

(3) Electronic copy or digital image in color of one of the following unexpired documents:

(A) A valid state issued driver's license;

(B) A valid state issued Identification Card;

(C) A United States Passport or other photo identification issued

by the United States government; or

(D) Other documentation that the Department deems sufficient to establish identity;

(4) A digital photograph as established in OAC 310:681-1-8 (relating to applicant photograph); and

(5) If a temporary patient applicant is under the age of eighteen (18), in addition to complying with paragraphs (1), (2), and (3) of this subsection, applicant shall also comply with OAC 310:681-2-2(a)(1)-(7).

(b) Digital images of the records required in this Section shall be of sufficient clarity that all text is legible. See the requirements specified in OAC 310:681-1-8 (relating to applicant photograph) for resolution guidance.

(c) The fee for a temporary patient license shall be the fee established in statute at 63 O.S. § ~~420A~~ 420 et seq.

(d) Application fees are nonrefundable.

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

(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.

~~(b)~~ (c) **Caregiver license term.** Caregiver's licenses may not extend beyond the expiration date of the underlying patient license regardless of the issue date.

~~(e)~~ (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.

~~(d)~~ (e) **Change in information.** ~~It is the responsibility of the license holder to notify the Department in writing within thirty (30) days of any changes in contact information.~~ 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.

~~(e)~~ (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 Oklahoma Administrative Code 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 Oklahoma Administrative Code 310:681.

~~(f)~~ (g) **Renewal fee.** The fee for renewal shall be the fee established in statute or under this Chapter for the license at 63 O.S. § 420A et seq. Application fees are nonrefundable.

~~(g)~~ (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; and

(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 30 days of submission. A physician termination renders the patient license null and void.

(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.

~~(h)~~ (j) **License revocation and suspension.** Except as otherwise provided in applicable Oklahoma law and these Rules, ~~Procedures~~ 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 ~~be~~ receive notified notice of alleged violation(s) of the Department rules and applicable law. ~~These procedures also provide for the licensee 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 ~~compliance~~ 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.

310:681-2-8. Possession limits [NEW]

(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;
- (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.

(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.

310:681-2-9. Prohibited Acts and penalties [NEW]

(a) A licensed patient shall not sell or otherwise transfer any medical marijuana or medical marijuana products to another individual or entity. Intentional and impermissible diversion of medical marijuana or medical marijuana products by a licensed patient may result in, for a first offense, a fine of \$200.00, and for a second offense, a fine of \$500.00 and revocation of license upon a showing that the violation was willful or grossly negligent.

(b) A licensed caregiver shall not sell or otherwise transfer any medical marijuana or medical marijuana products to any individual other than the licensed patient on whose behalf the caregiver is lawfully authorized to grow, possess, purchase or otherwise obtain said medical marijuana or medical marijuana products. Intentional and impermissible diversion of medical marijuana or medical marijuana products by a licensed caregiver may result in, for a first offense, a fine of \$200.00, and for a second offense, a fine of \$500.00 and revocation of license upon a showing that the violation was willful or grossly negligent.

(c) All medical marijuana grown by medical marijuana patient license holders or caregivers may only be grown on real property owned by the patient license holder or on real property for which the patient license holder has the property owner's written permission to grow medical marijuana on the property. The growth of medical marijuana in locations not permitted under this Subsection is prohibited.

(d) Any and all medical marijuana grown by licensed patients or caregivers shall not be accessible to a member of the general public.

(e) Any and all medical marijuana grown by licensed patients or

caregivers shall not be visible from any street adjacent to the property. Medical marijuana is "visible" if it is viewable by a normal person with 20/20 eyesight without the use of any device to assist in improving viewing distance or vantage point.

(f) No licensed patient or caregiver shall operate or otherwise use any extraction equipment or processes utilizing butane, propane, carbon dioxide or any potentially hazardous material in or on residential property.

310:681-2-10. Confidential patient information [NEW]

All records and information submitted to or maintained by the Department containing patient and caregiver information shall be kept confidential.

SUBCHAPTER 3. ~~TRANSPORTATION~~ TRANSPORTER LICENSE

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

(a) A medical marijuana ~~transportation~~ transporter license will shall be issued to qualifying applicants for a ~~commercial~~ grower, processor, or dispensary licenses at the time of approval. This license shall enable licensed growers, processors, and dispensaries 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 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. § 427(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.

(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.

~~(b) A transportation license shall enable the holder to transport marijuana from an Oklahoma dispensary, grower, or processor, to an~~

~~Oklahoma dispensary, grower, or processor.~~

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

(a) All medical marijuana and medical marijuana products shall be transported:

(1) In ~~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 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 and shall be readily accessible.

~~(b)(d)~~ Commercial licensees or their authorized agents or employees shall Licensed transporter agents shall carry a copy of the commercial transporter license or the grower, processor, or dispensary transportation only license, and the transporter agent's license and- transportation license while transporting medical marijuana. Penalties for violations of this subsection may include a \$50.00 fine against the individual transporter and a \$500.00 fine against the employing commercial transporter, grower, processor, or dispensary for whom the transporting agent is transporting medical marijuana or medical marijuana products at the time of the violation.

~~(e)~~ (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 [NEW]

(a) License required. Only agents, employees, officers, or owners of commercial transporters, growers, processors, or dispensaries 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 \$100.00 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 (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; 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 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 Oklahoma Administrative Code 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 Oklahoma Administrative Code 310:681.

310:681-3-4. Employer deactivation of transporter agent license [NEW]

(a) Commercial transporters, growers, processors, or dispensaries employing a transporter agent shall notify the Department within fourteen (14) days in the manner and on the form prescribed by the Department 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 is responsible for destroying or returning to the Department any deactivated transporter agent license.

310:681-3-5. Information contained on a transporter agent license [NEW]

(a) A qualifying applicant for a transporter agent license shall be issued a registry identification card, otherwise referred to as a transporter agent license.

(b) The transporter agent shall carry the transporter agent license and a copy of his or her employer's transporter license at all times during transportation of medical marijuana or medical marijuana products.

(c) The transporter agent license shall at a minimum contain the following information:

(1) The digital photograph of the license holder;

(2) The name and date of birth of the license holder;

(3) The type of license;

(4) The date the license expires; and

(5) The unique license number assigned to the license holder.

(d) Licensees shall not accept any medical marijuana or medical marijuana products from a transporter agent who is not in possession of a transporter agent license.

310:681-3-6. Inventory manifests [NEW]

(a) Commercial transporters, growers, processors, and dispensaries shall utilize an electronic inventory management system to create and maintain 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 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, or dispensary 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 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 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) years from the date of receipt.

(g) An inventory manifest shall not be altered after departing from the originating licensee's premises, except for the addition of the printed names, titles, and signatures of any personnel accepting delivery on behalf of the receiving licensee.

(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 medical marijuana and/or medical marijuana products shall be immediately returned to originating licensee who retains legal ownership of the products; and

(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. MEDICAL RESEARCH FACILITIES AND EDUCATION FACILITIES LICENSE

310:681-4-1. License required [NEW]

(a) No person or entity shall operate a research facility or education facility without first obtaining a license from the Department pursuant to 63 O.S. § 420 et seq., the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq., other applicable Oklahoma law, and the Rules in this Chapter. All research and development conducted by a medical marijuana research facility or education facility shall be conducted in furtherance of an approved research project. 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.

(b) All license 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.

(c) All research facility and education facility licenses shall be on forms prescribed by the Department.

(d) Application fees are nonrefundable.

(e) A medical marijuana research facility license may be issued for the following purposes, with the exception that biomedical and clinical research subject to federal regulations and institutional oversight is not subject to licensure or regulation by the Department:

(1) To test chemical potency and composition levels;

(2) To conduct clinical investigations of marijuana-derived-medicinal purposes;

(3) To conduct research on the efficacy and safety of administering marijuana as part of a medical treatment;

(4) To conduct genomic, horticultural, or agricultural research; and

(5) To conduct research on marijuana-affiliated products or systems.
(f) A medical marijuana education facility license may be issued for the following purposes, with the exception that biomedical and clinical research subject to federal regulations and institutional oversight is not subject to licensure or regulation by the Department:

- (1) To test cultivation techniques, strategies, infrastructure, mediums, lighting, and other related technology;
- (2) To demonstrate cultivation techniques, strategies, infrastructure, mediums, lighting, and other related technology;
- (3) To demonstrate the application and use of product manufacturing technologies;
- (4) To conduct genomic, horticultural, or agricultural research; and
- (5) To conduct research on marijuana-affiliated products or systems.

310:681-4-1.1 Responsibilities of the license holder [NEW]

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 licensed premises 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 facility 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 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.

310:681-4-2. Licenses [NEW]

(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.

(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 Oklahoma Administrative Code 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 Oklahoma Administrative Code 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.

(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 any changes that affect the licensee's qualifications for licensure. Licensees shall notify the Department in writing in advance of any change that may affect the licensee's qualifications for licensure by electronically submitting a change request, along with any relevant documentation, in accordance with the Department's instructions. 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) 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. § 427(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)(2);
(ii) Documents required under OAC 310:681-4-3(e)(3) 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 assigned or otherwise transferred from one person to another person or from one legal entity to another.

(2) Licenses shall not be changed from one license type to another.

(3) 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 [NEW]

(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;
- (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. § 427(E);
- (2) 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;
- (3) 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.
- (4) 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) 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. § 427(E);
- (2) An application for an education facility must include non-profit registration with the Oklahoma Secretary of State;
- (3) 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)

(4) If applicable, the education facility applicant must submit the curriculum and/or a description of the curricula that will be used; and

(5) 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.

(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 [NEW]

(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 the nonrenewal, suspension, 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.

(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.

(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 nonrenewal, suspension, or revocation of a license, or any other remedy or relief available under law. 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.

(i) 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.

310:681-4-5. Inventory tracking, records, and reports [NEW]

(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.

(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, and/or testing of medical marijuana and medical

marijuana products, including but not limited to 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.** Each research facility and education facility shall use the seed-to-sale 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. The system utilized by each licensee shall be a system that:

(1) Documents the chain of custody of all medical marijuana and medical marijuana products, including every transaction with another licensee, patient, or caregiver;

(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 entire life span of a licensee's stock of medical marijuana and medical marijuana products, including, at a minimum:

(A) when medical marijuana seeds are planted;

(B) when medical marijuana plants are harvested and/or destroyed;

(C) when medical marijuana is transported, 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;

(E) 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.

(e) **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 the nonrenewal, suspension, 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 nonrenewal, suspension, 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 of \$500.00 for each violation and any other administrative action and penalty authorized by law.

310:681-4-6. Penalties [NEW]

(a) **Failure to file timely reports.** If a research facility licensee wholly fails to submit a 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 of \$500.00 and any other administrative action and penalty authorized by law.

(b) **Fraudulent reports.** Within any two (2) year period of time, if the a licensee has submitted one (1) or more reports containing gross errors that cannot reasonably be attributed to normal human error, the following penalties shall be imposed:

(1) First fraudulent report(s): One thousand dollar (\$1,000.000) fine. If said fine is not paid to the Department within thirty (30) calendar days of licensee receiving notice of the fine, the license shall be revoked.

(2) Any additional fraudulent report(s): Five thousand dollar (\$5,000.000) fine. If said fine is not paid to the Department within thirty (30) calendar days of licensee receiving notice of the fine, the license shall be revoked.

(c) **Unlawful purchase and sale.** Within any two year period of time, if the licensee has made an unlawful purchase or sale of medical marijuana, the following penalties shall be imposed:

(1) First unlawful purchase(s) or sale(s): One thousand dollar (1,000.00) fine. If said fine is not paid to the Department within thirty (30) calendar days after licensee receives notice of the fine, the license shall be revoked.

(2) Any additional unlawful purchase(s) or sale(s): Five thousand dollar (\$5,000.00) fine. If said fine is not paid to the Department within thirty (30) calendar days of licensee receiving notice of the fine, the license shall be revoked.

(d) **Noncompliance and criminal activity.** A research facility or education facility licenses shall be subject to 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 research facility or education facility 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.

SUBCHAPTER 5. ~~COMMERCIAL ESTABLISHMENTS~~ **MEDICAL MARIJUANA BUSINESSES**

310:681-5-1. License required [AMENDED]

(a) No person or entity shall operate a medical marijuana ~~dispensary, grower operation, processor, or research project business~~ without first obtaining a license from the Department pursuant to 63 O.S. § ~~420A~~ 420 et seq., the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq., other applicable Oklahoma

law, and the Rules in this Chapter. Only a person who is in compliance with the requirements of ~~63 O.S. § 420A et seq.~~ Oklahoma law and these Rules shall be entitled to receive or retain such a license.

(b) All commercial business 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.

(c) All commercial licenses/businesses shall be on forms prescribed by the Department.

~~(e)~~(d) Application fees are nonrefundable.

310:681-5-1.1. Responsibilities of the license holder [AMENDED]

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 ~~commercial establishment~~ licensed premises that is conspicuous ~~to consumers;~~
- (2) Comply with the provisions in this Chapter;
- (3) Allow representatives of the Department access to the ~~commercial establishment~~ medical marijuana business as specified under OAC 310:681-5-4 and OAC 310:681-5-~~(4)~~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 ~~commercial establishment~~ 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; ~~and~~
- (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 and a valid mailing address, if applicable—are complete, accurate, and updated in a timely manner in accordance with these Rules; and
- ~~(7)~~(8) If applicable, submit the annual renewal application and pay all renewal license and late fees, if any.

310:681-5-2. Licenses [AMENDED]

(a) **Timeframe.** A ~~commercial establishment~~ 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 ~~of 63 O.S. § 420A et seq.~~ set forth in Oklahoma law and this Chapter.

(b) **Location.** A business ~~establishment~~ 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 ~~of 63 O.S. § 420A et seq.~~ set forth in Oklahoma law and these rulesRules.

(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 Oklahoma Administrative Code 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 Oklahoma Administrative Code 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) Liquidation of products. ~~(3) A commercial establishment 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.~~

~~(A)(1) A commercial establishment medical marijuana business has thirty (30) days from date of expiration, revocation, suspension, or surrender of a commercial business license to liquidate and transfer all medical marijuana or medical marijuana products to another commercial establishment medical marijuana business that (1) the commercial establishment medical marijuana business may lawfully sell to and (2) is licensed to possess such medical marijuana or medical marijuana products.~~

~~(B)(2) Any medical marijuana or medical marijuana products not liquidated in accordance with OAC 310:681-5-2(d)(1) still in possession after date of expiration, revocation, suspension, or surrender, or medical marijuana products not liquidated after thirty (30) days, shall be disposed of as specified under OAC 310:681-5-10.~~

~~(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)~~ **(e) Change in information.**

(1) ~~The commercial licensee~~ 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 any changes that affect the licensee's qualifications for licensure. The licensee Licensees shall notify the Department in writing no less than fourteen (14) days in advance of any change that may affect the licensee's qualifications for licensure by electronically submitting a change request, along with any relevant documentation, in accordance with the Department's instructions. 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 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) that the location of the dispensary is at least one thousand (1,000) feet from any public and private school;
- (ii) A certificate of compliance as required in OAC 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. § 427(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) An 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) (6) 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.

~~(3) In the event of a change for which a licensee does not have prior notice that may affect the licensee's qualifications for licensure, the licensee shall notify the Department immediately upon learning of the change.~~

~~(e)~~ (f) **Transfer of license.**

(1) ~~Commercial Business~~ licenses may not be assigned or otherwise transferred from one person to another person, from one ~~commercial establishment~~ medical marijuana business to another, or from one legal entity to another.

(2) Licenses may not be changed from one business license type to another.

~~(f)~~ (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; ~~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); and

~~(C)~~ (D) Liquidate or dispose of Any any medical marijuana or medical marijuana products remaining in the possession of the licensee shall be disposed of in accordance with OAC 310:681-5-2(d) and OAC 310:681-5-10.

310:681-5-3. Applications [AMENDED]

(a) **Application fee.** An applicant for a ~~commercial establishment license~~ 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. § ~~420A~~420 et seq. and the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq.

(b) **Submission.** Applications for a ~~commercial~~ 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; ~~and~~

(4) Phone number and email of the establishment;

(5) Hours of operation for any licensed premises.

(c) **Individual applicant.** The application for a ~~commercial~~ business license made by an individual on ~~their~~ this 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; ~~and~~

(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

~~(6)-(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 ~~commercial 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) An attestation that the commercial entity will not be located on tribal lands;~~

~~(7)-(6) Telephone number and email address; and~~

~~(8)-(7) The name, residence address, and date of birth of each owner and each member, manager, and board member, if applicable.~~

(e) **Supporting documentation.** ~~For a determination that a commercial applicant meets the requirements of 63 O.S. § 420A et seq., each~~ 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 owners and principal officers of the commercial 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 a certificate of good standing from the Oklahoma Secretary of State issued within thirty (30) days of submission of the application, if applicable;

(3) If applicable, an electronic copy or digital image in color of a sales tax permit issued by the Oklahoma Tax Commission;

~~(3)-(4) An Affidavit of Lawful Presence for each owner;~~

~~(4)-(5) If a licensed dispensary, proof that the location of the dispensary is at least one thousand (1,000) feet from a public or private school. 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; and~~

~~(5)-(6) 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 established required in 63 O.S. § 420A et seq. the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq. and OAC 310:681-1-6 (relating to proof of residency); and~~

(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).

(7) 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. § 427(E);

(8) 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

(9) Any further documentation the Department determines is necessary to ensure the commercial applicant is qualified under ~~63 O.S. § 420A et seq.~~ 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.

(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.

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

(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;

(2) An Oklahoma identification card;

(3) An Oklahoma voter identification card;

(4) Utility bills, excluding cellular telephone and Internet bills;

(5) Residential property deeds or other official documentation establishing proof of ownership of Oklahoma residential property;

(6) Rental agreements for residential property located in the State of Oklahoma; and

(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

[NEW]

(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.

(b) Any license issued to an individual or entity listed above shall be subject to revocation.

310:681-5-4. Inspections [AMENDED]

(a) Submission of an application for a medical marijuana ~~processing~~ commercial license constitutes permission for entry to and inspection of the ~~processing licensee's premises~~ 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 the nonrenewal, suspension, or revocation of a license.

(b) The Department may perform ~~two an annual unannounced~~ on-site ~~inspection~~ inspections per calendar year of a ~~licensed processor's~~ operations ~~each licensed grower, processor, dispensary, or commercial transporter~~ to determine, assess, and monitor compliance with ~~63 O.S. § 420A et seq.,~~ applicable Oklahoma law and these Rules and, if applicable, food safety/preparation standards.

(c) If the Department receives a complaint concerning a licensed processor's noncompliance with 63 O.S. § 420A et seq. and this Chapter, the Department may conduct additional unannounced, on-site inspections beyond an annual inspection.

(c) The Department shall conduct one on-site inspection of a testing laboratory applicant prior to initial licensure and one 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.

(e) The Department ~~may~~ shall refer all complaints alleging criminal activity or other violations of Oklahoma law that are made against a licensed processor licensee to appropriate Oklahoma state or local law enforcement or regulatory authorities.

~~(d)~~(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.

~~(e)~~(g) The Department may review any and all records of a licensed processor 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 nonrenewal, suspension, or revocation of a license, or any other remedy or relief available under law. All records shall be kept on-site and readily accessible.

~~(f) All commercial licensees shall provide the Department access to any material and information necessary in a reasonable amount of time not to exceed fifteen (15) days for determining compliance with 63 O.S. § 420A et seq. and this Chapter.~~

~~(g)~~(h) If the Department identifies a violation of 63 O.S. § 420A420 et seq., the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq.; and these Rules or this Chapter during an inspection of the licensed processor business, the Department shall take administrative action in accordance with 63 O.S. § 423A and the Oklahoma law, including the Oklahoma Administrative Procedures Act, 75 O.S. §§ 250 et seq.

~~(h)~~(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 deficiencies-violations.

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

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

[AMENDED]

(a) **Monthly reports.** ~~Each commercial licensee shall utilize an inventory management system to maintain records and~~ 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 ~~from a licensed processor~~ in pounds;
- ~~(B) The amount of marijuana purchased from a licensed grower in pounds;~~
- ~~(C)~~ (B) The amount of marijuana sold or otherwise transferred to licensees and the type of licensee in pounds;
- ~~(D)~~ (C) The amount of marijuana waste in pounds;
- ~~(E)~~ (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;
- ~~(F)~~ (E) Total dollar amount of all sales to medical marijuana patients and caregivers;
- ~~(G)~~ (F) Total dollar amount of all taxes collected from sales to medical marijuana patients and caregivers; and
- ~~(H)~~ (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. § ~~420A~~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;
- ~~(B)~~ (C) The amount of marijuana sold or otherwise transferred to processor licensees in pounds;
- ~~(C) The amount of marijuana sold to researcher, dispensary, and processor licensees 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 ~~to processor, dispensary, and researcher licensees;~~ 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. § ~~420A~~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 ~~from grower licensees~~ in pounds;
- (B) The amount of marijuana sold or otherwise transferred to dispensary, processor, and researcher licensees 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. § ~~420A~~420 et seq. and the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq.

~~(4) Researcher reports shall include:~~

- ~~(A) The amount of marijuana purchased from commercial establishments in pounds;~~
- ~~(B) The amount of medical marijuana used for research;~~
- ~~(C) The amount of marijuana waste in pounds;~~
- ~~(D) 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~~
- ~~(E) Any information the Department determines is necessary to ensure that all marijuana grown in Oklahoma is accounted for as required under 63 O.S. § 420A et seq.~~

(4) Submission 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, in accordance with the Oklahoma Medical Marijuana Protection Act, 63 O.S. § 427.1 et seq., and these Rules shall be sufficient to satisfy monthly reporting requirements.

(b) **Records.** Pursuant to the Department's audit and inspection responsibilities, ~~commercial establishments~~ medical marijuana business shall keep onsite and readily accessible, either in paper or electronic form, a copy of the ~~following records for at least seven~~ (7) years from the date of creation: 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 as 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) If As applicable, documents relating to the processing and preparation of medical marijuana products, which may include but is not limited to any documents related to the processing, preparation, and/or testing of medical marijuana and medical marijuana products, including but not limited to 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 identification number associated with the receiving license~~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; ~~sold.~~
- (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. Documentation of every instance in which marijuana was purchased, which shall include:

(A) The license number of the selling commercial establishment; and

(B) The quantity and type of medical marijuana purchased.

(5) If researcher, documentation of every instance in which medical marijuana was used for research, including the quantity and type of medical marijuana used.

(c) **Patient information.** Records containing private patient information shall not be retained by a medical marijuana business for more than sixty (60) days without the patient's or caregiver's consent. "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.

(e) (d) **Inventory.** Each ~~commercial~~ business licensee shall use the seed-to-sale 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. The system utilized by each licensee shall be a system ~~obtain and maintain an~~ electronic inventory management system that:

(1) Documents the chain of custody of all medical marijuana and medical marijuana products, including every transaction with another commercial licensee, patient, or caregiver;

(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 tracks~~ tracking and documentation of the entire life span of a licensee's stock of medical marijuana and medical marijuana products, ~~from the time the medical marijuana is propagated at the time it is sold to a patient or caregiver;~~ including, at a minimum:

(A) When medical marijuana seeds are planted;

(B) When medical marijuana plants are harvested and/or destroyed;

(C) When medical marijuana is transported, 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;

(E) 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.

~~(d)~~(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 the nonrenewal, suspension, 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 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.

~~(2) All commercial licensees shall provide the Department access to any material and information necessary in a reasonable amount of time not to exceed fifteen (15) days for determining compliance with 63 O.S. § 420A et seq. and this Chapter.~~

(3) If the Department identifies a violation of 63 O.S. § 420A~~420~~ et seq., the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq.; or these ~~rules~~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) If the Department receives a complaint concerning a commercial license holder's noncompliance with 63 O.S. § 420A et seq. or these rules, the Department may conduct additional unannounced, on-site audits.~~ 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 of \$500.00 for each violation and any other administrative action and penalty authorized by law.

310:681-5-6.1. Penalties [AMENDED]

(a) **Failure to file timely reports.** If a commercial licensee wholly fails to submit a 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 of \$500.00 and any other administrative action and penalty authorized by law ~~revoked~~ ~~subject to Subsection (d).~~

(b) **Inaccurate reports.** Within any two (2) year period of time, if ~~the Department makes a finding the~~ a licensee has submitted one (1) or more reports containing gross errors that cannot reasonably be attributed to normal human error, the following penalties shall be imposed:

(1) ~~First finding of~~ inaccurate report(s): Five thousand dollar (\$5,000.000) fine. If said fine is not paid to the Department within thirty (30) calendar days of licensee receiving notice of the fine, the license shall be revoked.

(2) ~~Any additional finding by the Department of~~ inaccurate report(s): Revocation of license.

(c) **Unlawful purchase and sale.**

(1) ~~Within any two year period of time, if the Department makes a finding that~~ the licensee has made an unlawful purchase or sale of medical marijuana, the following penalties shall be imposed:

(A) ~~First finding of~~ unlawful purchase(s) or sale(s): ~~Five~~ One thousand dollar (~~\$5,000.000~~1,000.00) fine. If said fine is not paid to the Department within thirty (30) calendar days after licensee receives notice of the fine, the license shall be revoked.

(B) ~~Any additional finding by the Department of~~ unlawful purchase(s) or sale(s): ~~Revocation of license~~ Five thousand dollar (\$5,000.00) fine.

(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 may shall be subject to nonrenewal, revocation, ~~or~~ suspension, monetary penalties, and any other penalty authorized by law upon a determination by the Department that the ~~commercial establishment licensee~~ has not complied with 63 O.S. § 420A et seq. applicable Oklahoma law or this Chapter, or upon official notification to the Department that the ~~commercial establishment licensee~~ has engaged in criminal activity in violation of Oklahoma law.

(e) ~~License revocation and suspension~~ **Administrative penalties.** Procedures for ~~revocation and suspension of licenses~~ 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 ~~be notified~~ receive notice of alleged violation(s) of the Department rules and applicable law. These procedures also provide for

~~the licensee~~ 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 ~~compliance~~ 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.

310:681-5-8. Composition of ~~medical marijuana industry expert board~~/food safety standards board [AMENDED]

(a) The ~~Medical Marijuana Industry Expert Board~~/Food Safety Standards Board shall be comprised of 12 Oklahoma residents appointed by the Commissioner of Health and shall serve at the pleasure of the Commissioner of Health. 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 ~~Medical Marijuana Industry Expert Board~~/Food Safety Standards Board (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. ~~By every July 1 thereafter, the~~ The Board shall review, and submit if necessary, recommendations regarding rule promulgation and standards 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 [AMENDED]

(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. § ~~420A~~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. § ~~420A~~420 et seq. or these rules.

(d) **Board meetings.** The ~~Medical Marijuana Industry Expert Board~~/Food Safety Standards Board shall meet as regularly as its members deem necessary to review Oklahoma food safety laws and these rules and to take action, including amending and/or adding recommended standards to the Oklahoma Board of Health or the Commissioner of Health.

(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. § ~~420A~~420.

(1) Title 21, part 101 of the Code of Federal Regulations ("CFR"), 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. § ~~420A~~420 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 Title 21, Part 120 of the Code of Federal Regulations, 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) **Required testing procedures.** In light of the medical nature of marijuana authorized under 63 O.S. § 420A et seq. and to ensure the suitability and safety for human consumption of food products containing medical marijuana, processors are required to test food products containing medical marijuana for microbials, solvent and chemical residue, metals, pesticide residue, potency, and contaminants and filth in accordance with the following standards and thresholds.~~

~~(1) **Frequency.** Processors shall on a quarterly basis test one lot of each type of edible medical marijuana product.~~

~~(2) **Allowable thresholds.** Products that fail to meet the thresholds as set forth below must be rejected and/or recalled immediately. In the event of recall, processors shall immediately notify the Department and all commercial establishments to which the recalled product was or may have been sold or transferred of the recall. Upon notification of the recall, the Department should work with dispensaries to notify patients who received the recalled product.~~

~~(3) **Retention of test results and records.** Processors shall retain all test results and related records for three (3) years.~~

~~(4) **Microbiological testing.**~~

~~(A) All products shall be tested for aerobic plate count.~~

~~(B) Product test results shall validate that less than one colony forming unit (CFU) per gram of tested material is present for E. coli or Salmonella species or the product shall be rejected and/or recalled.~~

~~(C) Products shall be tested for the presence of yeast and molds. Product test results shall validate less than 104 CFU or the product shall be rejected and/or recalled.~~

~~(D) Test reports shall include method reference.~~

~~(5) **Solvent and chemical residue.**~~

~~(A) Food products containing medical marijuana shall be tested for the following solvents to the maximum extent~~

~~practical:~~

- ~~(i) Acetone < 1,000 ppm~~
- ~~(ii) Benzene < 2 ppm~~
- ~~(iii) Butanes/ Heptanes < 1,000 ppm~~
- ~~(iv) Hexane < 60 ppm~~
- ~~(v) Isopropyl Alcohol < 1,000 ppm~~
- ~~(vi) Pentane < 1,000 ppm~~
- ~~(vii) Propane < 1,000 ppm~~
- ~~(viii) Toluene < 180 ppm~~
- ~~(ix) Total Xylenes (m, p, o-xylenes) < 430 ppm~~

~~(B) Test reports shall provide specific data for all listed and detected solvents.~~

~~(C) The test report shall list any solvents listed above that could not be tested for.~~

~~(D) If the test equipment's Limit of Detection (lowest possible detection limit) is above the specified limit for a solvent, the equipment's Limit of Detection amount will be considered sufficient to exceed safe contamination limits.~~

~~(E) 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.~~

~~(6) **Metals.**~~

~~(A) Testing for heavy metals shall include but is not limited to lead, arsenic, cadmium, and mercury.~~

~~(B) Test results shall meet the following thresholds:~~

- ~~(i) Lead - max limit < 1ppm~~
- ~~(ii) Arsenic - max limit < 0.4 ppm~~
- ~~(iii) Cadmium - max limit < 0.44 ppm~~
- ~~(iv) Mercury - max limit < 0.2 ppm~~

~~(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.~~

~~(7) **Pesticide residue.**~~

~~(A) Processors shall test all product batches for pesticides; 0.1 ppm or a positive result at the Limit of Detection (equipment's lowest possible detection amount) will be considered to exceed safe residue limits.~~

~~(B) Pesticide residue testing shall analyze samples for the presence of chlorinated hydrocarbons, organophosphates, carbamates, pyrethroids, neonicotinoids, acaricides, fungicides, and bactericides to the maximum extent practical.~~

~~(C) If the cannabis concentrate used to make an infused product was tested for pesticides and test results indicate the lot was within established limits, then the infused product does not require additional testing for pesticides.~~

~~(8) **Potency.** Processors shall test products for and provide results for levels of total THC.~~

~~(9) **Contaminants and filth.** Processors shall inspect all products~~

~~for contaminants and filth.~~

~~(A) Contaminants include any biological or chemical agent, foreign matter, or other substances not intentionally added to products that may compromise food safety or suitability.~~

~~(B) Processors shall document allowable thresholds for physical contaminants as part of the product test plan. Inspection requirements should be included in the operation's product test plan for third party testing, if applicable.~~

~~(C) Inspection records shall indicate a continual process of physical inspection has taken place for all batches.~~

~~(h)~~ **(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.

310:681-5-9. Standards for handling and processing medical marijuana and medical marijuana products [AMENDED]

These rules do not relieve commercial licensees of any obligations under Oklahoma law, statutes, and rules, including 63 O.S. § 1-1101 et seq., 63 O.S. § 1-1401 et seq., the Oklahoma Administrative Code ("OAC") 310:257, and OAC 310:260, to the extent they are applicable and do not conflict with 63 O.S. § ~~420A~~420 et seq.

310:681-5-10. Medical marijuana waste disposal [AMENDED]

~~(a) All medical marijuana plant material and waste generated during the cultivation, production, processing, handling, and testing of medical marijuana and medical marijuana products must be stored, managed, and disposed of in accordance with these ~~rules~~ Rules, the Oklahoma Medical Marijuana Waste Management Act, 63 O.S. § 427a et seq., and any other applicable Oklahoma statutes and rules, except that medical marijuana waste shall not be subject to the provisions of the Uniform Controlled Dangerous Substances Act, 63 O.S. § 2-101 et seq., including but not limited to the waste and disposal standards set forth under the Uniform Controlled and Dangerous Substances Act, 63 O.S. § 2-101 et seq., and the Department of Environmental Quality rules, OAC Title 252.~~

~~(b) Licensees may dispose of root balls, stems, fan leaves, seeds, and the mature stalks or fiber produced from such stalks at the license premises by open burning, incineration, burying, mulching, composting or any other technique approved by the Department of Environmental Quality.~~

310:681-5-12. Marijuana transaction limitations [AMENDED]

(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 of marijuana, one (1) ounce of marijuana concentrate, seventy-two (72)

ounces 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) ~~Commercial establishments~~ 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. ~~§420A420 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) ~~Verification of individual licenses, in~~ 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).

310:681-5-17. Entry to ~~commercial establishments~~ licensed premises
[AMENDED]

No minors under the age of eighteen(18) may enter ~~commercial establishments~~ licensed premises unless the minor is ~~a patient license holder~~ accompanied by ~~their~~ his or her parent or legal guardian.

310:681-5-18. Prohibited acts [AMENDED]

(a) No commercial ~~establishment~~ licensee shall allow the consumption of alcohol or the smoking or vaping of, medical marijuana, or medical marijuana products on the premises.

(b) No commercial ~~establishment~~ licensee shall employ any person under the age of eighteen (18).

(c) No dispensary shall allow for or provide the delivery of medical marijuana or medical marijuana products to licensed patients ~~patient license holders~~ or ~~caregiver's~~ caregivers ~~license holders~~.

(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.

~~(d)~~(e) No commercial ~~establishment~~ licensee shall engage in false advertising, ~~as prohibited under 63 O.S. §§ 1-1102 & 1-1402.~~

~~(e)~~(f) No commercial ~~establishment~~ licensee shall sell or offer to sell medical marijuana products by means of any advertisement or promotion that includes ~~including~~ 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 licensee shall operate or otherwise use any extraction equipment or processes utilizing butane, propane, carbon dioxide or any potentially hazardous material in residential property.

(k) Licensees shall only purchase, obtain, or otherwise accept the transfer of medical marijuana or medical marijuana products from an Oklahoma-licensed medical marijuana business. No licensee shall purchase medical marijuana or medical marijuana products from any unlicensed or out-of-state individual or entity.

SUBCHAPTER 6. COMMERCIAL FACILITIES LICENSEES

310:681-6-1. General security requirements for commercial establishment licensees [AMENDED]

(a) Commercial licensees shall implement appropriate security measures to deter and prevent the unauthorized entrance into areas containing marijuana and the theft and diversion of marijuana.

(b) Commercial licensees are responsible for the security of all marijuana items on the licensed premises or all marijuana items in their possession during transit.

310:681-6-2. Construction of premises [AMENDED]

All commercial establishments licensees shall meet the standards of any applicable state and local electrical, fire, plumbing, waste and building specification codes including but not limited to the codes adopted by the Oklahoma Uniform Building Code Commission as set forth in OAC Title 748, Chapter 20.

SUBCHAPTER 7. PACKAGING, AND LABELING, AND ADVERTISING

310:681-7-1. Labeling and packaging [AMENDED]

(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:

(1) Labels, ~~and~~ packages, and containers shall ~~may~~ 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 ~~packages~~ 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 false or misleading statements.

(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.

(e) **Label requirements.**

(1) Medical marijuana and medical marijuana product labels shall contain, at a minimum, the following information:

(A) The Oklahoma Uniform Symbol in the manner and form prescribed by the Department;

(B) THC potency;

(C) Terpenoid potency; and

(D) 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.

310:681-7-2. Prohibited products [AMENDED]

(a) No commercial ~~establishment~~ licensee shall manufacture, process, or offer for sale or consumption any medical marijuana product intended to be attractive to children or minors.

(b) No commercial ~~establishment~~ licensee, other than a licensed dispensary, shall offer for retail sale any marijuana seedlings or mature plants. No mature plants are authorized in the possession of either a commercial ~~establishment~~ licensee or patient license holder until 60 days after August 27, 2018. No seedlings are authorized in the possession of a commercial ~~establishment~~ license holder until 7 days after August 27, 2018.

310:681-7-3. Advertising [NEW]

(a) Commercial licensees shall not engage in, circulate, or otherwise cause the dissemination of advertising that contains any materials prohibited under Oklahoma law and these rules.

(b) Advertising for medical marijuana and medical marijuana products shall not contain any statements, illustrations, or other material that:

- (1) Is deceptive, false, or misleading;
- (2) Promotes overconsumption;
- (3) Represents that the use of marijuana has curative or therapeutic effects;
- (4) Depicts a child or other person under legal age to consume marijuana;
- (5) Depicts objects such as toys, cartoons, cartoon characters, or similar images, which suggest the presence of a child, or any other depiction designed in any manner to be especially appealing to children or other persons under legal age to consume marijuana;
- (6) Has any manner or design that would be especially appealing to children or other persons under eighteen (18) years of age.

SUBCHAPTER 8. LABORATORY TESTING

310:681-8-1. Testing standards and thresholds [NEW]

(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, 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.** Growers shall separate all harvested medical marijuana into harvest batches not to exceed ten (10) pounds. Processors shall separate all medical marijuana product lots into production batches not to exceed ten (10) pounds.

(c) **Frequency.** Growers and processors shall ensure samples from each harvest batch and production batch are tested in accordance with the Oklahoma Medical Marijuana and Patient Protection Act, 63 O.S. § 427.1 et seq., and these Rules. 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. Processors shall not process, sell, or otherwise transfer any medical marijuana products from any medical marijuana production batch until samples of the production batch have passed all tests in accordance with this Subchapter.

(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.

(2) Processors shall not process, sell, or otherwise transfer any medical marijuana products from any medical marijuana production batch until samples of the production batch have passed all tests in accordance with this Subchapter.

(3) Dispensaries shall not purchase, accept transfer of, or sell any medical marijuana or medical marijuana products that have not passed all tests in accordance with this Subchapter. Dispensaries shall obtain and maintain copies of the certificate of analysis (COAs) for all medical marijuana and medical marijuana products the dispensary purchases. Growers and processors shall provide dispensaries with copies of certificates of analysis upon request.

(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 upon demand. The costs for all sampling and tests conducted pursuant to these rules shall be the financial responsibility of the business licensee.

(f) **Prohibited transfers.** Growers and processors 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 set forth in this Subchapter.

(f) **Recall.** In the event that any medical marijuana or medical marijuana products that exceed allowable testing thresholds or that otherwise fail to meet standards set forth in this Subchapter are sold or otherwise transferred, the following shall occur:

(1) Any commercial licensee with knowledge of such event shall immediately notify the Department;

(2) All such medical marijuana and medical marijuana products shall be immediately recalled; and

(3) 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.

(g) **Retention of test results and records.** Processors and growers shall retain all test results and related records for at least two (2) years.

(h) **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.

(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.

(5) **Pesticide residue.** All harvest batch samples shall be tested for the following pesticides, and shall not exceed the associated limits:

<u>(A) Spiromesifen</u>	<u>< 0.05 ppm</u>
<u>(B) Spirotetramat</u>	<u>< 0.05 ppm</u>
<u>(C) Tebuconazole</u>	<u>< 0.5 ppm</u>
<u>(D) Etoxazole</u>	<u>< 0.5 ppm</u>
<u>(E) Imazalil</u>	<u>< 0.5 ppm</u>
<u>(F) Imidacloprid</u>	<u>< 0.5 ppm</u>
<u>(G) Malathion</u>	<u>< 0.5 ppm</u>
<u>(H) Myclobutanil</u>	<u>< 0.5 ppm</u>
<u>(I) Azoxystrobin</u>	<u>< 0.5 ppm</u>
<u>(J) Bifenazate</u>	<u>< 0.5 ppm</u>
<u>(K) Abamectin (Avermectins: Bla & Blb)</u>	<u>< 0.5 ppm</u>
<u>(L) Permethrin (mix of isomers)</u>	<u>< 0.5 ppm</u>
<u>(M) Spinosad (Mixture of A and D)</u>	<u>< 0.5 ppm</u>

(6) **Potency.** Processors and growers shall test harvest batch and production batch samples for levels of total THC and terpenoid potency.

(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) There must be no visual evidence of mammalian excreta, bugs, animal parts, or any other material not intentionally added.

(C) Growers and processors shall document allowable thresholds

for physical contaminants as part of the product test plan. Inspection requirements should be included in the operation's product test plan for third party testing, if applicable.

(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.

(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 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.

(i) Remediation and retesting, general.

(1) If a sample fails testing under this Subchapter, the harvest batch or production 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 failed testing and has been remediated or decontaminated must be re-tested and successfully pass all the analyses required under this Subchapter. If the harvest batch or product batch fails to pass testing after remediation or decontamination, the harvest batch or production batch must be disposed of in accordance with the Waste Management Act, 63 O.S. § 427a et seq. and these Rules.

(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.

(A) Any remediation methods or remediation solvents used on medical marijuana or medical marijuana products must be disclosed to the testing laboratory.

(4) Growers and processors 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.

(j) Remediation and retesting, microbiological impurities testing.

(1) If a sample from a 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) 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.

(3) A batch that is decontaminated in accordance with subsection (1) or (2) 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.

(4) 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.

(k) Remediation 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 remediated using procedures that would reduce the concentration of solvents to less than the action level.

(2) A batch that is remediated in accordance with subsection (1) of this section 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 remediated or is remediated 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.

(l) Remediation 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 remediation as described in subsection (1) of this section must be sampled and tested in accordance with these Rules.

(m) Remediation and retesting, residual pesticide testing.

(1) If a sample from a batch fails residual pesticide testing, the batch may not be remediated 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.

(n) Remediation and retesting, heavy metals testing.

(1) If a sample from a batch fails heavy metals testing, the batch may not be remediated 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.

(o) Remediation and retesting, mycotoxin testing.

(1) If a sample from a batch fails mycotoxins testing, the batch may not be remediated and must be disposed in accordance with the Oklahoma Medical Marijuana Waste Management Act, 63 O.S. § 427a et seq., and these Rules.

(p) Remediation and resting, 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 remediation as described in subsection (1) of this section 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.

310:681-8-2. General operating requirements and procedures [NEW]

(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 be from one of these entities in both chemistry and biology, or cannabis.

(b) Proficiency testing. The laboratory shall be subject to proficiency testing by the Department or its designee at a frequency and at times 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 testing. The Department or its designee may require submission of samples from the licensed laboratory for purposes of proficiency testing.

(2) The quality assurance laboratory shall obtain reserve samples from licensed laboratories for the purposes of proficiency 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 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.

(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.

(c) **Conflict of interest.** A person who is a direct beneficial owner or an indirect beneficial owner of a licensed dispensary, commercial grower, or processor shall not be an 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.

(d) **Safety standards.** Licensed laboratories must comply with Occupational Safety and Health Administration (OSHA) Standard 29 CFR 1910.1450.

(e) **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.

(f) Equipment.

(1) Equipment used for analysis must have a Limit of Detection (LOD) capable of detecting the thresholds listed in OAC 310:681-8-1(h).

(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.

(g) 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) 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.

(h) 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 Occupational Safety and Health Administration (OSHA) Standard 29 CFR 1910.1450; and

(11) Such other materials as the Department may require.

(i) **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.

310:681-8-3. Sampling requirements and procedures [NEW]

General requirements. Samples must be collected in accordance with OAC 310:681-8-3(c). Individuals collecting samples are called "Samplers."

(1) Samplers must:

(A) Follow the approved sampling policies and procedures of the laboratory that will be testing the samples collected. Samplers shall have access to a copy of the laboratory's standard operating procedures while they are collecting the samples; and

(B) 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 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) Samples shall only be collected from harvest batches and production batches in final form.

(6) The sampler shall collect both a primary sample and a reserve sample from each harvest batch and production batch.

(7) The primary sample and reserve sample shall be stored and analyzed separately. The reserve sample is used for quality control purposes only.

(8) 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 use a sample field log to record the following information for each sampled batch:

(A) Laboratory's name, address, and license number;

(B) Sampler's name(s) and title(s) and the names of others onsite;

(C) Date and time sampling started and ended;

(D) Grower's or processor's name, address, and license number;

(E) Batch number of the batch from which the sample was obtained;

(F) Sample matrix;

(G) Total batch size, by weight or unit count;

(H) Total weight or unit count of the primary sample;

(I) Total weight or unit count of the reserve sample;

(J) The unique sample identification number for each sample;

(K) Name, business address, and license number of the person who transports the samples to the laboratory;

(L) Requested analyses;

(M) Sampling conditions, including temperature;

(N) Problems encountered and corrective actions taken during the sampling process, if any; and

(O) 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) A laboratory must maintain the documentation required in these rules for at least two (2) 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 is collected from different areas of the batch following the laboratory's approved protocol. The sample is then 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, obtain an amount sufficient to be aliquoted into a primary sample and a reserve sample, which shall be equal in amounts. 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 is then 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.

(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;

(I) Chain-of-custody documentation for each sample in 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:

(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.

(3) The COA shall contain, at minimum, the following information:

(A) The name, address, license number, and contact information of the laboratory that conducted the analysis;

(i) If the laboratory sends a sample to another laboratory for testing, the reference laboratory must be identified as having performed that test.

(B) The name, address, and license number of the requester;

(C) 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;

(D) The unique sample identifier;

(E) Batch number of the batch from which the sample was obtained;

(F) 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;

(G) The analytical methods used, including at a minimum identification of the type of analytical equipment used (e.g., GC, HPLC, UV, etc.);

- (H) The reporting limit for each analyte tested;
- (I) 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; and
- (J) 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.
- (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) When reporting results for any analytes that were detected below the analytical method limit of quantitation (LOQ), indicate "<LOQ";
 - (D) 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 to submit samples for additional testing, including testing for analytes that are not required by these Rules, at the licensee's expense.

310:681-8-4. Laboratory quality assurance and quality control [NEW]

(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.
- (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;
 - (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 the chart below, 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.

310:681-8-5. Quality assurance laboratory [NEW]

(a) Purpose. The Department is authorized to contract with a private laboratory for the purpose of evaluating the day-to-day operations of licensed laboratories. Any such contracted laboratory is prohibited from conducting any other commercial medical marijuana testing in this state.

(b) Accreditation. The quality assurance laboratory must be accredited by or 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. Accreditation or application for accreditation must be from one of these entities in both chemistry and biology or cannabis.

(b) Duties. On behalf of the Department, a contracted private laboratory shall have the authority to:

- (1) Conduct Inter-Laboratory Control Testing of laboratory licensees and applicants in a manner and frequency approved by the Department;
- (2) Inspect and assess testing equipment of licensed testing laboratories;
- (3) Access and test LQC samples;
- (4) Inspect and obtain copies of all laboratory documents and records, including but not limited to SOPs, COAs, testing reports, policies, and manuals;
- (5) Interview laboratory employees, owners, and agents for the purpose of evaluating compliance with Oklahoma law and these Rules;
- (6) Other actions as deemed appropriate by the Department to ensure compliance with Oklahoma law and these Rules.

SUBCHAPTER 9. WASTE DISPOSAL FACILITIES

310:681-9-1. License or permit required [NEW]

(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, 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.

(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.

310:681-9-1.1. Responsibilities of the license or permit holder [NEW]

Upon acceptance of the license or permit issued by the Department, the license holder in order to retain the license shall comply with the provisions in OAC 310:681-5-1.1.

310:681-9-2. Licenses and permits [NEW]

(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 of a medical marijuana waste facility for the following:

(A) Failure to meet the requirements for licensure set forth in the Oklahoma Medical Marijuana Waste Management Act, 63 O.S. § 427a et seq., or Oklahoma Administrative Code 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 Oklahoma Administrative Code 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 any changes that affect the licensee's qualifications to receive a license or permit. Licensees shall notify the Department in writing in advance of any change that may affect the licensee's qualifications for licensure by electronically submitting a change request, along with any relevant documentation, in accordance with the Department's instructions. 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 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(e) 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 310:681-9-4 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 310:681-9-4(e) (1);

(ii) An affidavit of lawful presence for each new owner;

(iii) Documents required under OAC 310:681-9-4(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.

(f) Transfer of license or permit.

(1) Waste disposal facility licenses and permits may not be assigned or otherwise transferred from one person to another person or from one legal entity to another.

(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 [NEW]

(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;

(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) A certificate of good standing from the Oklahoma Secretary of State, if applicable;

(3) An Affidavit of Lawful Presence for each owner;

(4) 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 of the facility;

(5) 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);

(6) Proof of sufficient liability insurance. Liability insurance or a letter of inurability 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 each occurrence;

(B) Pollution Legal Liability: \$5,000,000 each occurrence;

(7) Relevant waste permit(s) from the Oklahoma Department of Environmental Quality or the Oklahoma Department of Agriculture; and

(8) 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 [NEW]

(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. § 427 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 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;
 - (B) Pollution Legal Liability: \$5,000,000 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.

310:681-9-5. Inspections [NEW]

(a) Submission of an application for a medical marijuana waste disposal facility license or permit 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 the nonrenewal, suspension, or revocation of a license.

(b) The Department may perform one annual unannounced on-site inspection of each licensed and/or permitted premises to determine, assess, and monitor compliance of applicable Oklahoma law and these Rules.

(c) The Department shall conduct one on-site inspection of a waste disposal facility license or permit applicant prior to approving the application to determine if the proposed site and facility are physically and technically suitable, and that all application information and documentation is true and correct. The inspection shall also ensure the applicant meets all requirements in OAC 310:681-9-6.

(d) The Department may conduct additional inspections to ensure correction of or investigate violations of applicable Oklahoma law and these Rules.

(e) The Department shall refer all complaints alleging criminal activity or other violations of Oklahoma law that are made against a waste disposal facility to appropriate Oklahoma state or local law enforcement or regulatory authorities.

(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.

(g) The Department may review any and all records of a waste disposal facility and may require and conduct interviews with such persons or entities and persons affiliated with the facility, 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 available under law. All records shall be kept on-site and readily accessible.

(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., the Oklahoma Medical Marijuana Waste Management Act, 63 O.S. § 427a et seq., and these Rules. During an inspection of the waste disposal facility, the Department shall take administrative action in accordance with Oklahoma law, including the Oklahoma Administrative Procedures Act, 75 O.S. § 250 et seq.

(i) Except as otherwise provided in Oklahoma law or these Rules, a correctable violation identified during an inspection shall be corrected within thirty (30) days of receipt of a written notice of the violation.

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

(k) A waste disposal facility permit that has been revoked shall be reinstated upon correction of each deficiency and remittance of a reinstatement fee of five hundred dollars (\$500.00).

310:681-9-6. Security requirements [NEW]

(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 II non-residential 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:

(A) 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) years from the date of such inventory or record, for inspecting and copying.

310:681-9-7. Audits and inventory [NEW]

(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 the nonrenewal, suspension, or revocation of a license.

(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 nonrenewal, suspension, 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 of \$500.00 for each violation and any other administrative action and penalty authorized by law.

(b) **Inventory.** Each waste disposal facility shall use the seed-to-sale 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. The system utilized by each licensee shall be a system that:

(1) Documents the chain of custody of all medical marijuana and medical marijuana products, including every transaction with another commercial licensee;

(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 entire life span of a licensee's stock of medical marijuana and medical marijuana products, including, at a minimum:

(A) when medical marijuana seeds are planted;

(B) when medical marijuana plants are harvested and/or destroyed;

(C) when medical marijuana is transported, 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;

(E) all samples sent to a testing laboratory or used for internal quality testing or other purposes;

(4) Tracks medical marijuana using an assigned batch number and bar code.

310:681-9-8. Penalties [NEW]

(a) **Unlawful transfer.** Within any two year period of time, if a waste disposal facility licensee has engaged in unlawful transfer of medical marijuana, the following penalties shall be imposed:

(1) First unlawful transfer(s): One thousand dollar (\$1,000.00) fine. If said fine is not paid to the Department within thirty (30) calendar days after licensee receives notice of the fine, the license shall be revoked.

(2) Any additional unlawful transfer(s): Five thousand dollar (\$5,000.00) fine. If said fine is not paid to the Department within thirty (30) calendar days after licensee receives notice of the fine, the license shall be revoked. 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.

(b) **Noncompliance and criminal activity.** Waste disposal facility licenses and permits 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.

(c) **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 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.

310:681-9-9. Waste Disposal [NEW]

(a) **Permissible methods.** Waste shall be disposed through either a process which renders the waste unusable through physical destruction or a recycling process that the waste disposal facility is authorized to conduct pursuant to Oklahoma law.

(b) **Unusable and unrecognizable.**

(1) Medical marijuana waste facilities shall render medical marijuana waste (except hazardous waste) unusable and unrecognizable through one of the following methods. Other methods to render marijuana waste unusable and unrecognizable must be approved by the Department before implementation.

(A) Grinding and incorporating the medical marijuana waste with the non-consumable, solid wastes listed below such that the resulting mixture is at least 50 percent non-marijuana waste, and such that the resulting mixture cannot easily be separated and sorted:

(i) Paper waste;

(ii) Plastic waste;

(iii) Cardboard waste;

(iv) Food waste;

(v) Grease or other compostable oil waste;

(vi) Bokashi, or other compost activators;

(vii) Soil;

(viii) Sawdust; and

(ix) Other wastes approved by the Department that will render the medical marijuana waste unusable and unrecognizable.

(2) Medical marijuana waste facilities shall only use methods or materials permitted under their licensure with the Oklahoma Department of Environmental Quality or the Oklahoma Department of Agriculture and any applicable laws.

(3) Disposal of hazardous waste shall be conducted in a manner consistent with federal, state and local laws, regulations, rules or other requirements.

(c) **Applicable laws apply.** Medical marijuana waste, including any hazardous waste, shall be stored, secured, managed, and disposed in accordance with all applicable state and local statutes, rules, regulations, ordinances, or other requirements.

SUBCHAPTER 10. RECEIVERSHIP

310:681-10-1. Certificate of Authority [NEW]

(a) In the event that a licensed dispensary, grower, or processor is foreclosed, is the subject of an order appointing a receiver, becomes insolvent or bankrupt, or otherwise ceases operations, a temporary

Certificate of Authority may be issued to a secured party, court-appointed receiver, trustee, court-appointed personal representative, or other individual determined by the Department to have legal authority over the operation and/or disposition of the assets of the licensee. The temporary Certificate of Authority shall authorize the holder to continue operation, without obtaining a separate license, at a licensed dispensary, grower, or processor for a reasonable period of time for the orderly disposition of the business.

(b) A secured party, court-appointed receiver, trustee, personal representative, or other person requesting a Certificate of Authority must meet the requirements set forth in OAC 310:681-5-3 and OAC 310:681-5-3.2. A party that is issued a Certificate of Authority is subject to the same restrictions and obligations as any commercial licensee.

(c) A person requesting a temporary Certificate of Authority shall submit the form documentation provided by the Department in a manner prescribed by the Department.

(d) There shall be no additional fee for a Certificate of Authority to operate a grower, processor, or dispensary.

(e) A request for Certificate of Authority shall include the following documentation:

(1) Documents establishing proof of identity as established in OAC 310:681-1-7(b) (relating to proof of identity);

(2) 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 agreements, certificate of limited partnership, resolution of a board of directors, or other similar documents;

(3) 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);

(4) A criminal background check conducted by the Oklahoma State Bureau of Investigation establishing that the applicant does not have a disqualifying criminal conviction.

(5) A receiver, personal representative, or trustee must provide the Department with the following information:

(A) Official documentation proving that the person is the legal trustee, receiver, or personal representative for the business, or otherwise has legal authority over the operation and/or disposition of assets of the licensee, such as a court order, letters of administration, or other official documentation the Department deems sufficient.

(B) Any further documentation the Department determines is necessary to ensure the secured party is qualified under Oklahoma law and this Chapter.

(6) A secured party must provide the Department with the following information and documents:

(A) Proof of a security interest in the licensed business;

(B) Proof of the licensee's default on the secured debt;

(C) Proof of legal access to the real property; and

(D) Any further documentation the Department determines is necessary to ensure the secured party is qualified under Oklahoma

law and this Chapter.

310:681-10-2. Term and renewal of Certificate of Authority [NEW]

(a) A Certificate of Authority shall be valid for sixty (60) days. The Department may renew the Certificate of Authority upon proof that more time is necessary to allow for the orderly disposition of the business.

(b) A Certificate of Authority may not extend beyond the expiration date of the underlying grower, processor, or dispensary license regardless of the issue date.

(c) A Certificate of Authority does not replace a grower, processor, or dispensary license, which remains in effect and subject to renewal requirements.

(d) Upon termination or expiration of the Certification of Authority, all medical marijuana or medical marijuana products in the custody or possession of the holder of the Certificate of Authority must be disposed of or liquidated in accordance with the Oklahoma Medical Marijuana Waste Management Act, 63 O.S. § 427a et seq., and this Chapter.

310:681-10-3. Responsibilities of the Certificate of Authority holder [NEW]

The holder of a Certificate of Authority shall comply with the provisions stated in 310:681-5-1.1.

310:681-10-4. Revocation of Certificate of Authority [NEW]

The Department may revoke or refuse to issue or extend a Certificate of Authority for any of the reasons that the Department may revoke or refuse to issue or renew a license under Oklahoma law or these Rules.

APPENDIX A. TESTING THRESHOLDS [NEW]

<u>MICROBIOLOGICAL TESTING</u>		
<u>Substance</u>	<u>Acceptable Limits Per Gram</u>	<u>Product to be Tested</u>
<u>Shiga-Toxin producing E. coli (STEC)-Bacteria</u>	<u>< 1 Colony forming Unit (CFU)</u>	<u>Medical Marijuana; Medical Marijuana Products, including medical marijuana concentrates but not including rectal administration products, vaginal administration products, pressurized metered dose inhaler products, and metered dose nasal spray products</u>
<u>Salmonella species-Bacteria</u>	<u>< 1 Colony forming Unit (CFU)</u>	
<u>Aspergillus niger</u>	<u>Absent in 1 gram</u>	
<u>Aspergillus fumigatus</u>	<u>Absent in 1 gram</u>	
<u>Aspergillus terreus</u>	<u>Absent in 1 gram</u>	
<u>Aspergillus flavus</u>	<u>Absent in 1 gram</u>	
<u>Total Mold</u>	<u><10⁴ Colony forming unit (CFU)</u>	
	<u><10¹ Colony forming unit</u>	<u>Metered dose nasal spray</u>

	(CFU) FU/gm or CFU/ml	products; pressurized metered dose inhaler products; and vaginal administration products
	< 10 ² CFU/gm or CFU/ml	Rectal Administration products
<u>Total Yeast</u>	<10 ¹ Colony forming unit (CFU) FU/gm or CFU/ml	Medical marijuana and medical marijuana products that are administered via inhalation.
<u>Total aerobic microbial count</u>	< 10 ² CFU/gm or CFU/ml	Metered dose nasal spray products; pressurized metered dose inhaler products; or vaginal administration products
	< 10 ³ CFU/gm or CFU/ml	Rectal Administration products
<u>Staphylococcus aureus</u>	Absent in 1ml or 1 gm	Metered dose nasal spray products; pressurized metered dose inhaler products; or vaginal administration products
<u>Pseudomonas aeruginosa</u>	Absent in 1ml or 1 gm	Metered dose nasal spray products, pressurized metered dose inhaler products, or vaginal administration products
<u>Bile tolerant gram negative bacteria</u>	Absent in 1ml or 1 gm	Metered dose nasal spray products; and pressurized metered dose inhaler products
<u>Candida albicans</u>	<10 ⁴ Colony forming unit (CFU)	Medical marijuana and medical marijuana products

MYCOTOXINS

<u>Substance</u>	<u>Acceptable Limits Per Gram</u>	<u>Product to be Tested</u>
Aflatoxins (B1, B2, G1, and G2)	< 20 ppb (total of B1 + B2 + G1 + G2)	Medical Marijuana Products
Ochratoxin A	< 20 ppb	

RESIDUAL SOLVENTS AND CHEMICAL RESIDUE

<u>Substance</u>	<u>Acceptable Limits Per Gram</u>	<u>Product to be Tested</u>
Acetone	< 1,000 ppm	Medical Marijuana Products
Butanes	< 1,000 ppm	
Heptanes	< 1,000 ppm	
Isopropyl Alcohol	< 1,000 ppm	
Propane	< 1,000 ppm	
Benzene	< 2 Parts ppm	

<u>Toluene</u>	<u>< 180 ppm</u>	
<u>Pentane</u>	<u>< 1,000 ppm</u>	
<u>Hexane</u>	<u>< 60 ppm</u>	
<u>Total Xylenes (m,p,o-xylenes)</u>	<u>< 430 ppm</u>	
<u>Methanol</u>	<u>< 600 ppm</u>	
<u>Ethyl Acetate</u>	<u>< 1000 ppm</u>	
<u>Ethanol</u>	<u>< 5,000 ppm</u>	<u>Medical marijuana products that are administered via inhalation.</u>

METALS

<u>Substance</u>	<u>Acceptable Limits Per Gram Based on Intended Use</u>	<u>Product to be Tested</u>
<u>Metals (Arsenic, Cadmium, Lead, and Mercury)</u>	<u>Inhaled Product or administration by metered dose nasal spray or pressurized metered dose inhaler:</u> <u>Lead - Max Limit: < 0.5 ppm</u> <u>Arsenic - Max Limit: < 0.2 ppm</u> <u>Cadmium - Max Limit: < 0.2 ppm</u> <u>Mercury - Max Limit: < 0.1 ppm</u> <u>Topical and/or Transdermal:</u> <u>Lead - Max Limit: < 10 ppm</u> <u>Arsenic - Max Limit: < 3 ppm</u> <u>Cadmium - Max Limit: < 3 ppm</u> <u>Mercury - Max Limit: < 1 ppm</u> <u>Oral Consumption, rectal or vaginal administration:</u> <u>Lead - Max Limit: < 1 ppm</u> <u>Arsenic - Max Limit: < 1.5 ppm</u> <u>Cadmium - Max Limit: < 0.5 ppm</u> <u>Mercury - Max Limit: < 1.5 ppm</u>	<u>Medical Marijuana and Medical Marijuana Products</u>

APPENDIX B. LQC RESULTS [NEW]

<u>Laboratory Quality Control Sample</u>	<u>Acceptance Criteria</u>
<u>Method blank sample for chemical analysis</u>	<u>Not to exceed LOQ</u>
<u>Reference material and certified reference material for chemical analysis</u>	<u>The laboratory shall establish the 99% confidence interval for control performance. If insufficient historical data exists to establish the 99% confidence interval, the laboratory will use 80%-120% as</u>

	<u>an interim limit.</u>
<u>Laboratory replicate sample</u>	<u>Relative % difference (RPD) no greater than 20%</u>
<u>Matrix spike or matrix spike duplicate sample for chemical analysis</u>	<u>The laboratory shall establish the 99% confidence interval for control performance. If insufficient historical data exists to establish the 99% confidence interval, the laboratory will use 80%-120% as an interim limit.</u>
<u>CCV for chemical analysis</u>	<u>% recovery between 85% to 115%</u>
<u>Marijuana-derived product reserve sample</u>	<u>RPD no greater than 20%</u>
<u>Marijuana reserve sample</u>	<u>RPD no greater than 30%</u>