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 [NEW]
Subchapter 2. Medical Marijuana Licenses [NEW]
Subchapter 3. Transportation License [NEW]
Subchapter 4. Medical Research License [NEW]
Subchapter 5. Commercial Establishments [NEW]
Subchapter 6. Commercial Facilities [NEW]
Subchapter 7. Packaging and Labeling [NEW]
Subchapter 8. Laboratory Testing [RESERVED]
Appendix A. [RESERVED]

SUMMARY:

This Chapter is proposed to make permanent the sets of emergency rules adopted August 3rd and December 20th, 2018, with amendments. This proposed rule combines emergency rules from multiple adoptions into one comprehensive Chapter and adopted as permanent.

The proposed rulemaking would make permanent the 2018 emergency rules at OAC 310:681 the Department issued to fulfill requirements resulting from the passage of State Question 788, as codified at 63 O.S. § 420A, *et seq*. State Question 788, as codified at 63 O.S. § 420 (C) states that "a regulatory office shall be established under the Oklahoma State Department of Health." Subchapter 1(General Provisions) of the proposed rule establishes an office with the title of the Oklahoma Medical Marijuana Authority and defines terms and requirements. Subchapter 2 (Medical Marijuana Licenses) establishes processes for the issuance of patient and caregiver licenses authorizing access to medical marijuana and associated products. The subchapter also establishes processes and terms for surrender, renewal and expiration of patient and caregiver licenses. Subchapter 3 (Transportation Licenses) establishes standards for issuance of licenses to qualifying applicants to transport medical marijuana products. Subchapter 4 (Medical Research Licenses) reserves a subchapter of 310:681, pursuant to 63 O.S. § 425A(H). Subchapter 5 of the Chapter establishes rules for licensing of commercial establishments (dispensaries, laboratories, growers, processors and research entities) for the growth, processing and dispensing of medical marijuana. Penalties as established by law at 63 O.S. § 420 *et seq.* are listed in the subchapter. Commercial entities are subject to requirements for inventory tracking, record retention, reporting and audits in the subchapter. Operations of licensed processors are subject to annual, unannounced on-site inspection by the Department. Licensed Processors are required to label and package foods in compliance with Title 21, part 101 of the Code of Federal Regulations, as incorporated in the proposed section of rule (310:681-5-8.1(e)(1) Additionally, licensed processors would be required to test food products containing medical marijuana for

microbials, solvent and chemical residue, metals, pesticide residue, potency and contaminants and filth under the proposed rule. Furthermore, the rule clarifies that licensed processors are not relieved of any obligations under existing laws, rules and regulations. The regulations propose optional Hazard Analysis and Critical Control Plans to be adopted by licensed processors. A set of required laboratory testing procedures and allowable thresholds are established for food products containing medical marijuana. Subchapter 6 (Commercial Facilities) establishes general security and construction requirements for licensed commercial entities. Subchapter 7 (Packaging and Labeling) requires standards for packaging and labeling of medical marijuana. Subchapter 8 (Laboratory Testing) reserves a subchapter of 310:681.

AUTHORITY:

Commissioner of Health, 63 O.S. § 1-104, and 63 O.S. § 420(A) *et seq.*

COMMENT PERIOD:

February 15, 2019 through March 20, 2019. Persons wishing to submit comments may do so in person, by mail, or by email through March 21, 2019 at: Oklahoma State Department of Health, Attn: Agency Rule Liaison, Health Policy, Partnerships and Planning. 1000 Northeast Tenth Street, Oklahoma City, OK 73117-1207, or OSDHRules@health.ok.gov

PUBLIC HEARING:

Pursuant to 75 O.S. § 303 (A), the public hearing for the proposed rulemaking in this chapter shall be on March 18, 2019, at the Oklahoma State Department of Health, 1000 Northeast Tenth Street, Oklahoma City, OK 73117-1207, on the first floor beginning at 10:00 a.m. In the event of state offices closing due to inclement weather, there will be an alternate hearing date on March 20, 2019, at the same location on the first floor beginning at 10:00a.m.

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 before March 20, 2019.

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.health.ok.gov.

RULE IMPACT STATEMENT:

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

CONTACT PERSON:

Spencer Kusi, Agency Rule Liaison, Oklahoma State Department of Health, 1000 N.E. 10th Street, Oklahoma City, OK 73117-1207; e-mail: OSDHRules@health.ok.gov

INITIAL RULE IMPACT STATEMENT

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

1. **DESCRIPTION:** (*a brief description of the proposed rule* [75 O.S. § 303(D)(2)(a)])

This Chapter is proposed to make permanent the sets of emergency rules promulgated on August 3rd and December 20th, 2018, with amendments. This proposed rule combines emergency rules from multiple adoptions into one comprehensive Chapter for adoption as permanent rules.

An initial set of emergency rules promulgated in July 2018 were superseded and replaced in their entirety by a second set of approved emergency rules promulgated in August 2018. The third and final set of emergency rules promulgated contained amendments and additions to these emergency rules to implement the recommendations for food safety standards as required under 63 O.S § 423A. The following summarizes changes made to the affected sections from emergency versions. However, all sections of the Chapter have been included for permanent consideration because of the status of these rules as emergency rules.

310:681-1-1. Purpose; Removed limitation prohibiting any powers not specifically enumerated in the Chapter.

310:681-1-4. Definitions: Added the term "Application Status," which means the status of a submitted application and includes the following additional status terms: "Pending," "Rejected," "Approved," and "Denied." Definition of "Batch" is modified for clarification on how to identify batch for medical marijuana and medical marijuana products and concentrates. "Batch number" clarifies that the number should be assigned prior to testing or sale. "Control Number" is changed to "License Number." "Dispense" has been edited to apply to retail sales to what type of approved buyers. "Dispensary" has been modified to add individual as an approved owner type and added clarification on parent purchasers. "Disqualifying Criminal Conviction" added incarceration during submission. "Entity" was modified from individual to sole proprietorship for clarity. The term "Grower" was modified to remove researcher as an allowable recipient for them to sell to. "License" was added to be more specific to the actual license details in current practice. "Manufacture" was removed as it is not referred to in permanent rules. The definition of "Medical Marijuana" is modified to added inclusions for concentrate and products and exclude industrial hemp. The term "Minor" was included to match language of the state question. "Process" was added to recognize how products and materials are created. "Processor" was further edited to reflect the emergency rules. The term "Revocation" identified the appropriate avenue that will be used for rescinding a license. "Transportation License" was added to coincide with the current process for receive and transport.

310:681-1-5. Criminal History Screening (for commercial applicants only). Adds disqualifying conviction as a qualifier for receipt or renewal of a commercial license.

310:681-1-6. Proof of residency. Adds color, electronic submission and unexpired to all acceptable documents. Also adds the requirement for a valid residential address.

310:681-1-7. Proof of identity. Adds other documentation that the Department deems sufficient to offer additional options when necessary for approval.

310:681-1-9. Recommending physician registration. Requires a physician wishing to register to include documentation to support unexpired board certification.

310:681-2-1. Application for patient license. Requires a valid mailing address with no exception.

310:681-2-2. Applications for patient license for persons under age eighteen (18). Clarifies applications requirements for minors.

310:681-2-3. Application for caregiver's license. Clarifies that the current process does not allow a caregiver to apply for a license until after the patient has been approved and assigned a license number.

310:681-2-4. Application for temporary patient license. Clarifies that other documentation deemed sufficient can be used to establish identity when necessary.

310:681-2-5. Term and renewal of medical marijuana license. In addition to a full term, the process for surrendering a license voluntarily is outlined. Revocation and suspension procedures for licenses will follow the Oklahoma Procedures Act.

310:681-3-1. License for transportation of medical marijuana. Removes availability of a transportation license for a researcher in accordance with 63 O.S. § 424A

310:681-3-2. Requirements for transportation of marijuana. Additional requirements for transport of medical marijuana include carrying a copy of the business transportation license at all times and implementation of security measures.

310:681-5-1.1. Responsibilities of a license holder. Adds responsibilities to license holders to post the license on premises, comply with the rules, and allow access by the Department for inspections and audits as set forth in 63 O.S. § 420A et seq. and these rules. License holders must also comply with directives such as corrective action involving audits, reports, or response to emergencies. License holders must also accept all notices from the Department. The license holder will be subject to remedies available in accordance with those authorized in law. Requirement to renew and pay any applicable fees is also required.

310:681-5-2. Licenses. Identifies action for failure to renew a license and requirement to cease operating without a license immediately unless the thirty-day window to liquidate medical marijuana products is applicable. The process for changing information will only be accepted in electronic form and per the Departments instructions. Transfers are not permitted.

310:681-5-6-1 Penalties. Adds penalties of revocation or suspension for noncompliance and criminal activity. Also clarifies that the penalties will be implemented in accordance with the Oklahoma Administrative Procedures Act, 75 O.S. § 250 *et seq.*

310:681-5-7. Tax on retail medical marijuana. Requires that all licensed dispensaries hold or obtain a tax commission permit.

310:681-5-12. Marijuana transaction limitations. Adds the allowable transaction limitations between a patient or caregiver and a processor. Adds requirement that a commercial entity verify and ensure transactions are with a medical marijuana patient, caregiver, or commercial license holders. This requires a minimum verification of the name, expiration date, and valid, unexpired license number.

2. **DESCRIPTION OF PERSONS AFFECTED AND COST IMPACT RESPONSE:** (*a description of the persons who most likely will be affected by the proposed rule, including classes that will bear the costs of the proposed rule, and any information on cost impacts received by the agency from any private or public entities* [75 O.S. § 303(D)(2)(b)])

The classes of persons potentially affected by the proposed rules include patients and caregivers seeking licenses to use medical marijuana and commercial entities involved with the growing, processing, and dispensing of medical marijuana and its derived products. State Question 788, as codified at 63 O.S. § 420A(D) establishes application fees of $100 for the general patient population,

which are reduced to $20 for individuals enrolled with Medicare or Medicaid. Commercial establishments and business owners seeking an application are subject to application fees of $2,500, as required by State Question 788 and codified at 63 O.S. § 421A(A), 63 O.S. § 422A(A), and 63 O.S. § 423A(A). The Department anticipates that the majority of persons affected by the proposed fees will be patients seeking to apply for a medical marijuana license. Indirect costs may involve those associated with the resources needed to furnish and submit various documents proving eligibility for the desired application category. For example, patients seeking licenses must furnish copies of proof of residency, proof of identity, photo identification and a recommendation form signed by a qualified physician under Subchapter 1 (General Provisions) and Subchapter 2 (Medical Marijuana Licenses) of the proposed rule.

Individuals associated with entities applying for commercial licenses subject to Subchapter 5 (Commercial Establishments) and Subchapter 6 (Commercial Facilities) of the proposed rule will experience indirect costs related to fees to undergo a criminal history screening, obtaining registration from the Oklahoma Bureau of Narcotics and Dangerous Drugs, and obtaining a permit from various entities such as the Oklahoma Tax Commission, the Department of Agriculture, local municipal permits and other permits and licenses that might apply. Commercial entities may also experience indirect costs related to ongoing preparation and monitoring activities, such as construction standards, security, and monthly reporting requirements proposed in this rule. The Department has implemented an electronic submission system for commercial entities to submit monthly reports to remain in compliance with 310:681-5-6.

The classes of persons potentially affected by rules pertaining to food safety 310:681-5-8.1 includes owners and operators of licensed processors of edible medical marijuana. The Department, as required by law at 63 O.S. § 423A(C), anticipates that the requirements on licensed processors will be in line with current guidelines placed on other types of food processors. Processors shall be required to label and package foods in compliance with Title 21, part 101 of the Code of Federal Regulations, as incorporated in the proposed section of rule (310:681-5-8.1) Additionally, licensed processors required to test food products containing medical marijuana for microbials, solvent and chemical residue, metals, pesticide residue, potency, and contaminants and filth. Licensed processors would be responsible for direct and indirect compliance costs to ensure all requirements for edible medical marijuana products are met.

3. **DESCRIPTION OF PERSONS BENEFITING, VALUE OF BENEFIT AND EXPECTED HEALTH OUTCOMES:** *(a description of the classes of persons who will benefit from the proposed rule [75 O.S. § 303(D)(2)(c)])*

The classes of persons who are likely to benefit from the proposed rules include the population of patients consuming medical marijuana 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, temporary patient, or caregiver license. State Question 788, as codified at 63 O.S. § 420A(M) states, "All applications for a medical license must be signed by an Oklahoma Board certified physician." Controlling the issuance of patient licenses to only those who have first consulted with a medical professional, as proposed by the Department reduces the risk of harm to patients. The National Academies of Sciences, Engineering, and Medicine issued a report in 2017 titled *The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research*.[1] The summary to this systematic review of medical marijuana's effects states:

[1] National Academies of Sciences, Engineering, and Medicine. 2017. *The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research*. Washington, DC: The National Academies Press. https://doi.org/10.17226/24625.

> Despite this reported rapid rise in the use of cannabis, both for medical purposes and for recreational use, conclusive evidence regarding the short- and long-term health effects of cannabis use remains elusive. While a myriad of studies have examined cannabis use in all its various forms (Calabria et al., 2010; Whiting et al., 2015, 2016; WHO, 2016), often these research conclusions are not appropriately synthesized, translated for, or communicated to policy makers, health care providers, state health officials, or other stakeholders who have been charged with influencing and enacting policies, procedures, and laws related to cannabis use. Unlike other substances whose use may confer risk, such as alcohol or tobacco, no accepted standards for the safe use or appropriate doses are available to help guide individuals as they make choices regarding the issues of if, when, where, and how to use cannabis safely and, in regard to therapeutic uses, effectively (Freeman et al., 2014; Marsot et al., 2016). Moreover, studying the potential health impacts of cannabis presents its own set of unique challenges. Current challenges include the existence of certain regulations and policies that restrict access to cannabis products suited for research purposes (e.g., Schedule 1 status; regulatory approvals), the limited availability of funding for comprehensive cannabis research, and crosscutting methodological challenges. Additionally, researchers are often unable to obtain the necessary quantity, quality, or type of cannabis product to address cutting-edge public health research questions.

The Department intends to monitor and track adverse events related to medical marijuana by maintaining partnerships with entities including, but not limited to, hospitals and the Oklahoma Center for Poison and Drug Information. Monitoring adverse events in this manner is consistent with the Department's existing responsibilities and powers authorized under the Oklahoma Healthcare Information Systems Act, codified at 63 O.S. §1-115 *et seq.*

Subchapter 5 (Commercial Establishments) contains specific standards which apply to edible medical marijuana products, produced by licensed processors. Consumers of edible medical marijuana are likely to have more specific information on the contents of products they purchase, due to the regulations at 310:681-5-8.1. 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. The Department anticipates that the proposed rules will have similar benefits to those derived from other existing rules on processors of other types of foods. The Department will accept public comments from the persons who may potentially benefit from the rule in writing and by public hearing.

4. **ECONOMIC IMPACT, COST OF COMPLIANCE AND FEE CHANGES:** (*a description of the probable economic impact of the proposed rule upon affected classes of persons or political subdivisions, including a listing of all fee changes and, whenever possible, a separate justification for each fee change* [75 O.S. §303(D)(2)(d)])

There are no fee changes in the current proposed rules. 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 statues and detailed separately below:

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

Individual Temporary License: $100.00 (OAC 310:681-2-4, as authorized by 63 O.S. § 420A(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. § 420A(K)).

- There is not a cost paid by applicants for a caregiver license. However, there is a requirement that the caregiver is established on a licensed patient's behalf. Potentially, the caregiver may pay on the patient's behalf, contributing the $100 or $20 fee.

Retail Dispensary License: $2,500 for license, penalty of $5,000 for initial reporting violations. (OAC 310:681-5-3, as authorized by 63 O.S. § 421A(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.

Grower License: $2,500 for license, penalty of $5,000 for initial reporting violations. (OAC 310:681-5-3, as authorized by 63 O.S. § 422A(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.

Processor License: $2,500 for license, penalty of $5,000 for initial reporting violations and $500.00 per inspection-related violation. (OAC 310:681-5-3, as authorized by 63 O.S. §423A(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.
- Additional costs related to Subchapter 6 (Commercial Facilities) are related to building construction, security and product safety standards. Processors must also maintain compliance with standards for equipment and methods of preparation in OAC 310:681-6-10. Processed products are subject samples for laboratory testing as specified in Subchapter 8 (Testing Standards for Marijuana). Exact costs for these procedures are not yet known with specificity.

Research License: There is no fee authorized in statute for this license.

- Additional costs related to Subchapter 6 (Commercial Facilities) are related to building construction, security and product safety standards. Researchers must also maintain compliance with institutional review and human subject's standards, as described in Subchapter 4 (Medical Research Licenses). Exact costs for these procedures are not yet known with specificity.

Transportation License: There is no fee authorized in statute for this license.

- Transportation licenses are issued and included on condition of a valid commercial entity license, which generally requires a $2,500 application fee and maintenance of records, pursuant to 63 O.S. § 424A(A).

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. 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 probable costs and benefits to the agency and to any other agency of the implementation and enforcement of the proposed rule, the source of revenue to be used for implementation and enforcement of the proposed rule, and any anticipated effect on state revenues, including a projected net loss or gain in such revenues if it can be projected by the agency [75 O.S. §303(D)(2)(e)])*

   The cost to the Department to implement the program is budgeted up to $8.5 million for the first year to cover the costs borne by the OSDH. The range is based primarily upon the need for information technology systems dedicated to automate the required licensure processes and systems in an expedited manner. The proposed rules will be implemented by additional staff working to process and review license applications, reports and other required compliance activities within the Oklahoma Medical Marijuana Authority. The source of revenue will be a combination of state appropriated funds to OSDH,; tax collections identified for program costs by the State Question on all medical marijuana sells, and revenue collected through the program's license fees. Due to the unknown volume of licenses and product costs, the anticipated effects on state revenues cannot be projected at this time.

6. **IMPACT ON POLITICAL SUBDIVISIONS:** (*a determination of whether implementation of the proposed rule will have an economic impact on any political subdivisions or require their cooperation in implementing or enforcing the rule* [75 O.S. §303.D.2(f)])

   The proposed rule involves implementing a statewide system of licensure for medical marijuana patients and commercial entities. As required by 63 O.S. § 420A(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. 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. 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.

7. **ADVERSE EFFECT ON SMALL BUSINESS: (***a determination of whether implementation of the proposed rule may have an adverse economic effect on small business as provided by the Oklahoma Small Business Regulatory Flexibility Act* [75 O.S. § 303(D)(2)(g)]) [12]

   The current set of proposed rules has a minimal expected impact on small business. Permits and other license fees are not set forth in rule, but rather in statute.

8. **EFFORTS TO MINIMIZE COSTS OF RULE:** *(an explanation of the measures the agency has taken to minimize compliance costs and a determination of whether there are less costly or nonregulatory methods or less intrusive methods for achieving the purpose of the proposed rule [75 O.S. § 303(D)(2)(h)])*

   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:** (*a determination of the effect of the proposed rule on the public health, safety and environment and, if the proposed rule is designed to reduce significant risks to the public health, safety and environment, an explanation of the nature of the risk and to what extent the proposed rule will reduce the risk* [75 O.S. § 303(D)(2) (i)])

   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:** ***(****a determination of any detrimental effect on the public health, safety and environment if the proposed rule is not implemented [75 O.S. § 303(D)(2)(j)])*

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

    The Department will accept public comments regarding the rule in writing and by public hearing.

11. **PREPARATION AND MODIFICATION DATES** *(the date the rule impact statement was prepared and if modified, the date modified [75 O.S. § 303(D)(2)(k)])*

    This rule impact statement was prepared on January 24, 2019.

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

SUBCHAPTER 1. GENERAL PROVISIONS

310:681-1-1. Purpose

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. 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

(a) Pursuant to 63 O.S. § 420A(C), 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. 10th 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

All licenses and rights granted under 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

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

"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" 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 and this Chapter for a license.

"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.

"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.

"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.

"Commercial Establishment" ("Establishment") or **"Commercial Licensee"** means an individual or entity licensed under this Chapter as a medical marijuana dispensary, grower, processor, or researcher.

"Commercial License" means a license issued to a medical marijuana dispensary, grower, processor, or researcher.

"Commissioner" means the 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., 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 of medical marijuana, medical marijuana concentrate, or a medical marijuana products to a qualified patient, the qualified patient's parent(s) or legal guardian(s) if qualified patient is a minor, and a licensed caregiver.

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

"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.

"Entity" means a 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.

"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 licensed by the Department pursuant to 63 O.S. § 422A, which allows the grower to grow, harvest, dry, cure, and package medical marijuana according to this Chapter for the purpose of selling to a dispensary or processor.

"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."

"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" as used in 63 O.S. § 422A(C) means a processor.

"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.

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

"Medicaid" means the federal program that is also commonly known 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 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.

"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 patient, including but not limited to oils, tinctures, edibles, pills, topical forms, gels, creams, and other derivative forms.

"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 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.

"Oklahoma Resident" ("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.

"Oklahoma Uniform Symbol" means the image, established by the Department and made available to commercial licensees, indicating the package contains marijuana and must be printed at least one-half inch in size by one-half inch in size in color.

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

"Package" or **"Packaging"** means any container or wrapper that a grower or processor may use for enclosing or containing medical marijuana or medical marijuana products.

"Patient" or **"Qualified patient"** means a person that has been properly issued a medical marijuana license pursuant to 63 O.S. § 420A et seq. and these rules.

"Physician" means a doctor of medicine or a doctor of osteopathic 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.

"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 an 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.

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

"Processor" means an individual or entity that has been licensed by the Department pursuant to 63 O.S. § 423A, which allows the processor to: purchase medical marijuana from a grower or processor; process, package, and sell medical marijuana to a dispensary or processor; and may process medical marijuana received from a qualified patient into a medical marijuana concentrate, for a fee.

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

"Retailer" as used in 63 O.S. § 420A et seq. means a 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 pursuant to 63 O.S. § 420A et seq. and this Chapter is rescinded.

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

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

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

"Transportation License" means a license issued automatically to commercial licensees upon approval of a commercial license, 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.

310:681-1-5. Criminal history screening

(a) **Parties subject to screening.** Prior to issuance of any dispensary, grower, processor, transportation, or 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

(3) For research license applicants, all principal investigators involved in the research project.

(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 issued a license authorized by this Chapter, is required to obtain an Oklahoma State Bureau of Narcotics and Dangerous Drugs Control ("OBNDD") registration 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

(a) Applicants shall establish their 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

Applicants 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.

310:681-1-8. Applicant photograph

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

(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) The physician's medical license number; and

(4) 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

(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.

SUBCHAPTER 2. MEDICAL MARIJUANA LICENSES

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

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

(1) The applicant's first name, middle name, last name and suffix, if applicable;

(2) The applicant's valid mailing address;

(3) The applicant's date of birth;

(4) The applicant's telephone number and email address;
(5) The signature of the applicant attesting the information provided by the applicant is true and correct; and
(6) The date the application was signed.

(b) An application must be submitted within thirty (30) days of signature or it will be rejected by the Department.

(c) A complete application shall include the following documentation or the application will be rejected:

(1) Documents establishing the applicant is an Oklahoma resident as established in OAC 310:681-1-6 (relating to proof of residency).
(2) Documents establishing proof of identity as established in OAC 310:681-1-7 (relating to proof of identity).
(3) A digital photograph as established in OAC 310:681-1-8 (relating to applicant photograph).
(4) A certification and recommendation from an Oklahoma 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 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 et seq.

(5) Application fees are nonrefundable.

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

(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(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 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 et seq.

(5) Application fees are nonrefundable.

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

(a) Applications for a caregiver's license for caregivers of a licensed patient may be made at any time during the term of the patient license.

(b) Only one caregiver's license shall be issued for each patient license, except in the case of a licensed patient under the age of eighteen (18) whereby two (2) parents and/or legal guardians may be recognized as the minor's caregivers, if such minor is homebound.

(c) A caregiver's application will be accepted for a patient who has a physician's attestation that the patient is homebound or does not have the capability to self-administer or purchase medical marijuana due to developmental disability or physical or cognitive impairment and would benefit by having a designated caregiver to manage medical marijuana on the behalf of the patient as provided in OAC 310:681-2-1(c)(4)(E)(iv).

(d) The caregiver's application shall be made on a form provided by the Department and shall include the following:

(1) All information and documentation for the caregiver provided for in OAC 310:681-2-1(a) and (c) except there shall be no medical certification from an Oklahoma 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.

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

(a) A caregiver's license shall be withdrawn for any patient that provides written or electronic notification to the Department, on the Department provided form, of their wish to withdraw the caregiver's authorization. This withdrawal shall not be subject to appeal.

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

(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 et seq.
(d) Application fees are nonrefundable.

310:681-2-5. Term and renewal of medical marijuana license
(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 revoked by the Department or voluntarily surrendered by the patient.
(b) **Caregiver License Term.** Caregiver's licenses may not extend beyond the expiration date of the underlying patient license regardless of the issue date.
(c) **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; however, temporary patient licenses may not extend beyond the expiration date of the underlying out-of-state medical marijuana patient license.
(d) **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.
(e) 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.
(f) **Renewal Fee.** The fee for renewal shall be the fee established in statute for the license at 63 O.S. § 420A et seq. Application fees are nonrefundable.
(g) **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.

(h) **License revocation and suspension.** Procedures for 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 notified of alleged violation(s) of the Department rules and applicable law. These procedures also provide for the licensee 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.

310:681-2-6. Information contained on patient and caregiver license

Licenses issued pursuant to Sections 310:681-2-1, 2, 3, and 4 of this Subchapter shall contain the following:

(1) The digital photograph of the license holder;
(2) The name and date of birth of the license holder;
(3) The name of parent(s) or legal guardian(s) of minor license holder, if applicable;
(4) The city and county of residence of the license holder;
(5) The type of license;
(6) The date the license expires; and
(7) The unique 24-character license number assigned to the license holder and caregiver, if applicable.

310:681-2-7. Medical marijuana license verification system

The Department will make available on its website and via telephone a system by which authenticity and validity of medical marijuana patient and caregiver licenses may be verified.

310:681-2-8. [RESERVED]

310:681-2-9. [RESERVED]

310:681-2-10. [RESERVED]

310:681-2-11. Restrictions on smokable medical marijuana and medical marijuana products

All smokable, vaporized, vapable and e-cigarette medical marijuana and medical marijuana products smoked by a patient license holder are subject to the same restrictions for tobacco under Section 1-1521 et. seq. of Title 63 of Oklahoma statutes, commonly referred to as the "Smoking in Public Places and Indoor Workplaces Act."

310:681-2-12. [RESERVED]

310:681-2-13. [RESERVED]

SUBCHAPTER 3. TRANSPORTATION LICENSE

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

(a) A medical marijuana transportation license will be issued to qualifying applicants for a commercial licenses at the time of approval.
(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

(a) All medical marijuana shall be transported in a locked container, shielded from public view, and clearly labeled "Medical Marijuana or Derivative."
(b) Commercial licensees or their authorized agents or employees shall carry a copy of the commercial license and transportation license while transporting medical marijuana.
(c) Commercial licensees shall implement appropriate security measures to deter and prevent the theft and diversion of marijuana during transportation.

SUBCHAPTER 4. MEDICAL RESEARCH LICENSE [RESERVED]

310:681-4-1. [RESERVED]

310:681-4-2. [RESERVED]

310:681-4-3. [RESERVED]

SUBCHAPTER 5. COMMERCIAL ESTABLISHMENTS

310:681-5-1. License required

(a) No person or entity shall operate a medical marijuana dispensary, grower operation, processor, or research project without first obtaining a license from the Department pursuant to 63 O.S. § 420A et seq. and the Rules in this Chapter. Only a person who is in compliance with the requirements of 63 O.S. § 420A et seq. and these Rules shall be entitled to receive or retain such a license.
(b) All commercial licenses shall be on forms prescribed by the Department.
(c) Application fees are nonrefundable.

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

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

(1) Post the license in a location in the commercial establishment that is conspicuous to consumers;
(2) Comply with the provisions in this Chapter;
(3) Allow representatives of the Department access to the commercial establishment as specified under OAC 310:681-5-4 and OAC 310:681-5-6;
(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 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) If applicable, submit the annual renewal application and pay all renewal license and late fees, if any.

310:681-5-2. Licenses

(a) **Timeframe.** A commercial establishment 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. and this Chapter.

(b) **Location.** A business establishment license shall only be valid for a single location at the address 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. and these rules.

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

(B) Any medical marijuana 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) **Change in information.**

(1) The commercial licensee 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) The licensee 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.

(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) **Transfer of license.**

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

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

(f) **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 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) Any medical marijuana remaining in the possession of the licensee shall be disposed of in accordance with OAC 310:681-5-10.

310:681-5-3. Applications

(a) **Application fee.** An applicant for a commercial establishment 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. § 420A et seq.

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

(3) GPS coordinates of the establishment; and

(4) Phone number and email of the establishment.

(c) **Individual applicant.** The application for a commercial license made by an individual on their 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 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) 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 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) Telephone number and email address; and

(8) 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 application shall be accompanied by the following documentation:

(1) A list of all persons and/or entities that have an ownership interest in the commercial applicant;

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

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

(4) If a licensed dispensary, proof that the location of the dispensary is a 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) 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 in 63 O.S. § 420A et seq. and OAC 310:681-1-6 (relating to proof of residency); and

(6) Any further documentation the Department determines is necessary to ensure the commercial applicant is qualified under 63 O.S. § 420A et seq. and this Chapter to obtain a commercial license.

310:681-5-4. Inspections

(a) Submission of an application for a medical marijuana processing license constitutes permission for entry to and inspection of the processing licensee's premises during hours of operation and other reasonable times. Refusal to permit such entry or inspection shall constitute grounds for the nonrenewal, suspension, or revocation of a license.

(b) The Department may perform an annual unannounced on-site inspection of a licensed processor's operations to determine compliance with 63 O.S. § 420A et seq., 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. The Department may refer all complaints

alleging criminal activity or other violations of Oklahoma law that are made against a licensed processor to appropriate Oklahoma state or local law enforcement or regulatory authorities.
(d) 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) The Department may review any and all records of a licensed processor 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.
(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) If the Department identifies a violation of 63 O.S. § 420A et seq. or this Chapter during an inspection of the licensed processor, the Department shall take administrative action in accordance with 63 O.S. § 423A and the Oklahoma Administrative Procedures Act, 75 O.S. §§ 250 et seq.
(h) Violations shall be corrected within thirty (30) days of receipt of a written notice of deficiencies.
(i) If processor fails to correct the violations within thirty (30) days, the processor will be subject to a fine of $500.00 for each deficiency.

310:681-5-5. [RESERVED]

310:681-5-6. Inventory tracking, records, reports, and audits
(a) **Monthly reports.** Each commercial licensee shall utilize an inventory management system to maintain records and shall complete a monthly report on a form 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) The amount of marijuana sold to licensees and the type of licensee;
(D) The amount of marijuana waste in pounds;
(E) 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) Total dollar amount of all sales to medical marijuana patients and caregivers;
(G) Total dollar amount of all taxes collected from sales to medical marijuana patients and caregivers; 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 et seq.

(2) Grower reports shall include:
(A) The amount of marijuana harvested in pounds;
(B) The amount of marijuana sold 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 processer, 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 et seq.
(3) Processor reports shall include:
(A) The amount of marijuana purchased from grower licensees in pounds;
(B) The amount of marijuana sold 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 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.

(b) **Records.** Pursuant to the Department's audit responsibilities, commercial establishments shall keep a copy of the following records for at least seven (7) years from the date of creation:
(1) Business records, which may include but is not limited to as manual or computerized records of assets and liabilities, monetary transactions, journals, ledgers, and supporting documents, including agreements, checks, invoices, and vouchers.
(2) If applicable, documents relating to the processing and preparation of medical marijuana products, which may include but is 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, which shall include:
(A) The identification number associated with the receiving

license; and

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

(4) 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) **Inventory.** Each commercial licensee shall obtain and maintain an electronic inventory management system that:

(1) Documents the chain of custody of all medical marijuana and medical marijuana products;

(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 tracks 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;

(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) **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. 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 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.

(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 et seq. or these rules during an audit of the commercial licensee, the Department shall take administrative action against the licensee in accordance with the Oklahoma 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.

310:681-5-6.1. Penalties

(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 30 days of the Department's written notice, the license shall be revoked subject to Subsection (d).

(b) **Inaccurate reports.** Within any two (2) year period of time, if the Department makes a finding the 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.** 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:

(1) First finding of unlawful purchase(s) or sale(s): Five thousand dollar ($5,000.000) 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 finding by the Department of unlawful purchase(s) or sale(s): Revocation of license.

(d) **Noncompliance and criminal activity.** Commercial licenses may be subject to revocation or suspension upon a determination by the Department that the commercial establishment has not complied with 63 O.S. § 420A et seq. or this Chapter, or upon official notification to the Department that the commercial establishment has engaged in criminal activity in violation of Oklahoma law.

(e) **License revocation and suspension.** Procedures for 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 notified of alleged violation(s) of the Department rules and applicable law. These procedures also provide for the licensee 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.

310:681-5-7. Tax on retail medical marijuana sales

(a) The tax on retail medical marijuana sales by a dispensary is established at seven percent (7%) of the gross dollar amount received by the dispensary for the sale of any medical marijuana or medical marijuana product. This tax will be collected by the dispensary from the customer who must be a licensed medical marijuana patient or caregiver.
(b) A dispensary shall either hold or obtain an Oklahoma sales tax permit from the Oklahoma Tax Commission in compliance with OAC 710:65-19-216.
(c) Reports and payments on gross sales, tax collected, and tax due shall be remitted to the Oklahoma Tax Commission by every dispensary on a monthly basis. No additional reporting regarding gross sales, tax collected, and tax due shall be made to the Department.
(d) Dispensary reporting and remittance shall be made to the Oklahoma Tax Commission on a monthly basis. Reports and remittances are due to the Oklahoma Tax Commission no later than the 20th day of the month following the month for which the report and remittances are made.
(e) All dispensaries required to report and remit medical marijuana tax shall remit the tax and file their monthly tax report in accordance with the manner prescribed by the Tax Commission.
(f) The report shall contain the following information:
(1) Dispensary name, address, telephone number and dispensary license number;
(2) Reporting month and year;
(3) Total gross receipts for the preceding month from sales of medical marijuana or any medical marijuana product;
(4) The amount of tax due as described in (a) of this Section; and
(5) Such other reasonable information as the Tax Commission may require.
(g) If a due date for the tax reporting and remittance falls on a Saturday, Sunday, a holiday, or dates when the Federal Reserve Banks are closed, such due date shall be considered to be the next business date.
(h) Pursuant to 63 O.S. § 426, proceeds from the sales tax levied shall first be distributed to the Oklahoma State Department of Health for the annual budgeted amount for administration of the Oklahoma Medical Marijuana Authority Program. All distributions will be made monthly to the Department until full reimbursement is reached for the annual budgeted cost of the program. If tax levies are not sufficient to reimburse the Department for the full annual budgeted cost, then all tax levies collected during the fiscal shall be remitted to the Department.

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

(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 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.

310:681-5-8.1. Food Safety Standards for Processors

(a) **Purpose.** This Section sets forth the food safety standards that processors must comply with in the preparation, production, manufacturing, processing, handling, packaging, and labeling of edible medical marijuana products.

(b) **Existing law.** This Section does not relieve licensed processors of any obligations under existing laws, rules, and regulations, including 63 O.S. § 1-1101 et seq., OAC 310:257, and OAC 310:260, to the extent they are applicable and do not conflict with 63 O.S. § 420A 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 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.

(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 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(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, acaracides, 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) **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

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 et seq.

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

All medical marijuana waste generated during production, processing and testing must be stored, managed, and disposed of in accordance with these rules and any other applicable Oklahoma statutes and rules,

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.

310:681-5-11. [RESERVED]

310:681-5-12. Marijuana transaction limitations

(a) A single transaction by a dispensary with a patient, or the parent(s) or legal guardian(s) if patient is under eighteen (18) years of age, or caregiver shall be limited to three (3) ounces 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 shall verify and ensure that all medical marijuana transactions are conducted with medical marijuana patient, caregiver, or commercial license holders and shall take all reasonable steps necessary to prevent the sale or other transfer of medical marijuana to a person or entity who does not hold a valid, unexpired license issued by the Department under 63 O.S. §420A 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 addition to the items required in Subsection (c)(1) above, shall include 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).

310:681-5-13. Loss and theft

If a commercial licensee has reason to believe that an actual loss, theft, or diversion of medical marijuana has occurred, the commercial licensee shall notify immediately the Department and law enforcement. The commercial licensee shall provide the notice by attaching and submitting electronically a signed statement that details the estimated time, location, and circumstances of the event, including an accurate inventory of the quantity and type of medical marijuana unaccounted for due to diversion or theft. The notice shall be provided no later than twenty-four hours after discovery of the event.

310:681-5-14. [RESERVED]

310:681-5-15. [RESERVED]

310:681-5-16. [RESERVED]

310:681-5-17. Entry to commercial establishments

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

310:681-5-18. Prohibited acts

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

(b) No commercial establishment 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 patient license holders or caregiver's license holders.

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

(e) No commercial establishment shall sell or offer to sell medical marijuana products by means of any advertisement or promotion 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.

310:681-5-19. [RESERVED]

SUBCHAPTER 6. COMMERCIAL FACILITIES

310:681-6-1. General security requirements for commercial establishment

(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

All commercial establishments 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.

310:681-6-3. [RESERVED]

310:681-6-4. [RESERVED]

310:681-6-5. [RESERVED]

310:681-6-6. [RESERVED]

310:681-6-7. [RESERVED]

310:681-6-8. [RESERVED]

310:681-6-9. [RESERVED]

310:681-6-10. [RESERVED]

310:681-6-11. [RESERVED]

SUBCHAPTER 7. PACKAGING AND LABELING

310:681-7-1. Labeling

The following general label and packaging requirements, prohibitions and exceptions apply:

(1) Labels and packages may not be attractive to minors.

(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.

(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."

310:681-7-2. Prohibited products

(a) No commercial establishment 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, other than a licensed dispensary, shall offer for 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.

SUBCHAPTER 8. LABORATORY TESTING [RESERVED]

310:681-8-1. [RESERVED]

310:681-8-2. [RESERVED]

310:681-8-3. [RESERVED]

310:681-8-4. [RESERVED]

310:681-8-5. [RESERVED]

310:681-8-6. [RESERVED]

310:681-8-7. [RESERVED]

APPENDIX A. [RESERVED]