

- **TITLE 310. Oklahoma State Department of Health**

- CHAPTER 681. Medical Marijuana Control Program

- [OAR Docket #18-639]

**AGENCY NOTE:**

The Board of Health adopted new emergency rules on August 1, 2018, to supersede all rules identified in this rulemaking action. The new superseding Chapter was approved by the Governor on August 6, 2018, and will be published in a later edition of the Oklahoma Register.

**RULEMAKING ACTION:**

EMERGENCY adoption

**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. Labeling [NEW]

Subchapter 8. Testing Standards for Marijuana [NEW]

Appendix A. Supporting Tables for Subchapter 8 (Relating to Testing Standards for Marijuana) [NEW]

**AUTHORITY:**

Oklahoma State Board of Health; Title 63 O.S. Section 1-104, and Title 63 O.S. § 420 *et seq.*

**ADOPTION:**

July 10, 2018

**EFFECTIVE:**

Immediately upon Governor's approval or August 25, 2018, whichever is later.

**APPROVED BY GOVERNOR:**

July 11, 2018

**EXPIRATION:**

Effective through September 14, 2019, unless superseded by another rule or disapproved by the legislature.

**SUPERSEDED EMERGENCY ACTIONS:**

"n/a"

**INCORPORATION BY REFERENCE:**

**Incorporated standards:**

National Institute of Standards and Technology (NIST) Handbook 130 (2017), "Uniform Packaging and Labeling Regulation"

US Food and Drug Administration's "Bacterial Analytical Manual", 2016

US Food and Drug Administration's "Guidelines for the Validation of Chemical Methods for the FDA FVM Program", 2nd Edition, 2015.

AOAC International's "Official Methods of Analysis for Contaminant Testing of AOAC International", 20th Edition, 2016

United States Pharmacopeia and the National Formulary's "Methods of Analysis for Contaminant Testing", 2016

**Incorporating rules:**

310:681-7-1(d)(2)(B)

310:681-8-5(b)(A)

310:681-8-5(b)(B)

310:681-8-5(b)(C)

310:681-8-5(b)(D)

**Availability:**

8:00 a.m. to 5:00 p.m., Monday through Friday, Oklahoma State Department of Health, 1000 NE 10th St., Oklahoma City, OK 73117.

**FINDING OF EMERGENCY:**

Pursuant to Title 75 O.S. Section 253, the Department seeks Emergency adoption of the proposed rules. Emergency rulemaking is sought pursuant to the passage of State Question 788 and as codified at 63 O.S. § 420 *et seq.* Title 63 O.S. § 420(C) states: "A regulatory office shall be established under the Oklahoma State Department of Health which will receive applications for medical license recipients, dispensaries, growers, and packagers within sixty (60) days of the passage of this initiative." Title 63 O.S. § 423(C) states: "within sixty (60) days of passage of this initiative, make available a set of standards which will be used by licensed processors in the preparation of edible marijuana products."

The language requires the Department to create a process to receive, review and issue patient license applications, within approaching timeframes given the recent passage of State Question 788 on June 26, 2018. Delay in adoption of rules, until the forthcoming legislative session would cause the Department to fail to comply with state law, therefore satisfying a finding of an emergency pursuant to 75 O.S. § 253(A)(1)(c).

This Emergency rulemaking action is necessary to promulgate rules to implement the provisions in the new law pertaining to regulations on medical marijuana products, and individual and commercial licensees.

**GIST/ANALYSIS:**

These proposed rules will implement the agency's requirements from the passage of State Question 788 and as codified at 63 O.S. § 420 *et seq.*. The proposed regulations set forth the Department's definitions and requirements for the approvals of medical marijuana patient, caregiver, dispensary, laboratory, grower and packager licenses.

**CONTACT PERSON:**

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**PURSUANT TO THE ACTIONS DESCRIBED HEREIN, THE FOLLOWING EMERGENCY RULES ARE CONSIDERED PROMULGATED UPON APPROVAL BY THE GOVERNOR AS SET FORTH IN 75 O.S., SECTION 253(F), AND EFFECTIVE UPON APPROVAL BY THE GOVERNOR OR AUGUST 25, 2018, WHICHEVER IS LATER:**

*[OAR Docket #18-639; filed 7-25-18]*

## **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" and shall be a division of the Oklahoma State Department of Health. Only the powers enumerated under this Chapter shall be proper. Any power not specifically enumerated is prohibited.

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

(a) All license applications, inquiries, and other correspondence shall be directly electronically received, processed, and regulated by the Oklahoma State Department of Health by the "Oklahoma Medical Marijuana Authority" division or its designee.

(b) All applications 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/>

(c) 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 Title 63 O.S. § 420 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:

**"Acquire" or "Acquisition"** means coming to possess marijuana by means of any legal source herein authorized, from an authorized source, and in accordance with Title 63 O.S. § 420 et seq. and the rules of this Chapter.

**"Applicant"** means the natural person in whose name a license would be issued, with the exception of a patient license, or any entity the natural person represents or on whose behalf the application is being submitted. All applicants under these provisions must be at least twenty-five years of age to be eligible to be an applicant.

**"Approved Laboratory"** means a laboratory that is accredited by The NELAC Institute (TNI), ANSI/ASQ National Accreditation Board or other accrediting organization that has developed and maintained an independent system, based upon International Organization for Standardization and International Electrotechnical Commission (ISO/IEC) 17025 standards or other appropriate ISO/IEC standards as determined by the Department, for providing laboratories with an impartial review of laboratory operations.

**"Batch"** means, with regard to usable marijuana, a homogenous, identified quantity of usable marijuana, no greater than ten (10) pounds, that is harvested during a specified time period from a specified cultivation area, and with regard to oils, vapors and waxes derived from usable marijuana, means an identified quantity that is uniform, that is intended to meet specifications for identity, strength, and composition, and that is manufactured, 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 testing to allow for inventory tracking and traceability.

**"Cannabidiol ("CBD")"** means a cannabinoid and the primary non-psychoactive ingredient found in marijuana, Chemical Abstracts Service Number 13956-29-1.

**"Cannabidiolic Acid ("CBDA")"** means one of the primary cannabinoids produced on the stems, leaves and flowers of some varieties of marijuana plants.

**"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")** means an 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 Application"** means a document prepared in accordance with the rules and the forms and instructions provided by the Department, including any supporting documentation required by the Department and the license fee.

**"Control Number"** means the tracking number issued with a license to purchase medical marijuana.

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

**"Dispense"** means the selling of medical marijuana or a medical marijuana product to a qualified patient or the patient's designated caregiver that is packaged in a suitable container appropriately labeled for subsequent administration to or use by a qualifying patient.

**"Dispensary"** means an entity that has been licensed by the Department pursuant to Title 63 O.S. § 421 and this Chapter, which allows the entity to purchase medical marijuana from a processor licensee or grower licensee and sell medical marijuana only to qualified patients and caregivers.

**"Dispensary Manager"** means a person who a current licensed pharmacist in good standing with the Oklahoma Board of Pharmacy and is knowledgeable in the specialized functions of medical marijuana product preparation and dispensing, including the safety standards and quality assurance. This knowledge may be obtained through training programs and/or previous experience in a medical marijuana dispensary.

**"Disqualifying Felony Conviction"** means:

(A) Any non-violent felony conviction within two (2) years of submitting an application to the Department;

(B) Any violent felony conviction for an offense listed in Title 57 O.S. § 571(2) within five (5) years of submitting an application to the Department;

(C) Any felony conviction for which the sentence, including any terms of supervised or unsupervised probation, have not been completed at the time application is made for a license; or

(D) Any misdemeanor conviction which requires the convicted person to be incarcerated at the time application is made for commercial license.

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

**"Grower"** or **"Commercial Grower"** means an entity that has been licensed by the Department pursuant to Title 63 O.S. § 422, which allows the entity to grow, harvest, and package medical marijuana according to this Chapter for the purpose of selling medical marijuana to a dispensary, processor or researcher.

**"Harvest Lot"** means a specifically identified quantity of marijuana that is uniform in strain, cultivated utilizing the same growing practices, harvested at the same time at the same location and cured under uniform conditions.

**"ISO/IEC 17025"** means the International Organization of Standards/International Electrotechnical Commission standards 17025 that is published by the International Organization for Standardization and the International Electrotechnical Commission and included as a standard in general requirements for the competence of testing and calibration laboratories.

**"Licensee"** means any natural born person or entity that holds a marijuana license provided for in this Chapter, excluding inmates of the Oklahoma Department of Corrections.

**"Limited-access area"** means an area in which medical marijuana and medical marijuana products are stored or held and is only accessible to a licensee and its employees and contractors.

**"Lot"** means an identified portion of a batch, that is uniform and that is intended to meet specifications for identity, strength, and composition; or in the case of a vapor, oil, or wax derived from usable marijuana, an identified quantity produced in a specified period of time in a manner that is uniform and that is intended to meet specifications for identity, strength and composition.

**"Manufacture"** means the process of converting harvested plant material into medical marijuana concentrate by physical or chemical means for use as an ingredient in a medical marijuana product.

**"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, fiber produced from the stalks, oils 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, or the sterilized seed of the plant that is incapable of germination.

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

**"Medicaid"** means the federal program which is also commonly known as "SoonerCare."

**"Medical Marijuana"** means marijuana that is grown, processed, dispensed, tested, possessed, or used for a medical purpose.

**"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, intended to be refined for use as an ingredient in a medical marijuana product and not for administration to a qualified patient.

**"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, forms medically appropriate for administration by a vaporization or a nebulizer, patches, tinctures, and liquids excluding live plant 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;

**"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 is an income tax payer in the State of Oklahoma and can provide proof of residency as required by OAC 310:681-1-6.

**"Out-of-State medical marijuana 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 310:681-2-2.

**"Owners" and "Ownership interest"** means:

(A) All shareholders owning five percent (5%) or more of a corporate entity and all officers of a corporate entity;

(B) All partners of a general partnership;

(C) All general partners and all limited partners that own five percent (5%) or more of a limited partnership;

(D) All members that own five percent (5%) or more of a limited liability company;



(E) All beneficiaries that hold a five percent (5%) or more beneficial interest in a trust and all trustees of the trust;

(F) All persons or entities that own a five percent (5%) or more interest in a joint venture;

(G) All persons or entities that own a five percent (5%) or more interest in an association;

(H) The owners holding a five percent (5%) or more interest of any other type of legal entity; or

(I) Any other person holding at least a five percent (5%) interest in any entity which owns, operates, or manages a commercial facility.

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

**"Packager"** means a processor as defined in this Chapter. Packager is a term used in Title 63 O.S. § 422(C), relating to processors.

**"Patient"** or **"Qualified patient"** means a person that has been properly issued a medical marijuana license pursuant to Title 63 O.S. § 420 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 and has been issued a current and active registration from the United States Drug Enforcement Administration (DEA) and the Oklahoma Bureau of Narcotics and Dangerous Drugs (OBNDD) to prescribe controlled substances.

**"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"** means the part of a label on a package or container that is most likely to be displayed, presented, shown or seen under customary conditions of display for sale or transfer.

**"Principal Officer"** means the governing person(s) of a given entity, including but not limited to: Limited Liability Company (LLC) member/manager, president, vice president, secretary, treasurer, CEO, director, partner, general partner, limited partner.

**"Processor"** means an entity that has been licensed by the Department pursuant to Title 63 O.S. § 423, which allows the entity to: purchase marijuana from a commercial grower; prepare, manufacture, package, sell to and deliver medical marijuana products to a dispensary licensee or other processor

licensee; and may process marijuana received from a qualified patient into a medical marijuana concentrate, for a fee.

**"Process Lot"** means any amount of cannabinoid concentrate of the same type and processed at the same time using the same extraction methods, standard operating procedures and from the same batch or batches of harvested marijuana.

**"Proper Identification"** means a motor vehicle operator's license or other official state issued identification that contains a photograph of the applicant and includes the residential or mailing address of the purchaser, other than a post office box number.

**"Retailer"** means a dispensary. Retailer is used in Title 63 O.S. § 420 et seq., as it relates to dispensaries.

**"Resident"** means a person who is an income tax payer in the State of Oklahoma and can provide proof of residency as required in OAC 310:681-1-6, excluding inmates in the custody of the Department of Corrections.

**"Revocation"** means the Department's final decision that any license issued pursuant to this Chapter is rescinded because the individual or entity does not comply with the applicable requirements in this Chapter.

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

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

**"Tetrahydrocannabinol Content" or "THC Content"** means the sum of the amount of THC and 87.7 per cent of the amount of THCA present in the product or plant material.

**"Tetrahydrocannabinol ("THC")"** means the primary psychoactive cannabinoid in marijuana formed by decarboxylation of naturally occurring tetrahydrocannabinolic acid, which generally takes place by heating.

**"Tetrahydrocannabinolic Acid ("THCA")"** means the dominant cannabinoid that occurs naturally in most varieties of marijuana.

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

### **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 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) Individuals applying on behalf of an entity;
- (3) All principal officers of an entity;
- (4) All owners of an entity.

(b) **Fees.** All applicable fees charged by the Oklahoma State Bureau of Investigation vendor are the responsibility of the applicant.

(c) **Registration.** Prior to the issuance of any dispensary, grower, processor, or research license authorized by this Chapter, the applicant shall obtain an Oklahoma Bureau of Narcotics and Dangerous Drugs Control registration.

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

Sufficient documentation of proof of residency shall include one of the following:

- (1) An unexpired Oklahoma issued driver's license;
- (2) An Oklahoma voter identification card;
- (3) A utility bill for the calendar month preceding the date of application, excluding cellular telephone and internet bills;
- (4) A residential property deed to property in the State of Oklahoma; or
- (5) A current rental agreement for residential property located in the State of Oklahoma.

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

Applicants shall establish their identity through submission of a color copy or digital image of one of the following unexpired documents:

- (1) Front and back of an Oklahoma Driver's License;
- (2) Front and back of an Oklahoma Identification Card;

(3) A United States Passport or other photo identification issued by the United States government;

(4) Certified copy of the applicant's birth certificate for minor applicants who do not possess a document listed in subsections (1), (2), or (3); or

(5) A tribal identification card approved for identification purposes by the Oklahoma Department of Public Safety.

### **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) The 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 must 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 and has been issued a current and active registration from the United States Drug Enforcement Administration (DEA) and the Oklahoma Bureau of Narcotics and Dangerous Drugs (OBND) to prescribe controlled substances.

(b) 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 credentials, education, area of board certification, training and experience, and supporting documentation when available.

(3) The physician's medical license number.

(4) A certification by the physician that states:

(A) That the physician's Oklahoma license to practice medicine is active and in good standing.

(B) If the physician has been subject to any type of professional disciplinary action that would prevent the physician from carrying out the responsibilities under the Act and this part, together with, if applicable, an explanation of the professional disciplinary action.

(C) That the physician does not hold any direct or economic interest in a commercial establishment, grower, commercial grower, manufacturer, or processor, as defined in 310:681-1-4.

(c) All applications for patient licenses will be returned to the patient as incomplete until the recommending physician complies with the registration provisions of this rule.

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

(a) Any Physician, before making a recommendation for medical marijuana or medical marijuana products under these provisions, shall be in "good standing" with their licensure board and must have completed all required training as required by their licensure board for the recommendation of medical marijuana or medical marijuana products to patients prior to recommending a patient for a patient medical marijuana license. Additionally, the physician must comply with all continuing education requirements generally and specifically required by their board of licensure for the recommendation of medical marijuana under these provisions. Resident physicians do not meet the definition of Physician under this Section and any recommendation for a patient medical marijuana license will not be processed by the Department.

(b) Accepted standards a reasonable and prudent physician shall follow when recommending medical marijuana to a patient include the following:

(1) Establishment of a bona fide physician-patient relationship in which physician has ongoing responsibility for the assessment, care and treatment of a patient's medical condition or an aspect of the patient's medical condition;

(2) Documentation of an in-person (tele-medicine is prohibited) medically reasonable assessment by the recommending physician of the patient's medical history and current medical condition including physical examination within the past 30 days;

(3) Diagnosis of a medical condition, in the physician's opinion, the qualifying patient is likely to receive therapeutic or palliative benefit from the medical use of marijuana to treat or alleviate the medical condition.

(4) Discussion of the risks and benefits of the use of medical marijuana with the patient to include:

(A) The risk of cannabis use disorder, including in adolescent and young adult users;

(B) The risk for exacerbation of psychotic disorders and adverse cognitive effects for children and young adults;

(C) The variability and lack of standardization of marijuana preparations and the effect of marijuana;

(D) The increased risk of motor vehicle crashes while under the influence of marijuana;

(5) Provision of follow-up care and management of the patient's medical condition for which use of medical marijuana is recommended, including any follow-up examination necessary to determine the efficacy of marijuana for the patient's medical condition. All recommendations for medical marijuana shall be governed by the standards for prescription of controlled dangerous substances as codified by the Oklahoma Board of Medical Licensure at OAC 435:10-7-11 the Board of Osteopathic Examiners

at OAC 510:5-9-2, including a review by the physician, at least annually, of the necessity of the medical need for the continuing recommendation of medical marijuana.

(6) Maintenance of accurate and complete medical records.

(7) Provision of screening for substance abuse or mental health disorders and determination that issuance of the subsequent medical marijuana recommendation does not present an undue risk of abuse, addiction, or diversion and documents that determination.

(8) Physicians are prohibited from issuing a recommendation for approval of medical marijuana license to females of childbearing years without first performing a pregnancy test on the patient. If the patient is pregnant, the physician may make the recommendation for medical marijuana to the patient if the physician determines that the benefits of the recommendation outweigh the risk of potential harm to the fetus.

(9) Physicians are prohibited from issuing a recommendation for approval of a patient license to themselves, their family members of the first or second degree, their co-workers, or employees; and

(10) A physician who recommends use of medical marijuana shall not:

(A) Accept, solicit, or offer any form of pecuniary remuneration from or to a caregiver, dispensary, processor, or commercial grower;

(B) Offer a discount or any other thing of value to a patient who uses or agrees to use a particular caregiver or dispensary;

(C) Examine a patient for the purposes of recommending medical marijuana at a location where medical marijuana is dispensed;

(D) Hold a patient medical marijuana license in his or her personal capacity or as a caregiver if actively marking recommendations under these provisions for other patients;

(E) Hold any economic interest in an enterprise that grows, transports, processes, or dispenses medical marijuana.

(11) If after a physician completes a follow-up examination and review pursuant to subsection (6) and determine the continued use of medical marijuana by the patient no longer meets the standards set forth in subsection (3) the physician shall so notify the Department.

(12) Check the qualifying patient's profile on the Oklahoma Prescription Drug Monitoring Program each time a recommendation for approval of the marijuana medical license is made to the Department to:

(A) Determine whether a patient may be under treatment with a controlled substance by another physician or health care provider;

(B) Determine the controlled substance history of the patient; or

(C) Recommend a change of amount or form of medical marijuana.

## **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 residence address and mailing address. If the applicant proves Oklahoma residence, but does not have a fixed residential address, then the address where the applicant can receive mail;

(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 pledging the applicant will not divert marijuana to any individual or entity that is not lawfully entitled to possess marijuana; 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) The following documentation shall accompany the application or the application will be rejected:

(1) An affidavit of lawful presence form as prescribed by the Department.

(2) Documents establishing the applicant is an Oklahoma resident as established in 310:681-1-6 (relating to proof of residency).

(3) Documents establishing proof of identity as established in 310:681-1-7 (relating to proof of identity).

(4) A digital photograph as established in 310:681-1-8 (relating to proof of identity).



(5) 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 license 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 bonafide physician-patient relationship with the patient/ applicant which includes ongoing care, treatment and follow-up of the patient/applicant's medical condition(s);

(ii) The physician has conducted an in-person physical examination of the patient/applicant within the previous thirty (30) calendar days;

(iii) The physician has discussed the risks and benefits of the use of medical marijuana with the patient applicant or the patient/applicant's custodial parent or legal guardian;

(iv) 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;

(v) 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 310:681-1-9.1, (relating to recommending physician standards);

(vi) 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; and

(vii) The information provided by the physician in the certification is true and correct;

(viii) Stating the method by which the physician verified the patient's identity as is provided in 310:681-1-7; and,

(ix) The physician has participated in all mandatory continuing medical education as required by their licensing board.

(d) Payment of the application fee as established in Title 63 O.S. § 420(D) is required unless the applicant is insured by Medicaid, Medicare or SoonerCare.

(1) If the applicant is insured by Medicaid, Medicare or SoonerCare 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, or the application fee is paid.

(4) All applicants who are verified as being insured by Medicaid, Medicare or SoonerCare shall pay a reduced application fee as established in Title 63 O.S. § 420(D).

(5) Application fees are nonrefundable.

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

(a) Patient licenses may be issued for applicants under the age of eighteen (18) by submitting the same documentation as is required by 310:681-2-1, and the following:

(1) The application shall require the recommendation by two (2) physicians, both of whom must be either a pediatrician or pediatric subspecialist, dated within thirty (30) days of each other who do not practice together or who are not otherwise in a business relationship and both recommendations must state the same diagnosis for which the recommendation of medical marijuana or medical marijuana products is made;

(2) The application must be completed listing the minor as the applicant, but shall also include the same information as is required in 310:681-2-1(a) for the minor's parent(s) or legal guardian(s);

(3) The proof of residency information required shall be provided for the minor's parent(s) or legal guardian(s);

(4) Identification and residency documents shall be provided for the parent(s) or legal guardian(s);

(5) A digital photograph, as established in 310:681-1-8 (relating to proof of identify), shall also be included of the minor's parent(s) or legal guardian(s);

(6) 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 must be submitted;

(7) The signature and date of each parent or legal guardian must be included on the application. In the event one of the parents or legal guardians has abandoned the minor or is otherwise unavailable a notarized affidavit stating the reasons the parent or legal guardian cannot sign (except in the case of refusal or disagreement) is sufficient if approved by the Department;

(8) An attestation by the parent or legal guardian that the information provided in the application is true and correct must be included on the application; and

(9) The minor applicant is not required to submit any documents listed in 310:681-1-6 (residency).

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

(c) Under no circumstances shall a minor patient license holder be authorized to consume, smoke, or inhale any smokable or vapable medical marijuana or smokable or vapable medical marijuana products.

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

(a) Applications for a Caregiver's License for caregivers of a patient may accompany the original applications in 310:681-2-1 and 310:681-2-2 or 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 issued except in the case of a patient/applicant under the age of eighteen (18) whereby two (2) parents and/or legal guardians may be recognized as the minor's caregivers. Any variance from the number of patient licenses per caregiver shall be evaluated by the Department pursuant to the variance procedure set forth in 310:681-2-12.

(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 310:681-2-1(c)(5)(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 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 appointing the Caregiver as their designee under this provision. If the patient license holder is incapacitated, 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) If the patient is a license holder, the patient control number shall be included in the application.

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

A Caregiver's license for a specific patient 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 310:681-2-1(a) (relating to patient license application);

(2) Color copy or digital image file of the front and back of applicant's unexpired out-of-state medical marijuana patient license;

(3) Color copy or digital image file of one of the following unexpired documents:

(A) Front and back of a valid state issued Driver's License;

(B) Front and back of valid state issued Identification Card;

(C) A United States Passport or other photo identification issued by the United States government; or

(D) Certified copy of the applicant's birth certificate for minor applicants who do not possess a document listed in subsections (A), (B), or (C).

(4) A digital photograph as established in 310:681-1-8 (relating to proof of identity); and

(5) If temporary patient applicant is under the age of eighteen (18), in addition to complying with subsections (1) (2) and (3), applicant shall also comply with 310:681-2-2(2), (5), (6), (7), and (8).

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

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

#### **310:681-2-5. Term and Renewal of medical marijuana license**

(a) Medical marijuana patient licenses issued under 310:681-2-1 and 310:681-2-2 shall be for a term of two (2) years from the date of issuance, unless the physician's recommendation is terminated pursuant to 310:681-1-9.1(11) or revoked by the Department. Minor patient licenses are valid for two years, or until the minor turns eighteen (18) years of age, whichever is sooner, unless either of the physician's recommendations are terminated pursuant to 310:681-1-9.1(11).

(b) Caregiver's Licenses may not extend beyond the expiration date of the underlying Patient license regardless of the issue date.

(c) Temporary patient licenses issued under 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) 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 310:681-2-1, 310:681-2-2, 310:681-2-3 and/or 310:681-2-4.

(e) The fee for renewal shall be the fee established in statute for the license at 63 O.S. § 420 et seq.

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

Licenses issued pursuant to Sections 310:681-2-1, 2 and 3 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 city and county of residence of the license holder;
- (4) The type of license;
- (5) The date the license expires;

(6) The unique 24 character control number assigned to the license holder; and if applicable

(7) The unique 24 character control number assigned to the license holder for which the caregiver, parent or legal guardian is licensed to purchase medical marijuana.

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

(a) The Department will make available on its website and via telephone a system by which authenticity and validity of a medical marijuana license and a transport license may be verified. This system shall be made available to all law enforcement and regulating entities as determined by the Department.

(b) Before any sale or service is provided to any patient or caregiver, the licensed establishment shall validate the authenticity of the patient or caregiver's license, including other establishments, patients, and caregivers, using the license verification system.

**310:681-2-8. [RESERVED]**

**310:681-2-9. Patient and caregiver disposal of medical marijuana**

(a) An individual who is no longer licensed, or no longer eligible, under sections 310:681-2-1, 2 and 3 of this Subchapter shall dispose of any usable marijuana and medical marijuana product in their possession by:

(1) Surrendering the marijuana to an Oklahoma law enforcement agency; or

(2) Rendering it unusable in accordance with subsection (d) of 310:681-5-10.

(b) Except as provided in this section, a caregiver who is no longer licensed with the Department or a patient who is no longer eligible may not transfer, share, give, sell, or deliver any usable marijuana in their possession to anyone, regardless of whether the individual possesses a valid medical marijuana license issued pursuant to this Subchapter.

(c) A caregiver who is no longer licensed with the Department or a patient who is no longer eligible may not dispose of usable marijuana in any manner other than as permitted by these rules.

(d) After the death of a patient, any usable marijuana that was in the patient's possession or in the possession of a patient's designated caregiver must be disposed of within fifteen (15) calendar days. The patient's caregiver or next of kin shall dispose of any usable marijuana and/or medical marijuana products as specified under (a) of this Section.

(e) After the death of a licensed caregiver, any usable marijuana and/or medical marijuana product that was in the caregiver's possession must be disposed of within fifteen (15) calendar days. The

licensed caregiver's next of kin shall dispose of any usable marijuana and/or medical marijuana product as specified under (a) of this Section or by allowing the patient for whom it was dispensed to take possession of the medical marijuana.

**310:681-2-10. Grounds for sanctions**

(a) The Department, after notice and hearing, may revoke or impose any one or more of the following sanctions on a patient or caregiver if the Department finds the individual engaged in any of the conduct set forth in paragraph (b) of this rule:

(1) Revoke, suspend, or refuse to renew a license; or

(2) Reprimand or place the licensee on probation.

(b) The Department may impose the sanctions listed in paragraph (a) of this rule if the Department finds:

(1) Any information provided to the Department by the patient or caregiver was false or misleading;

(2) The caregiver's patient has had their patient license suspended, revoked, or inactivated and the caregiver has not voluntarily relinquished their caregiver license to the Department;

(3) The patient or caregiver obtained an unlawful amount of medical marijuana in excess of the possession limits of Title 63 O.S. § 420(A);

(4) The patient or caregiver failed to report knowledge of conduct in violation of the medical marijuana control program;

(5) The patient or caregiver used or maintained medical marijuana in a manner that put others at an unreasonable risk or failed to take reasonable precautions to avoid putting others at risk;

(6) The patient or caregiver sold, transferred, shared, gave, or delivered any medical marijuana or medical marijuana product to any other person, including other patients or caregivers regardless of whether the individual possesses a valid medical marijuana license;

(7) The patient or caregiver allowed another to use the patient or caregiver's license;

(8) The patient was convicted of operating a vehicle, watercraft, or aircraft under the influence of medical marijuana;

(9) The patient knowingly violates 310:681-2-11 (Restrictions on smokable medical marijuana and medical marijuana products);

(10) The patient or caregiver knowingly violates Title 63 O.S. § 420 et seq. or the rules in this Chapter;  
or

(11) The physician's recommendation for medical marijuana is terminated pursuant to 310:681-1-9.1(11).

(c) All revocations and suspensions shall state the term of the revocation and suspension and shall also state the first date the license holder is eligible to reapply for the license.

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

(a) All smokable, vaporized, vapable and e-cigarette medical marijuana and medical marijuana products ingested, smoked, or consumed by a patient license holder is 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."

(b) All smokable, vaporized, vapable and e-cigarette medical marijuana and medical marijuana products consumed or smoked by a patient medical marijuana license holder shall not be smoked nor consumed in the presence of a minor under the age of eighteen (18).

(c) Medical marijuana products may only be dispensed to a patient or caregiver in the following forms:

(1) pill;

(2) oil;

(3) topical forms, including gels, creams, or ointments;

(4) a form medically appropriate for administration by vaporization or nebulization, excluding flower, dry leaf or plant form;

(5) tincture; or

(6) liquid.

(d) Medical marijuana product may not be dispensed to a patient or a caregiver in flower, dry leaf or plant form.

### **310:681-2-12. Variance**

(a) **Purpose.** Those applicants and license holders subject to the requirements of this Chapter may request that a variance be granted from the requirements of this Chapter. Such variance shall only be



granted for the term of the current license period, or less. The fees authorized in 63 O.S. § 420 et seq. and this Chapter are not eligible for a variance.

(b) **Extension of time for application review.** A variance request filed in conjunction with an application for license, or renewal of license, shall extend the time allowed for the review of the application for license or renewal of license.

(c) **Application required.** Variances requested pursuant to this Section are subject to approval by the Department. In order to have the variance approved, an applicant or license holder must submit a written application on a form provided by the Department.

(d) **Denied until approved.** Any variance request shall be deemed denied unless the license holder subsequently receives notice of approval from the Department.

(e) **Annual review.** Variances may be reviewed and reconsidered for each successive licensing period. Prior to the expiration of the current license, the licensee must apply in writing for renewal of the variance, on a form provided by the Department. The process for approval of the renewal is the same as the process for granting the original variance. Each "renewal" shall be considered a new, separate variance, and must be independently justified.

(f) **Application form.** Any applicant or licensee requesting a variance shall apply in writing on a form provided by the Department. The form shall include:

(1) Information sufficient to reference any pending application for license or existing license.

(2) The section(s) of this Chapter for which the variance is requested;

(3) Reason(s) for requesting a variance;

(4) The specific variance requested; and

(5) Any documentation which supports the application for variance.

(g) **Criteria.** In consideration of a request for variance, the Department shall consider the following:

(1) Compliance with 63 O.S. Section 420 et seq. and this Chapter.

(2) The impact of the variance on public health and safety;

(3) The creation or avoidance of public nuisance; and

(4) Alternative policies or procedures proposed.

(h) **Incomplete variance applications.** If the Department finds that a request is incomplete, the Department shall advise the applicant in writing and offer an opportunity to submit additional or clarifying information. The applicant shall have thirty (30) calendar days after receipt of notification to submit additional or clarifying information in writing to the Department, or the request shall be considered withdrawn.

(i) **Department decision.** The Department shall permit or disallow the variance request in writing within forty-five (45) calendar days after receipt of the request.

(j) **Denial or revocation of variance.** Variances are not a part of the license. Denial of a variance is not subject to appeal. A variance may be revoked upon finding the licensee is operating in violation of the variance, or the variance jeopardizes public health and safety, constitutes a distinct hazard to life, or creates a public nuisance. The licensee shall not be entitled to a hearing prior to revocation, but will be provided written notice of any revocation along with instructions that the licensee must come into compliance by a date certain.

### **310:681-2-13. Homegrown medical marijuana**

(a) All medical marijuana grown at home by patient medical marijuana license holders can only be grown on residential real property owned by the patient license holder or on rented real property for which the patient license holder has the property owner's written permission to grow medical marijuana on the property.

(b) All homegrown medical marijuana plants must be grown so that the marijuana is not accessible to a member of the general public and is only accessible to the patient or caregiver. If grown outdoors, it must be grown behind a fence that is at least six (6) feet in height. The marijuana plants must be completely enclosed by the fence and the fence must be secured with a lock and key. No marijuana plants may be visible from any street adjacent to the property.

(c) All medical marijuana processed by a patient license holder must be processed in a closed-loop system and processing and extractions with butane are prohibited.

## **SUBCHAPTER 3. Transportation License**

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

(a) A marijuana transportation license will be issued to qualifying applicants for a commercial license at the time of approval if requested by the applicant.

(b) All employees, officers, and principals of the commercial entity or approved laboratory who will be transporting marijuana on behalf of the commercial entity must also have a transportation license issued in their individual name/capacity.

(c) A transportation license shall enable the holder to transport marijuana from an Oklahoma licensed dispensary, licensed grower, licensed laboratory, or licensed processor, to an Oklahoma licensed dispensary, licensed grower, licensed processor, licensed laboratory, or licensed researcher.

(d) Licensed research establishments with an approved transportation license may only transport for the purpose of transporting marijuana purchased from a licensed dispensary, licensed grower or licensed processor back to their approved research site.

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

(a) Vehicles used in the transport of medical marijuana between commercial establishments or Approved Laboratories shall be:

(1) Insured at or above the legal requirements in Oklahoma;

(2) Capable of securing medical marijuana during transport;

(3) Equipped with an alarm system;

(4) Free of any markings that would indicate the vehicle is being used to transport medical marijuana; and

(5) Staffed with a minimum of two (2) employees, principals or officers and transportation license holders of the commercial establishment or approved laboratory for whom the marijuana is being transported when a vehicle contains medical marijuana. At least one (1) transportation license holder shall remain with the vehicle at any time it contains medical marijuana.

(b) Individuals transporting medical marijuana shall:

(1) Be employed by or an officer or principal of an establishment with a valid medical marijuana dispensary, grower or processor license;

(2) Have a valid Oklahoma driver's license; and

(3) Have possession of their transportation license while operating the motor vehicle used to transport medical marijuana.

(c) All medical marijuana shall be transported in a locked container, shielded from public view, and clearly labeled "Medical Marijuana or Derivative."

(d) Prior to the transport of any medical marijuana, an inventory manifest shall be prepared at the origination point of the medical marijuana. The inventory manifest shall include the following information:

(1) For the origination point of the medical marijuana:

(A) The license number for the dispensary, grower or processor;

(B) Address of origination of transport; and

(C) Name and contact information for the originating licensee.

(2) For the end recipient license holder of the medical marijuana:

(A) The license number for the dispensary, grower, processor or researcher destination;

(B) Address of the destination; and

(C) Name and contact information for the destination licensee.

(3) Quantities by weight or unit of each type of medical marijuana product contained in transport;

(4) The date of the transport and the approximate time of departure;

(5) The arrival date and estimated time of arrival;

(6) Printed names and signatures of the personnel accompanying the transport; and

(7) Notation of the transporting licensee.

(e) A separate inventory manifest shall be prepared for each licensee receiving the medical marijuana.

(f) The transporting licensee entity shall provide the other licensee facility with a copy of the inventory manifest at the time the product changes hands and after the other licensee prints their name and signs the inventory manifest.

(g) An inventory manifest shall not be altered after departing the

originating premises other than in cases where the printed name and signature of receipt by the receiving licensee is necessary.

(h) A receiving licensee shall refuse to accept any medical marijuana or medical marijuana product that is not accompanied by an inventory manifest.

(i) Originating and receiving licensees shall maintain copies of inventory manifests and logs of quantities of medical marijuana received for three (3) years from date of receipt.

(j) Commercially licensed establishments may only transport from or to another commercially licensed establishment or approved laboratory per Title 63 O.S. § 424(B).

#### **SUBCHAPTER 4. Medical Research License**

##### **310:681-4-1. Purpose**

A marijuana research license allows a holder of the license to produce, process, and possess marijuana solely for human and plant research purposes.

##### **310:681-4-2. Standards**

(a) **Eligibility.** The Department will review applications and have a process to approve or deny the research project. The following provisions govern eligibility and continuing requirements for research license applications, prohibitions and restrictions.

(1) Other than the restrictions listed in this Section or outlined in law, any person, organization, agency, or business entity may apply for a marijuana research license.

(2) Other marijuana licensees may apply for a research license. Facilities at which the research is conducted must be wholly separate and distinct from the marijuana business, except:

(A) Licensed growers with a research license and approved research project may grow marijuana plants or possess marijuana for research purposes at the licensed grower's premises. However, all marijuana grown or possessed for research purposes or purposes other than those related to the research project must be kept wholly separated and distinct from commercial operations and must not be comingled with or diverted to marijuana grown for commercial purposes or purposes other than those related to the research project; and

(B) Licensed processors with a research license and approved research project may possess or process marijuana for research purposes at the licensed processor's premises. However, all marijuana possessed or processed for research purposes must be kept wholly separated and distinct from all marijuana possessed and processed for commercial purposes or purposes other than those related to the research project and must not be comingled with or diverted to marijuana possessed for commercial purposes or purposes other than those related to the research project. Researchers who are also licensed processors yet do not also hold a grower license may not grow marijuana plants for the purposes of research under a research license at the licensed processor's premises.

(3) All persons conducting research under the research license must be twenty-five (25) years of age or older.

(4) All research license applicants and those persons that have managing control over an organization, agency, or business entity must submit to a criminal background check as defined in 310:681-1-5 within five (5) days of submittal of an application and not have a disqualifying criminal conviction.

(b) **Restrictions on possession.** Except as otherwise provided in agency rule, no applicant for a research license may possess any marijuana plants or marijuana for research purposes unless and until the research project is approved and the applicant is notified the research license is approved in writing by the Department.

(c) **Restrictions on transport.** Persons working under the research license may not carry marijuana on their persons away from the approved research address except during transportation if the research license has applied for a transportation license. All requirements under the transportation license will apply.

(d) **Initial applications.**

(1) The applicant is responsible for ensuring no information is included in the research plan that may compromise the applicant's ability to secure patent, trade secret, or other intellectual property protection.

(2) All application documents must be submitted by a person who has the legal authority to represent the entity if the applicant is an entity other than an individual person.

(3) All documents must be submitted to the Department in a legible PDF format.

(4) All of the following information and documents are required for each initial application:

(A) A completed marijuana research license application as established in 310:681-5-3 (relating to applications).

(B) A research plan limited to four pages that includes the following information:

(i) Purpose and goal(s) of the proposed research project(s);

(ii) Key milestones and timelines for the research project(s);

(iii) Background and preliminary studies;

(iv) Amount of marijuana to be grown, if applicable, including the justification with respect to milestone tasks;

(v) Anticipated cost of the proposed research project(s) and funding available for the work. Funding of the proposed research must be disclosed by the applicant(s) in amount, timing and source(s);

(vi) Key personnel and organizations, including names and roles;

(vii) Facilities, equipment, security plans and other resources required and available for conducting the proposed research project(s);

(viii) A biosketch for each individual involved in executing the proposed research project limited to two (2) pages per individual performing technical and administrative functions essential to performing the proposed research, including proof that the individual is twenty-five (25) years of age or older. Biosketches must be prepared using the National Institutes of Health (NIH) biographical sketch format, available at <http://grants.nih.gov/grants/forms/new-renewal-revisions.htm>.

(C) Letters of support limited to two (2) pages per letter confirming the commitment of time and resources from external personnel or organizations if external personnel or organizations will participate in research activities under an approved research project. Letters of support are required to confirm the commitment of time and resources from personnel involved in the proposed research project(s) who are not employed at the applicant organization. Letters of support must include specific details regarding the type(s) and magnitude of the time and resources being committed to the proposed research project(s) and must be signed by individuals having the authority to make such commitments.

(D) For all projects involving human subjects, documentation of approval of the research project from an institutional review board (IRB) with federal wide assurance is required. Documents must be provided on IRB letterhead and be signed by authorized officials of those regulatory bodies.

(E) A research protocol approved by the IRB.

(F) A plan for waste disposal that meets the requirements as established in 310:681-5-10.

(G) Documents that do not conform to the requirements in subsection (d) of this Section may be withdrawn. All non-form documents must conform to the following requirements:

(i) Eight and one-half by 11-inch portrait-oriented page dimensions;

(ii) Single-spaced with all margins measuring at least one inch; and

(iii) At least 12-point font in Times New Roman or Arial, not proportionately reduced.

**(e) Review by the department.**

(1) The Department may assign, or contract with, external parties for the review of research applications.

(2) If the applicant submits application materials to the Department by the required deadline specified by the Department's application letter and the Department determines the additional application materials are complete and meet the document requirements specified in this section, the Department will proceed with reviewing the research project.

(3) If at any time during the process of review the Department finds that the application materials are not complete, the Department will notify the applicant the application is deemed withdrawn until such time as the application is corrected.

(4) The Department will supply a written evaluation with the approval recommendation status; determination(s) of the applicable research category or categories; and, as applicable, the reasons for a "Not Approved" recommendation. The Department will provide written evaluations to applicants following completion of the review process along with the Department's approval or denial of the research license.

**(f) Physical Plant.** The physical plant where the research will be conducted must meet the physical plant requirements in Subchapter 6 (relating to commercial establishments).

**(g) Research license withdrawal and denials.**

(1) The Department will withdraw an application if:

(A) The application or additional application materials are determined incomplete or incorrect by the Department or its designated reviewer;

(B) The additional application materials are not timely received by the Department as provided in this section; or

(C) The applicant(s) request withdrawal of a research license application at any time in the application process. The applicant must request the withdrawal in writing and is responsible for any review costs due to the reviewer. The voluntary withdrawal of a research license application does not result in a hearing right.

(2) The Department will deny a research license if:

(A) The scientific reviewer does not recommend approval of the license after reviewing the research proposal;



(B) The applicant does not meet the requirements for a license under this section; or

(C) The applicant provides false or misleading information in any of the materials it submits to the Department or the reviewer.

(3) If the Department denies a research application for the reasons provided in subsection (g)(2) of this Section the applicant is prohibited from reapplying for a research license for one (1) calendar year from the date of the Department's denial of the license.

**(h) Reporting required.**

(1) Monthly reporting on product consumption is required pursuant to Title 63 O.S. § 425(H).

(2) The Department may require additional reporting by, or auditing of, the research licensee as necessary, based on the nature of the research proposal.

(3) The research licensee shall report:

(A) Any circumstances that alter the scope of the research project;

(B) Any circumstances that require a change to the approved operating plan, the entity structure, or entity location; or

(C) Any security failures resulting in the loss of marijuana.

**(i) Adding an additional research project or changing existing approved research project process (after licensure).**

(1) A research licensee is restricted to only those research activities under a research project that have been reviewed and approved.

(2) Applications to add a new project or change an existing approved project must meet the same standards as those required for the initial application except that a new license application is not required. To apply to add a new research project or change an existing approved project, a research licensee shall submit all materials to the Department as required under subsection (d) of this section. Incomplete project applications will not be considered.

(3) The Department will review the application for a new research project or change to an existing approved research project pursuant to the requirements of this Subchapter. The Department will supply a written evaluation to the licensee after completing review of the application for a new research project or a change to an existing approved research project. Evaluations will provide the approval

recommendation status; determination(s) of the applicable research category or categories; and, as applicable, the reasons for a "Not Approved" recommendation.

**(j) Research license renewals.**

(1) Research license renewals operate on an annual basis, based on the license issuance date. The licensee must provide a status report to the Department or an application for a new research project if the licensee's ongoing approved research project will end within thirty days prior to or after the renewal date. The status report or application must be received by the Department sixty days prior to the license expiration.

(2) The Department will review the renewal application, the licensee's violation history, and criminal background check prior to renewal. If the violation history or criminal records disqualify the licensee from eligibility for a research license, the Department will provide written notice the license will not be renewed.

**(k) License revocation.**

(1) The Department may revoke an application for the following reasons:

(A) The Department has reason to believe that marijuana is being diverted from the research licensee;

(B) The research licensee operates outside the scope of the research project(s) approved under the license issued to the licensee;

(C) The applicant makes a misrepresentation of fact, or fails to disclose a material fact to the Department during the application process or any subsequent investigation after a license has been issued;

(D) The Department finds that the licensee possesses marijuana plants, marijuana, or marijuana products that are not included in the approved research project;

(E) The research licensee makes changes to their operating plan, entity structure, or location without prior approval from the Department; or

(F) The research licensee fails to maintain security requirements for the licensed research facility.

(2) A licensee may request voluntary cancellation of a license at any time. The licensee must request cancellation of a research license to the Department in writing. The voluntary cancellation of a research license does not result in a hearing right.

(l) **Disposal requirements.** Research licensees must dispose of marijuana as provided in 310:681-5-10 (relating to waste disposal).

(m) **Animal research.** Animal research is not authorized in this Chapter.

### **310:681-4-3. Inspections**

(a) Submission of an application for a research license constitutes permission for entry to and inspection of the 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. All inspections must be complete and approved prior to the issuance of any research license. Additionally, each licensee shall be inspected pursuant to this Section at least once in any twelve-month period.

(b) The Department may perform an annual unannounced on-site inspection of a commercial establishment to determine compliance with these rules or submissions made pursuant to this rule.

(c) If the Department receives a complaint concerning a research license holder's noncompliance with this Chapter, the Department may conduct additional unannounced, on-site inspections beyond an annual inspection. The Department shall refer all complaints alleging criminal activity that are made against a commercial licensee to appropriate Oklahoma state or local law enforcement authorities.

(d) If the Department discovers what it reasonably believes to be criminal activity during an inspection, the Department shall refer the matter to appropriate Oklahoma state or local law enforcement authorities for further investigation.

(e) The Department may review any and all records of a research license holder 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 research 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 this Chapter.

(g) If the Department identifies a violation of Title 63 O.S. § 420 et seq. or this Chapter during an inspection of the research licensee the Department shall provide an inspection report or a written notice of violation to the research licensee that includes the rule or statute violated.

## **SUBCHAPTER 5. Commercial Establishments**

### **310:681-5-1. License required**

(a) No entity shall operate a medical marijuana dispensary, grower operation, processor, or research project without first obtaining a license from the Department pursuant to the rules in this Chapter.

(b) All commercial licenses shall be on forms prescribed by the Department.

(c) Application fees are nonrefundable.

### **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 entity complies with the requirements of 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 310:681-5-3.

(2) Before renewing a license, the Department may require further information and documentation and may conduct additional background checks to determine the licensee continues to meet the requirements of these rules.

(3) A commercial establishment licensee whose license is not renewed shall cease all operations immediately upon expiration of the license.

(A) A commercial establishment has thirty (30) days from date of expiration to liquidate all pre-packaged medical marijuana products to another commercially licensed entity.

(B) Any medical marijuana after date of expiration, revocation or surrender, or prepackaged medical marijuana products not liquidated after thirty (30) days still remaining in the possession shall be disposed of as specified under OAC 310:681-2-9(a)(1) and (2).

(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 ten (10) days of any changes in contact information.

(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, and submit to the Department a new application as provided for in 310:681-5-3.

(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 transferred.

(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 310:681-5-2(c)(3)(A) and (B).

**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 Title 63 O.S. § 420 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;
- (4) Phone number and if available, email of the establishment; and
- (5) Operating hours 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 preferred telephone number and email address;
- (5) The applicant's telephone number and email address;
- (6) An attestation that the information provided by the applicant is true and correct;
- (7) A statement signed by the applicant pledging not to divert marijuana to any individual or entity that is not lawfully entitled to possess marijuana.

(d) **Application on behalf of an entity.** In addition to requirements of subsection (c), 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 principal officer.

(e) **Supporting documentation.** For a determination that an entity meets the requirements of Title 63 O.S. § 420 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 entity;

(2) A list of all creditors currently holding a secured or unsecured interest in the entity or the premises of the entity;

(3) A list of all persons or entities having a direct or indirect authority over the management or policies of the entity;

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

(5) Proof that the proposed location of the commercial establishment is at least one thousand (1,000) feet from a public or private school or a church. The distance specified shall be measured from any entrance of the school or church to the nearest property line point of the dispensary;

(6) If the proposed location is not owned by the individual applicant/entity: a copy of the lease and a written statement from the owner/landlord certifying consent that the applicant/entity, if awarded a license, may operate a medical marijuana commercial facility on the property;

(7) Documents establishing the applicant, principal officers, and seventy-five percent (75%) of the ownership interests are Oklahoma residents as established in 310:681-1-6 (relating to proof of residency);

(8) Provide a surety bond that meets the requirements of 310:681-5-19; and

(9) Designation of a successor-in-interest or designee of the Commercial Entity.

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

(a) Submission of an application for a commercial establishment license constitutes permission for entry to and inspection of the 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. All inspections must be complete and approved prior to the

issuance of any commercial establishment license. Additionally, each licensee shall be inspected pursuant to this Section at least once in any twelve month period.

(b) The Department may perform an annual unannounced on-site inspection of a commercial establishment to determine compliance with these rules or submissions made pursuant to this rule.

(c) If the Department receives a complaint concerning a commercial licensee's noncompliance with this Chapter, the Department may conduct additional unannounced, on-site inspections beyond an annual inspection. The Department shall refer all complaints alleging criminal activity that are made against a commercial licensee to appropriate Oklahoma state or local law enforcement authorities.

(d) If the Department discovers what it reasonably believes to be criminal activity during an inspection, the Department shall refer the matter to appropriate Oklahoma state or local law enforcement authorities for further investigation.

(e) 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 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 this Chapter.

(g) If the Department identifies a violation of Title 63 O.S. § 420 et seq. or this Chapter during an inspection of the commercial establishment the Department shall provide an inspection report or a written notice of violation to the commercial licensee that includes the rule or statute violated.

### **310:681-5-5. Plan of correction**

(a) If a violation is not corrected during the inspection or is a chronic, reoccurring violation, the Department may require the licensee to submit a plan of correction.

(b) Violations shall be corrected within thirty (30) days of receipt of the notice of violation.

(c) A plan of correction shall include:

(1) How and when the corrective action(s) will be accomplished;

(2) What changes will be made to ensure the violation identified by the Department does not recur; and

(3) How the establishment will monitor the corrective action(s) to ensure the violation does not recur.



(d) A commercial licensee shall provide the Department with a plan of correction within ten (10) business days of receipt of the notice of violation.

(e) Upon written request from the facility, the Department may extend the time period within which the violations are to be corrected where correction involves substantial structural improvement.

(f) A plan of correction is subject to acceptance or rejection by the Department.

(g) If the Department finds that the plan of correction does not meet the requirements for an acceptable plan of correction the Department will provide notice of the rejection and the reason for the rejection. The licensee shall have ten (10) working days after receipt of the notice of rejection in which to submit a modified plan. If the modified plan is not timely submitted, or if the modified plan is rejected, the Department shall impose a plan of correction, which the facility shall follow.

(h) Acceptance of the plan of correction by the Department does not release the licensee from the responsibility for compliance should the implementation not result in correction and compliance. Acceptance indicates the Department's acknowledgment that the licensee indicated a willingness and ability to make corrections adequately and timely.

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

(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) A detailed explanation of why any medical marijuana product purchased by the licensee cannot be accounted for as having been sold or still remaining in inventory;

(E) Total dollar amount of all sales to medical marijuana patients and caregivers; and

(F) Total dollar amount of all taxes collected from sales to medical marijuana patients and caregivers.

(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; and
- (G) Total dollar amount of all sales to processor, dispensary, and researcher licensees.

(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; and
- (E) The amount of marijuana waste in pounds.

(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, such as manual or computerized records of assets and liabilities, monetary transactions, journals, ledgers, and supporting documents, including agreements, checks, invoices, and vouchers;
- (2) 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;
- (3) Documentation of every instance in which marijuana was purchased, which shall include:

(A) The license number of the selling entity; and

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

(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;

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

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

(a) **Failure to file timely reports.** If a licensee files six (6) or more untimely reports within a two (2) year time period, the license shall be revoked.

(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) **Failure to correct deficiency.** If a commercial licensee fails to correct any violation of the rules set forth for dispensaries, processors, and growers within thirty (30) calendar days of receiving the Department's written notice, the following penalties shall be imposed:

(1) Five hundred dollar (\$500) fine for each deficiency not corrected.

(2) 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.

(e) **Other deficiencies.** Any commercial establishment who violates the following provisions shall be subject to revocation of license:

(1) Delivery of medical marijuana or marijuana products to patient or caregiver license holders outside of a dispensary;

(2) Consumption of alcohol, medical marijuana, or medical marijuana products on the premises of a commercial establishment;

(3) Employing persons under age twenty-one (21), or persons who do not pass the specified background check;

(4) Failure to post or maintain a surety bond in the amount specified; and

(5) In the case of dispensaries and processors, selling or dispensing medical marijuana products with THC levels above those specified.

(e) **Right to hearing.** The Department shall notify the licensee in writing of the Department's intent to take remedial action, to impose a fine, or to take action against the license issued; and of the rights of the licensee under this section, including the right to a hearing.

### **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) 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.

(c) 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.

(d) 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.

(e) 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.

(f) 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.

(g) 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 board**

(a) The Medical Marijuana Industry Expert Board/Food Safety 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 appointed must meet at least one of the following qualifications and only one member may be on the Board at any time from each of the following areas:

- (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 or
- (13) Food processor/manufacturer.

(b) The Medical Marijuana Industry Expert Board shall by December 1, 2018 and by every July 1 thereafter, and more often if required, submit to the Commissioner of Health recommendations regarding rule promulgation and standards related to the handling and processing of medical marijuana and medical marijuana products.

**310:681-5-9. Standards for handling and processing medical marijuana and medical marijuana products**

Oklahoma Administrative Rules 310:257 as well as all provisions under Subchapter 6 of this Chapter shall apply to all commercial licensees.

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

(a) **General.** All medical marijuana waste generated during production, processing and testing must be stored, managed and disposed of in accordance with these rules.

(b) **Evaluation for hazardous waste.** All medical marijuana waste generated during production, processing and testing must be evaluated against the state's hazardous waste regulations to determine if the medical marijuana waste is designated as hazardous waste. It is the responsibility of each medical marijuana waste generator to properly evaluate their medical marijuana waste to determine if it is designated as hazardous waste. If a generator's medical marijuana waste is designated as hazardous waste, the medical marijuana waste is subject to the hazardous waste management standards set by the Oklahoma Department of Environmental Quality in Oklahoma Administrative Code Title 252 Chapter 205.

(c) **Waste not designated as hazardous.** Medical marijuana waste not designated as hazardous waste must be rendered unusable in accordance with (d) of this Section prior to disposal. Medical marijuana waste rendered unusable must be disposed of in accordance with (e) of this Section.

(d) **Rendering unusable.** The required method for rendering medical marijuana waste unusable is by grinding the medical marijuana waste and incorporating it with other ground materials so the volume of the resulting mixture is less than fifty percent medical marijuana waste. All other methods for rendering medical marijuana waste unusable must be approved by the Department before implementation. There are two categories of ground material that can be incorporated with medical marijuana waste: compostable mix waste and noncompostable mix waste.

(1) Compostable mixed waste: medical marijuana waste to be disposed as compost feedstock or in another organic waste method, such as an anaerobic digester, may be mixed with:

(A) Food waste;

(B) Yard waste;

(C) Vegetable-based grease or oils; or

(D) Other wastes as approved by the Department.

(2) Noncompostable mixed waste: medical marijuana waste to be disposed in a landfill or another disposal method, such as incineration, may be mixed with these materials:

(A) Paper waste;

(B) Cardboard waste;

(C) Plastic waste;

(D) Soil; or

(E) Other wastes as approved by the Department.

(e) **Disposal.** Medical marijuana waste rendered unusable in accordance with (d) of this Section can be disposed. Disposal of the medical marijuana waste rendered unusable may be delivered to a permitted and state-approved solid waste facility for final disposition. Acceptable and Department-approved permitted solid waste facilities include:

(1) Compostable mixed waste: compost, anaerobic digester or other facility with the approval of the jurisdictional state or local health department.

(2) Noncompostable mixed waste: landfill, incinerator or other facility with the approval of the jurisdictional state or local health department.

(f) **Disposal onsite.** Disposal of the medical marijuana waste rendered unusable may be managed onsite by the generator in accordance with the standards set by the Oklahoma Department of Environmental Quality in Oklahoma Administrative Code Title 252 Chapter 205 Hazardous Waste Management.

(g) **Record of disposal.** Licensees shall maintain a record of the final destination of medical marijuana waste rendered unusable. The record shall be maintained for a period of three (3) years.

### **310:681-5-11. Recall procedures**

Each commercial licensee shall establish a procedure for issuing voluntary and mandatory recalls for medical marijuana.

#### **(1) Factors that require a recall.**

(A) Defective or potentially defective marijuana;

(B) Marijuana that has failed laboratory testing in accordance with these rules;

(C) Reasonable probability that use of the medical marijuana or exposure to the medical marijuana will cause serious adverse health consequences; or

(D) Any other instances as determined by the Department that would warrant recall.

#### **(2) Procedures.** The recall procedure shall include:

(A) The licensee's agent(s) who are responsible for overseeing the recall;



(B) The procedures for notifying patients, caregivers and necessary commercial licensees as applicable to each commercial license type;

(C) Instructions for patients, caregivers and applicable commercial licensees regarding proper product handling of any recalled marijuana;

(D) Notification of the recall to the Department.

### **310:681-5-12. Marijuana servings and transaction limitations**

(a) **Single serving.** A single serving of a medical marijuana product processed or dispensed shall not exceed ten (10) milligrams active tetrahydrocannabinol (THC) Medical marijuana products and Medical Marijuana Concentrate processed or dispensed shall have a THC content of not more than twelve percent (12%). Mature plants marijuana shall have a THC content of not more than twenty percent (20%).

(b) **Transaction limitation.** A single transaction by a dispensary with a patient or caregiver is limited to three (3) ounces of usable marijuana, one (1) ounce of marijuana concentrate, and/or seventy-two (72) ounces of medical marijuana products.

### **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 establishment shall notify immediately the Department, the Board of Pharmacy, and law enforcement. The commercial licensee shall provide the notice by submitting 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. Dispensing medical marijuana**

(a) Only a Dispensary Manager shall control and distribute all medical marijuana products.

(1) Only the Dispensary Manager shall be permitted to unlock the dispensary area or any additional storage areas for medical marijuana, except in extreme emergency.

(2) An extreme emergency shall be in case fire, water leak, electrical failure, public disaster or other catastrophe whereby the public is better served by overlooking the safety/security restrictions on medical marijuana.

(3) Medical marijuana products shall not be left outside the dispensary area when the Dispensary Manager is not in attendance.

(4) Each dispensary, in order to obtain and maintain a dispensary license, must have a Dispensary Manager as the Dispensary Manager in charge (DMIC). A DMIC is designated by his/her signature on the original dispensary application or by the appropriate notification to the Department and is responsible for all aspects of the operation related to the practice of dispensing medical marijuana and medical marijuana products. The Dispensary Manager in charge must only be employed at one medical marijuana dispensary. Therefore, no Dispensary Manager may serve as a DMIC in more than one dispensary at a time.

(b) Medical marijuana may not be dispensed in a licensed pharmacy.

(c) Prior to employment at a medical marijuana dispensary, the Dispensary Manager must obtain 4 hours of medical marijuana specific continuing education training each calendar year.

(d) The Dispensary Manager in charge is responsible for:

(1) The supervision of all employees as they relate to the dispensing of medical marijuana and medical marijuana products;

(2) Establishment of policies and procedures for safekeeping of medical marijuana products that satisfy Department requirements, including security provisions when the dispensary is closed and drug diversion prevention policy and procedures;

(3) Proper record keeping system for the purchase, sale, delivery, possession, storage, and safekeeping of medical marijuana and medical marijuana products;

(4) Annual inventory of all medical marijuana products completed between May 1 and July 1;

(5) Maintenance of medical marijuana physician recommendation files and records of all amounts of medical marijuana and medical marijuana products dispensed;

(6) Appropriate training of all dispensary employees and maintaining documentation of training on-site for inspection; and

(7) Failure of the dispensary to have a DMIC who fulfills these responsibilities is a violation of this code by both the dispensary and DMIC.

(e) The DMIC must be on-site at least 40 hours per week. In the absence of the DMIC, another Dispensary Manager with the proper training shall be on site.

(f) Responsibilities of dispensary and DMIC:

(1) The dispensary and DMIC are responsible to establish and maintain effective controls against errors or misfills.

(2) The dispensary and DMIC shall notify the Department immediately by certified mail of the separation of employment of any employee for any suspected or confirmed drug or dispensary related violation. If the DMIC is terminated for such reason, the owner or other person in charge of the dispensary shall notify the Board by certified mail.

(3) The dispensary and DMIC shall establish and maintain effective controls against the diversion of medical marijuana and medical marijuana products into other than legitimate medical, scientific, or industrial channels as provided by state or local laws or rules.

(4) The Dispensary Manager is responsible for certifying the final product and recommendation prior to dispensing to the patient.

(5) The dispensary and DMIC are responsible for supervision of all employees.

(6) The Dispensary Manager on duty must wear an appropriate identification badge allowing the public the ability to distinguish him/her from other dispensary employees.

(g) Before a Dispensary Manager dispenses medical marijuana or medical marijuana products or before a processor agent processes medical marijuana for a patient or caregiver, the agent shall:

(1) Verify the patient's or the caregiver's proof of identity by requiring the presentation of a valid photo identification as specified in OAC 310:681-1-7 (relating to proof of identify), in addition to a verified Department issued medical marijuana license;

(2) Provide the patient or caregiver required education materials provided by the Department;

(3) Enter the patient's identification card number or caregiver's identification card number into the medical marijuana electronic verification system to verify the validity of the license card;

(4) Keep a record of the following information pertaining to each sale or service for the patient or caregiver:

(A) The patient's control number and if applicable, the caregiver's control number;

(B) The amount and types of medical marijuana or medical marijuana products dispensed;

(C) The date the medical marijuana was dispensed; and

(D) The dispensary's dispensary license number;

(h) All licensed medical marijuana dispensaries and registered medical marijuana physicians shall collect and retain, all applicable data elements identified within the ASAP4 template prescribed by the Oklahoma Bureau of Narcotics and Dangerous Drugs Control (OBNDDC) Oklahoma Prescription Monitoring Program (OK PMP); and as set forth in the rules and requirements for the reporting and monitoring of Schedule II - V controlled substances dispensed and/or filled in Oklahoma; and available through the Oklahoma Data Submission Dispenser Guide.

### **310:681-5-15. Medical marijuana product storage standards**

The dispensary manager shall verify at least the following:

(1) Medical marijuana and Medical marijuana products requiring special storage conditions to insure their stability are properly stored.

(2) No outdated Medical marijuana and Medical marijuana products are stored in the dispensary and are removed from the dispensary not more than 1 month after the expiration date.

(3) Distribution records are properly and adequately documented and reported.

(4) All necessary and required security and storage standards are met.

(5) Metric-apothecaries' weight and measure conversion tables and charts are reasonably available

(6) Policies and procedures of the dispensary are followed.

### **310:681-5-16. Hours of operation**

A dispensary may only be open to the public and offer for sale medical marijuana and medical marijuana products Monday through Saturday from 8:00am to 12:00am with no sales or operation on Sunday.

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

No minors under the age of 18 may enter commercial establishments unless the minor is a patient license holder accompanied by their parent or legal guardian. In addition to commercial establishment employees and owners, transportation license holders only patient and caregiver license holders may enter dispensaries.

### **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 twenty-one (21) or allow any employee to commence or continue employment or volunteer with the commercial establishment until such person has been verified via an Oklahoma State Bureau of Investigations background check as established in OAC 310:681-1-5, that the employee has no felony convictions in the preceding two (2) years, nor any drug related misdemeanor convictions in the preceding two (2) years. It shall be the responsibility of the Commercial Establishment to ensure the background check is run and kept on file during the term of the employee or volunteer's employment, and for seven (7) years after the end of such employment.

(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 dispensary shall repackage or otherwise adulterate or change any medical marijuana product or concentrate.

(e) Dispensaries cannot be co-located with any other business entity (but may be co-located with other commercial establishments as defined herein) or a physician and may only sell or otherwise offer medical marijuana and medical marijuana products.

(f) No commercial establishment shall display more than two (2) separate signs. Signs shall only identify the business name. Signs shall be affixed to the building or permanent structure and each sign shall be limited to sixteen hundred (1,600) square inches. All exterior signage shall comply with local ordinances and requirements.

(g) No commercial establishment shall engage in advertising, assertions or statements on any product, any sign or display, or any document provided to a consumer that is false or untrue in any material particular, or that, irrespective of falsity, directly, or by ambiguity, omission, or inference, or by the addition of irrelevant, scientific or technical matter tends to create a misleading impression.

(h) No commercial establishment shall advertise in broadcast, cable, radio, print, and digital communications where at least 20 percent of the audience is reasonably expected to be 21 years of age or under including college student publications.

(i) 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 persons under 21 to purchase or consume marijuana or medical marijuana products.

(j) No licensee shall advertise medical marijuana products outdoors within one thousand (1,000) feet of any public or private school, church property primarily and regularly used for worship services and religious activities or public playground. The distance between the establishment and the school, church or playground shall be measured in a straight line from the nearest property line of the school or church to the nearest perimeter wall of the licensed premises of the establishment. If it is not possible to make a direct measurement because of obstructions or other hindrances, the measurement may be made by any reasonable method.

(k) No commercial establishment shall advertise on or in a public transit vehicle or public transit shelter, or on or in a publicly owned or operated property.

(l) No commercial establishment shall produce any items for sale or promotional gifts, such as T-shirts or novelty items, bearing a symbol of or references to marijuana or medical marijuana products, including logos.

(m) No commercial establishment shall advertise "free" or "donated" products. Promotions or inducements such as giveaways and coupons are prohibited.

(n) No commercial establishment shall display medical marijuana products or advertisements/signs in windows or in public view; and shall ensure law enforcement personnel have a clear and unobstructed view of the interior of the premises, including the area in which the cash registers are maintained, from the exterior public sidewalk or entrance to the premises. However, this latter requirement shall not apply to premises where there are no windows, or where existing windows are located at a height that precludes a view of the interior of the premises to a person standing outside the premises.

(o) No commercial establishment shall display or store medical marijuana products such that a customer has direct access to the product.

### **310:681-5-19. Surety bond**

(a) The licensee shall provide evidence of surety bond.

(b) The named insured on the bond shall be the Oklahoma State Department of Health.

(c) The surety bond shall be filed with the application for license.

(1) The bond shall be maintained through the term of license.

(2) The bond shall provide for the payment of financial penalties incurred during the course of operations of the licensee and shall include any financial penalties imposed or pending at the time of license revocation. The bond may also be utilized for any costs associated with disposing of unused medical marijuana and medical marijuana products or hazardous materials or waste.

(3) The bond shall be executed by a surety company licensed by the Oklahoma Insurance Commissioner.

(4) The bond shall be continuous in form or may be renewed annually. If renewed annually, the licensee shall file evidence of bond renewal with each license renewal.

(d) Termination of the surety bond shall not affect the liability of the surety for any penalties resulting from operations occurring before the effective date of termination.

(e) The amount of the bond shall be maintained at one hundred thousand dollars (\$100,000).

(f) Under the terms of the bond, any cancellation, expiration, or lapse in the bond shall require the surety to send notice by certified mail to the licensee and to the Department at least thirty (30) days in advance of cancellation, expiration, or lapse.

(g) The licensee shall also have requirements to ensure that the Department is notified of:

(1) Any lapse in coverage; or

(2) Termination of coverage at least thirty (30) days before termination.

## **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**

(a) **Enclosed and secure structure.** All growing, processing, and dispensing of marijuana, medical marijuana, and medical marijuana products shall take place within a building that:

(1) Has a complete roof enclosure supported by connecting walls, constructed of solid materials, extending from the ground to the roof;

(2) Is secure against unauthorized entry;

(3) Has a foundation, slab, or equivalent base to which the floor is securely attached;

(4) Meets performance standards ensuring growing and processing activities cannot be and are not perceptible from the structure in terms of:

(A) Common visual observation;

(B) Odors, smell, fragrances, or other olfactory stimulus;

(C) Light pollution, glare, or brightness;

(D) Adequate ventilation to prevent mold;

(E) Noise;

(F) Complete visual screening; and

(G) Is accessible only through lockable doors.

(b) **Access.** Commercial grade, non-residential door locks shall be installed on every external door, and gate if applicable. Only authorized personnel shall have access to locked and secured areas. Facilities shall maintain detailed records of employees with access to locked and secured areas. Records shall be made available to the Department upon request.

(c) **Plans and drawings.** Commercial establishments shall maintain detailed plans and elevation drawings of all operational areas involved with the growing, processing, and dispensing of medical marijuana.

(1) The plans and drawings shall identify the following:

(A) All limited access areas, ventilation systems, and equipment used for growing and processing;

(B) All entrances and exits to the facility;

(C) All windows, skylights, and retractable mechanisms built into the roof;

(D) The location of all security cameras;

(E) The location of all alarm inputs, detectors, and sirens;

(F) All video and alarm system surveillance areas;

(G) All growing and processing areas shall be labeled according to the specific activity occurring within the area;



- (H) All restricted and limited access areas shall be labeled accordingly; and
- (I) All non-production areas labeled according to their purpose.
- (2) Floor plans and elevation drawings shall be kept current and on the premises of the commercial establishment.
- (3) Plans and elevation drawings shall be made available to the Department upon request.
- (d) **Floors, walls, and ceilings.** Floors, walls, and ceilings shall be constructed in such a manner they may be adequately cleaned and kept clean and in good repair. Ceilings and ceiling tiles shall not allow access to the commercial establishment from adjacent properties.
- (e) **Lighting.** Commercial establishment facilities shall have adequate lighting in all areas where marijuana is stored and where equipment and utensils are cleaned.
- (f) **Plumbing.** Plumbing shall be of adequate size and design and adequately installed and maintained to carry sufficient quantities of water to required locations throughout the facility and to properly convey sewage and liquid disposable waste from the facility. There shall be no cross-connections between the potable and waste water lines. There shall be both hot and cold running water.
- (g) **Additional standards.** All facilities shall be constructed to 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 748, ch. 20.

#### **310:681-6-3. Limited-access areas**

- (a) Commercial licensees shall ensure that any person on the licensed premises, except for employees and contractors of the licensee, are escorted at all times by the licensee or at least one employee of the licensee when in the limited-access areas of the premises.
- (b) Entrances to all limited-access areas shall have a door and a lock meeting the requirements of OAC 310:681-6-2(b). The door shall remain closed when not in use during regular business hours.
- (c) All commercial licensees shall store their medical marijuana and medical marijuana products in a designated limited access area at all times.

#### **310:681-6-4. Alarm system**

- (a) All commercial establishments shall be equipped with an alarm system which, upon attempted unauthorized entry, shall transmit a signal directly to a central protection company or a local or State

police agency which has a legal duty to respond. A designated agent of the licensed commercial establishment shall also receive notification of any such signal.

(b) Alarm systems shall provide coverage for all points of ingress and egress to the facility, including, but not limited to, doorways, windows, loading bays, skylights, and retractable roof mechanisms.

(c) Alarm systems shall provide coverage of any room with an exterior wall, any room containing a safe, and any room used to grow or store medical marijuana.

(d) Alarm systems shall be equipped with a "panic device" that upon activation will not only sound any audible alarm components, but will also notify law enforcement.

(e) Alarm systems shall have "duress" and "hold up" features to enable an agent to activate a silent alarm notifying law enforcement of an emergency.

(f) Alarm systems must be equipped with failure notification systems to notify processor facilities and law enforcement of any failure in the alarm system.

(g) Alarm systems shall have the ability to remain operational during a power outage.

### **310:681-6-5. Video surveillance system**

(a) All commercial establishments shall be equipped with video surveillance systems consisting of the following:

(1) Digital video cameras;

(2) 24 hour per day, 7 day per week recording capabilities;

(3) The ability to remain operational during a power outage;

(4) Digital archiving capabilities;

(5) On-site and off-site monitoring capabilities; and

(6) All facilities must maintain at least one on-site display monitor connected to the surveillance system at all times. The monitor shall have a screen size of at least 12 inches.

(b) All commercial establishments shall maintain camera coverage of the following areas:

(1) All points of ingress and egress to the facility, including, but not limited to, doorways, windows, loading bays, skylights, and retractable roof mechanisms;

(2) Any room with an exterior wall, except restrooms, any room containing a safe, and any room or area used to grow, process, manufacture, or store medical marijuana;

(3) All areas in which any part of the disposal process of marijuana occurs; and

(4) All parking areas and any alley areas immediately adjacent to the building.

(c) All recording devices shall display an accurate date and time stamp on all recorded video.

(d) All recording devices shall have the capability to produce a still image from the video recording, and each facility shall maintain, on site, a video printer capable of immediately producing a clear still image from any video camera image.

(e) Access to on-site surveillance system controls and monitoring shall be limited to authorized personnel. Commercial establishments shall identify individuals with access to surveillance system controls and monitoring upon request by the Department.

(f) All surveillance recordings shall be maintained for a minimum of 90 days.

#### **310:681-6-6. Perimeter requirements**

(a) The perimeter of all commercial establishments shall be maintained in such a way to discourage theft and diversion of marijuana. All processor facilities shall maintain the following:

(1) Adequate lighting to facilitate surveillance; and

(2) Foliage and landscaping that does not allow for a person or persons to conceal themselves from sight.

(b) All stages of marijuana production, cultivation, and the disposal of marijuana and medical marijuana products, on the premises of a commercial establishment shall not be visible or accessible to the public.

(c) Except for licensed dispensaries, commercial establishments shall maintain any walls or fencing necessary to shield the operations of the facility from public access and view.

(d) Except for the licensed dispensaries, commercial establishments shall ensure any odors that may arise from any stage of marijuana production or the disposal of marijuana are not detectable by the public from outside the processor facility.

#### **310:681-6-7. Additional requirements for processors**

(a) All processors used in the extraction of marijuana must be located in a separate, completely enclosed room. The room must be equipped with a vented hood, and all extractions must occur under the vented hood. A Lower Explosive Limit (LEL) monitor that can detect, indicate and alarm when combustible gases or solvent vapors used in the extraction process are in the LEL safety range should be in the extraction room at all times.

(b) If extractions are to occur with CO<sub>2</sub>, the extraction room must have emergency relief valves in the extraction room that are piped to the outside of the building. The extraction room must also be equipped with a CO<sub>2</sub> concentration monitor.

(c) The facility must be equipped with point-source ventilation, or written procedures must be in place to provide for the use of NIOSH approved N95 disposable respirators during all phases of processing and these respirators must be on hand at all times, including prior to licensure.

(d) Processing and extracting with butane is specifically prohibited.

### **310:681-6-8. Processing requirements**

(a) All people who engage in product processing, shall be proficient in processing and should continually expand their processing knowledge by participating in seminars and/or studying appropriate literature. Documented training must be on-site and readily available for inspection by the Department.

(b) The Processor has the responsibility to:

(1) Ensure the validity of all recommendation orders

(2) Certify all recommendation orders.

(3) Approve or reject all components, drug product containers, closures, in-process materials, and labeling.

(4) Ensure preparations are of acceptable strength, quality, and purity.

(5) Verify all critical processes to ensure that procedures will consistently result in the expected qualities in the finished preparation.

(6) Prepare and review all processing records to ensure that no errors have occurred in the processing process.

(7) Ensure appropriate stability evaluation is performed or determined from the literature for establishing reliable beyond-use dating.

(8) Ensure the proper maintenance, cleanliness, and use of all equipment used in a processing practice; and,

(9) Ensure only authorized personnel shall be in the immediate vicinity of the processing operation.

(10) Perform final check of preparations prior to their release from the Processor:

(A) A check for processing accuracy must ensure accuracy of the label and volumes or quantities of all drugs and solutions

(B) A visual examination procedure must ensure:

(i) Comparison with original order for initial dispensing

(ii) Accuracy of calculations

(iii) Use of proper solutions, additives and equipment

(iv) Labels are complete

(v) Proper assignment of beyond use date and time

(vi) Integrity of the container, including visual defects

(vii) Proper storage

(viii) Absence of particulate matter, precipitates, turbidity, discoloration, evidence of contamination or other signs that the preparation should not be used

(C) The Processor shall reject and destroy all preparations that do not pass the final examination.

(D) The Processor shall document final preparation examinations prior to releasing the compounded preparations from the Processor.

(c) All processors must have available written policies and procedures for all steps in the processing of preparations. In addition, all policies and procedures shall address personnel education and training and evaluation, storage and handling, clothing, personal hygiene, handwashing, quality assurance, expiration dating, and other procedures as needed.

### **310:681-6-9. Processor processing areas**

(a) Processors engaging in processing shall have a specifically designated and adequate space for the orderly processing of recommendation orders, including the placement and storage of equipment and materials.

(b) The area(s) used for the processing of products shall be maintained in a good state of repair. These area(s) shall also be maintained in a clean and sanitary condition. Adequate washing facilities are to be provided and sewage, trash and other refuse in the processing area is to be disposed of in a safe, sanitary, and timely manner.

(c) Bulk chemicals or materials used in the processing of medical marijuana products must be stored as directed by the manufacturer, in a clean, dry area, under appropriate temperature conditions (controlled room temperature, refrigerator, or freezer in adequately labeled containers). Bulk products shall also be stored such that they are protected from contamination.

(d) Adequate lighting and ventilation shall be provided in all processing areas.

(e) Potable water shall be supplied under continuous positive pressure in a plumbing system free of defects that could contribute contamination to any compounded drug preparation.

(f) Purified water must be used for processing non-sterile product preparations when formulations indicate the inclusion of water.

### **310:681-6-10. Processing equipment**

(a) Equipment used in the processing of medical marijuana preparations shall be of appropriate design and capacity as well as suitably located to facilitate operations for its intended use, cleaning and maintenance.

(b) Processing equipment shall be of suitable composition so the surfaces that contact components shall neither be reactive, additive nor absorptive therefore not affecting or altering the purity of the compounded preparation.

(c) Equipment and utensils used for processing shall be thoroughly cleaned promptly after every use to prevent contamination and must be stored in a manner to protect them from contamination. A cleaning log is recommended.

(d) Defective equipment shall be clearly labeled as such.

(e) Automated, mechanical, electronic, limited commercial scale manufacturing or testing equipment, and other types of equipment may be used in the processing of drug products. If such equipment is used, it shall be routinely inspected, calibrated as necessary or checked to ensure proper performance. An equipment calibration log must be maintained.

### **310:681-6-11. Product processing controls**

(a) There shall be written procedures for the processing of medical marijuana preparations to assure that the finished products have the identity, strength, quality and purity they purport to have. These procedures should be available in either written form or electronically stored with printable documentation.

(b) The objective of the documentation is to allow another compounder to reproduce an equivalent product at a future date.

(c) Documentation shall include a listing of the components, their amounts (in weight or volume), the order of component mixing, and a description of the processing process (e.g. log, formula worksheet, original prescription, etc.) In addition, all equipment and utensils and the container/closure system, relevant to the processing procedure shall be listed.

(d) These written procedures shall be followed in the execution of the processing procedure and are designed to enable a compounder, whenever necessary, to systematically trace, evaluate, and replicate the steps included throughout the preparation process of a compounded preparation.

(e) Components shall be accurately weighed, measured, and subdivided as appropriate. These operations should be checked and rechecked by the processing Processor manager, at each stage of the process, to ensure that each weight and measure is correct as stated in the written processing procedures.

(f) Written procedures shall be established and followed that describe the tests or examinations to be conducted on the preparation processed (e.g., degree of weight variation among capsules) to assure reasonable uniformity and integrity of processed preparations. Unless otherwise indicated or appropriate, compounded preparations are to be prepared to ensure that each preparation shall contain not less than 90% and not more than 110% of the theoretically calculated and labeled quantity of active ingredient per unit weight or volume and not less than 90% and not more than 110% of the theoretically calculated weight or volume per unit of the preparation. Such control procedures shall be established to monitor the output and to validate the performance of those processing processes that may be responsible for causing variability in the final drug preparation. These procedures shall include, but are not limited to, the following (where appropriate):

(1) Capsule weight variation to ensure that each unit shall be not less than 90% and not more than 110% of the theoretically calculated weight for each unit;

(2) Adequacy of mixing to assure uniformity and homogeneity;

(C) The processor shall label any excess processed preparation so as to reference them to the formula used, the assigned batch number, and beyond use date based on the processor's appropriate testing, published data, or regulatory standards.

## **SUBCHAPTER 7. Packaging and Labeling**

### **310:681-7-1. Labeling**

(a) **Purpose.** The purpose of this Subchapter is to set the minimum standards for the labeling of medical marijuana that is intended to be sold to a qualified patient or caregiver.

(1) **Labeling required.** Usable marijuana received or sold by a dispensary shall meet the labeling requirements in these rules.

(2) **Return or disposal of miss-labeled product.**

(A) A dispensary must return usable marijuana that does not meet labeling requirements in these rules to the entity who transferred it to the dispensary and document to whom the item was returned, what was returned and the date of the return; or

(B) Dispose of any usable marijuana that does not meet labeling requirements and that cannot be returned in the manner specified by 310:681-5-10.

(b) **Medical marijuana labeling requirements.** Prior to medical marijuana being sold to a qualified patient or caregiver, the packaging holding the usable marijuana must have a label that has the following information:

(1) Processor business or trade name and license number;

(2) Grower business or trade name and license number;

(3) A unique identification number;

(4) Date of harvest;

(5) Name of strain;

(6) Net weight in U.S. customary and metric units;

(7) Concentration of THC and CBD;

(8) Activation time expressed in words or through a pictogram;



(9) Name of the lab that performed any test, any associated test batch number and any test analysis date;

(10) Universal symbol;

(11) A warning that states: "For use by qualified patients only. Keep out of reach of children.";

(12) A warning that states: "Marijuana use during pregnancy or breastfeeding poses potential harms."; and

(13) A warning that states: "This product is not approved by the FDA to treat, cure, or prevent any disease".

**(c) Cannabinoid concentrates.**

(1) Prior to a cannabinoid concentrate being sold to another processor or a dispensary, or transferred to a patient or a caregiver the container holding the concentrate must have a label that has the following information:

(A) Dispensary business or trade name or license number;

(B) Business or trade name of processor that packaged the product;

(C) A unique identification number;

(D) Product identity);

(E) Date the concentrate was made;

(F) Net weight or volume in U.S. customary and metric units;

(G) If applicable, serving size and number of servings per container or amount suggested for use by the processor at any one time;

(H) Concentration or amount by weight or volume of THC and CBD in each amount suggested for use and in the container;

(I) Activation time, expressed in words or through a pictogram;

(J) Name of the lab that performed any test, any associated test batch number and any test analysis date;

(K) Universal symbol;

(L) The following statements that read:

- (i) "This product is not approved by the FDA to treat, cure, or prevent any disease";
- (ii) "For use by Oklahoma medical marijuana patients only. Keep out of reach of children";
- (iii) "DO NOT EAT" in bold, capital letters;
- (iv) "Marijuana used during pregnancy or breast feeding poses potential harm"; and
- (v) If processed for a patient, "Not for resale".

**(d) General label requirement, prohibitions and exceptions.**

(1) Principal Display Panel.

(A) Every container that contains usable marijuana for sale or transfer to a qualified patient or a caregiver must have a principal display panel.

(B) If a container is placed within packaging for purposes of displaying the marijuana item for sale or transfer to a qualified patient or designated caregiver, the packaging must have a principal display panel.

(C) The principal display panel must contain the product identity and universal symbol, and if applicable, the net weight.

(2) A label required by these rules must:

(A) Be placed on the container and on any packaging that is used to display the marijuana item for sale or transfer to a qualified patient or designated caregiver;

(B) Comply with the National Institute of Standards and Technology (NIST) Handbook 130 (2017), Uniform Packaging and Labeling Regulation, incorporated by reference;

(C) Be in no smaller than 8 point Times New Roman, Helvetica or Arial font;

(D) Statements required by subsections (c)(1)(L)(ii) and (iv) must be in at least 18 point;

(E) Be in English, though it can also be in other languages; and

(F) Be unobstructed and conspicuous.

(3) Usable marijuana may have one or more labels affixed to the container or packaging.

(4) Usable marijuana that is in a container that because of its size does not have sufficient space for a label that contains all the information required for compliance with these rules:

(A) May have a label on the container that contains usable marijuana and on any packaging that is used to display usable marijuana for sale or transfer to a patient or a caregiver that includes at least the following:

(i) Information required on a principal display panel, if applicable for the type of usable marijuana;

(ii) Processor business or trade name and license number;

(iii) a package unique identification number;

(iv) Concentration of THC and CBD; and

(v) Required warnings.

(B) Must include all other required label information not listed in subparagraph (4)(A) of this subsection on an outer container or package, or on a leaflet that accompanies the usable marijuana.

(5) Usable marijuana in a container that is placed in packaging that is used to display the usable marijuana for sale or transfer to a qualifying patient or designated caregiver must comply with the labeling requirements in these rules, even if the container qualifies for the exception under paragraph (4) of this subsection.

(6) The universal symbol:

(A) Must be at least 0.5 inches wide by 0.5 inches high and printed in red.

(B) May only be used by a processor licensee or researcher licensee.

(C) May be downloaded at: <https://www.ok.gov/health/>

(7) A label may not:

(A) Contain any untruthful or misleading statements including, but not limited to, a health claim that is not supported by the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), and for which there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims; or

(B) Be attractive to minors.

(8) Usable marijuana that falls within more than one category must comply with the labeling requirements that apply to both categories, with the exception of the "DO NOT EAT" warning if the product is intended for human consumption.

(9) The THC and CBD amount required to be on a label must be the value calculated by the laboratory that did the testing.

(10) If usable marijuana has more than one test batch number, laboratory, or test analysis date associated with the usable marijuana that is being sold or transferred, each test batch number, laboratory and test analysis date must be included on a label.

(11) If usable marijuana is placed in a package that is being re-used, the old label or labels must be removed and it must have a new label or labels.

(12) Exit packaging must contain a label that reads: "Keep out of reach of children."

(13) All medical marijuana and medical marijuana products must be packaged in child resistant packages.

(14) A warning that states "Women should not use marijuana or medical marijuana products during pregnancy because of the risk of birth defects."

(15) A warning that states: "The intoxicating effects of this product may be delayed up to two hours. Use of marijuana and medical marijuana products impairs your ability to drive a car or operate machinery."

(16) Name, address, and phone number of the dispensary,

(17) Date and identifying number,

(18) Name of the patient,

(19) Directions for use to the patient,

(20) Name of the recommending physician,

(21) Initials of the dispenser,

(22) Required precautionary information regarding controlled substances,

(23) Such other accessory or cautionary information as may be required or desirable for proper use and safety to the patient, and

(24) The name of the medical marijuana product, its strength, and the number of units dispensed.

(e) **Discontinued and outdated products.** The DMIC shall develop and implement policies and procedures to insure that discontinued and outdated products, and containers with worn, illegible or missing labels are quarantined in the dispensary for proper disposition.

(f) **Unique packaging, absence of appeal to children, packaging requirements.** Medical marijuana packaging shall not bear a reasonable resemblance to any commercially available product. Medical marijuana products shall be packaged to minimize appeal to children and shall not depict shapes, images, text, or designs appealing to children. Medical marijuana product packages must be:

(1) Plain;

(2) Designed to maximize the shelf life of contained medical marijuana products;

(3) Tamper-evident;

(4) Child proof;

(5) Protect the product from contamination and must not impart any toxic or deleterious substance to the product;

(6) Opaque; and

(7) Shall not depict any images or commercial logos.

### **310:681-7-2. Prohibited products**

(a) No commercial establishment shall manufacture or offer for sale or consumption any medical marijuana product intended to be attractive to children or minors including, but not limited to, the following:

(1) Gummy bears, lollipops, animal or other similarly shaped candies or products, fake cigarettes, or gummy worms.

(2) Products in a shape that bears the lines or contains characteristics of a realistic or fictional human or other being, animal, fruit, or other familiar shapes such as stars or flowers including artistic, caricature, or cartoon rendering.

(b) No commercial establishment 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**

### **310:681-8-1. General provisions**

(a) **Laboratory accreditation.** A laboratory that will perform testing of medical marijuana and marijuana-derived products must be accredited by The NELAC Institute (TNI), ANSI/ASQ National Accreditation Board or other similar accrediting entity as determined by the Department, using the ISO/IEC Standard 17025. Any laboratory conducting testing under these provisions shall not have any business nor personal connection to any commercial establishment for which the laboratory conducts testing.

(b) **Testing laboratory approval.** A laboratory must be approved by the Department specifically for the testing of medical marijuana and marijuana-derived products.

(c) **Testing categories.** A laboratory may apply to the Department to be licensed to perform testing of medical marijuana and marijuana-derived products so long as they are able to perform testing in the following categories:

- (1) Cannabinoids;
- (2) Residual pesticides;
- (3) Heavy metals;
- (4) Microbiological impurities;
- (5) Residual solvents and processing chemicals;
- (6) Water activity and moisture content;
- (7) Foreign materials;
- (8) Sterility; and
- (9) Such other testing categories as the Department may identify.

(d) **Laboratory approval.** A laboratory seeking an approval by the Department to test medical marijuana and marijuana-derived products, must submit a completed Medical Marijuana Laboratory Testing Request and supporting documentation, as appropriate, to the Department.

(1) A laboratory seeking an initial approval shall not begin testing medical marijuana or marijuana-derived products until the Department has approved the request;

(2) The approval shall be valid for 12 months;

(3) To renew the testing laboratory approval a completed Medical Marijuana Laboratory Testing Request form and appropriate documentation shall be received by the Department from the laboratory no later than 30 calendar days before the expiration of the current approval. Failure to receive a notice for approval renewal from the Department does not relieve a laboratory of the obligation to renew the approval as required.

(4) In the event the approval is not renewed prior to the expiration date, the laboratory must not test any marijuana or medical marijuana products or goods until the approval is renewed.

(e) **Request materials.** A laboratory approval requestor shall submit to the Department with each initial application and renewal application for continued approval the following items, unless as otherwise assured by the laboratory accrediting agency in written documentation to the Department that these items have been reviewed and approved by the accrediting agency as part of the laboratory accreditation process:

(1) Completed Medical Marijuana Laboratory Testing Request form;

(2) Electronic versions of the following documents:

(A) **Management Systems.** Documentation should include but is not limited to, a laboratory organization chart, including:

(i) Identification of key personnel, by name, lines of authority and responsibilities, having direct or indirect authority over the management or policies of the laboratory;

(ii) If the laboratory is part of a larger organization, a chart indicating the laboratory's position within the larger organization and the reporting relationships within the organization;

(iii) A list of all persons or business entities having any ownership interest in any property utilized by the laboratory, whether direct or indirect, and whether the interest is in land, building(s), or other material, including owners of any business entity that owns all or part of land or building(s) utilized; Organizational mission, goals, and objectives;

(iv) Administrative policies and procedures, including management controls to ensure consistent performance and continuous improvement;

(v) Copies of the laboratory applicant's articles of incorporation and by-laws, as applicable;

(vi) Proof that the laboratory applicant is in good standing with the Oklahoma Tax Commission;

(B) **Facilities.** A description of the facilities and equipment that shall be used in the operation of the laboratory, including:

(i) A complete and detailed diagram of the proposed premises to include boundaries of the property and proposed premises to be licensed; boundaries, dimensions, entrances and exits, interior partitions, walls, rooms, windows, doorways, and common or shared entryways, and a brief statement or description of the principal marijuana activities to be conducted therein; and the location of all cameras and assigned number to each camera for identification purposes;

(ii) The type of equipment used in medical marijuana testing, performance checks and function verification, testing and calibration schedules, maintenance, and representative records. Include the identification of external maintenance and calibration services if applicable;

(C) **Security Systems.** A security policy that describes the methods and devices that will be used to provide security for the marijuana samples in the laboratory.

(D) **Employees.**

(i) A list of employees of the laboratory, including their education, qualifications and experience;

(ii) Training documentation for each employee of the laboratory, indicating training sessions (with date, time, and place the employee received training) and topics covered (with names and titles of trainers/presenters) and including statements signed by the employee attesting to said training. Employee training at the time of his or her initial appointment must include, but is not limited to, safety and security training incorporating the proper use of security measures and controls that have been adopted by the laboratory, and specific procedural instructions regarding how to respond to an emergency, including robbery or a violent accident. Employee training at the time of his or her initial appointment must also include ethics and compliance training to assure integrity of laboratory operations;

(iii) Documentation that analysts have been assessed for competency/proficiency in analytical/administrative procedures (initial, 6 months, 12 months and annual thereafter);

(E) **Procedures.**

(i) Sample Management, including a description of how the laboratory will ensure and document chain of custody of samples held or tested by the laboratory, and processes for receipt, rejection, handling, storage and disposition of samples;



(ii) A list of the method(s) and products used for each medical marijuana analyte, including the reference and performance characteristics of each method;

(iii) Documentation demonstrating that the analytic methods used by the laboratory are appropriate for their intended purpose and that each analytic method, as performed by the laboratory, has been appropriately validated by the laboratory;

(iv) Standard operating procedures to be used by the laboratory, including but not limited to: pre-analytic (sampling processes, sample preparation, reagent and reference standard preparation), analytic (instrument operation, technical procedures and quality control criteria to be used in performing the analysis for each analyte), and post-analytic (data recording and calculation of results, data review, reporting and storage) processes.

**(F) Quality Systems.**

(i) Quality Assurance (QA) Manual that includes but is not limited to the QA Plan, QA Policies and QA Procedures to be followed by the laboratory;

(ii) A list of Proficiency Testing (PT) programs to be used for each analyte, and the most recent PT results for each analyte including the date of the PT, the score and any corrective action(s) taken, if required;

(iii) The laboratory's most recent inspection(s) by their accreditation agency and the laboratory's responses to any findings of non-compliance with standards or recommendations.

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

(f) **Provisional testing laboratory approval.** A laboratory may request a provisional Testing Laboratory license approval to receiving accreditation provided that the applicant meets all other requirements for a testing laboratory and submits to the Department a request in compliance with other rules of this Section and an attestation that the laboratory has or intends to seek accreditation for testing methods required by the rules.

(1) A provisional Testing Laboratory approval shall be valid for 12 months.

(2) To renew a provisional approval, a completed Medical Marijuana Laboratory Testing Request form and appropriate documentation shall be received by the Department from the laboratory no later than 30 calendar days before the expiration of the approval. Failure to receive a notice for approval renewal from the Department does not relieve a licensee of the obligation to renew the approval as required.

(3) In the event the approval is not renewed prior to the expiration date, the laboratory must not test any commercial marijuana goods until the approval is renewed.

(4) The approval renewal form shall contain the following:

(A) The name of the laboratory. For laboratories who are individuals, the requestor shall provide both the first and last name of the individual. For laboratories who are business entities, the laboratory shall provide the legal business name of the applicant;

(B) The approval number and expiration date;

(C) The laboratory's address of record and premises address; and

(D) An attestation that all information provided to the Department in the original request is accurate and current.

(5) The Department may renew a provisional approval for an initial renewal period of 12 months.

(6) After one renewal, the Department may renew the provisional approval for additional 12-month periods if the laboratory has submitted a request for accreditation.

(7) The laboratory shall notify the Department if the request for each accreditation is granted or denied within 5 business days of receiving the decision from the accrediting body. If the accrediting body grants or denies the laboratory's request for any accreditation before the expiration of the provisional approval, the Department may terminate the provisional approval at that time.

(8) The Department may revoke a provisional approval at any time.

(g) **Notification of changes.** Each approved Testing Laboratory shall notify the Department in writing within 10 business days of any change to any item listed in the Testing Laboratory Request for Approval form, with the exception of a change to standard operating procedures. The notification shall be signed by an owner.

(1) A change in location of premises requires submission of a new request. A laboratory shall not begin operating out of new premises until the Department has approved the request.

(2) Licenses are not transferrable. If one or more of the owners of a laboratory change, a new request shall be submitted to the Department within 10 business days of the effective date of the ownership change. A change in ownership occurs when a new person meets the definition of an owner. A change in ownership does not occur when one or more owners leave the business by transferring their ownership interest to the other existing owner(s). In cases where one or more owners leave the business by transferring their ownership interest to the other existing owner(s), the owner or owners that are transferring their interest shall provide a signed statement to the Department confirming that they have transferred their interest.

(h) **Physical plant.** The premises of the laboratory must meet the physical plant requirements relating to Commercial Establishments (as indicated in Subchapter 6). The laboratory applicant shall ensure:

(1) Adequate space for laboratory operations, including testing, sample and document storage;

(2) Provision of one or more secure, controlled access areas for storage of marijuana and marijuana-derived product test samples, marijuana-derived waste, and reference standards. Access to such storage areas shall be limited by the laboratory to authorized individuals;

(3) Compliance with all applicable local ordinances, including but not limited to zoning, occupancy, licensing, and building codes.

(i) **Identification cards.** Identification cards issued by the Department are the property of the Department and shall be returned to the Department upon the termination of the holder's employment with the laboratory, upon suspension, or revocation, or upon demand of the Department.

(j) **Term of approval.** Department approval of a laboratory for purposes of this rule shall be for a term of one year, and shall expire after that year, or upon closure of the laboratory. The laboratory shall apply for renewal of approval annually no later than 30 days prior to expiration.

(k) **Termination.** The Department may deny, withdraw, or suspend approval of a laboratory in accordance with this rule, upon determination by the Department that the laboratory has violated a provision of this rule, upon failure of proficiency testing, upon refusal of the laboratory to provide requested access to premises or materials, or upon failure of a laboratory to comply with any standard, procedure, or protocol developed, submitted, or maintained pursuant to this rule.

### **310:681-8-2. Requirements for testing**

(a) **Testing requirements for usable marijuana.** Growers must test every batch of usable marijuana, intended for use by a processor, prior to selling or transferring the usable marijuana for water activity and moisture content, unless the processor has a method of processing that results in effective sterilization.

#### **(b) Testing requirements for concentrates and extracts.**

(1) Processors shall not accept the transfer of usable marijuana that is not sampled and tested in accordance with these rules.

(2) Processors shall test every process lot of cannabinoid concentrate or extract for use by a patient, including marijuana received directly from a medical marijuana patient being processed into a concentrate for a fee pursuant to Title 63 O.S. § 423(C), or a fee prior to selling or transferring the cannabinoid concentrate or extract for the following:

- (A) THC and CBD concentration;
  - (B) Water activity and moisture content;
  - (C) Residual pesticides;
  - (D) Heavy metals;
  - (E) Mycotoxins;
  - (F) Microbiological impurities;
  - (G) Foreign materials; and
  - (H) Residual solvents and processing chemicals unless:
    - (i) Only a mechanical extraction process is used by the processor to separate cannabinoids from the marijuana; or
    - (ii) Only water, animal fat or vegetable oil is used by the processor as a solvent to separate the cannabinoids from the marijuana.
- (c) **Audit and random testing.** The Department may require a grower or processor to submit samples identified by the Department to a laboratory of the grower's or processor's choosing to be tested in order to determine whether the licensee is in compliance with these rules, and may require additional testing that is not required by these rules.

### **310:681-8-3. Standards for testing**

#### **(a) Cannabinoids.**

(1) A laboratory shall test for and report measurements for the following cannabinoids:

- (A) THC;
- (B) THCA;
- (C) CBD;
- (D) CBDA;
- (E) CBG; and

(F) CBN.

(2) A laboratory may test for and provide test results for additional cannabinoids if requested to do so by the requester of the laboratory testing.

(3) For each analyzed sample from a harvest-lot of useable marijuana, a laboratory shall report the following information in the Certificate of Analysis (COA):

(A) The concentration, to 3 significant figures, in milligrams per gram (mg/g) dry-weight sample of the cannabinoids listed in (1) of this subsection.

(B) The dry-weight percent of cannabinoids listed in (1) of this subsection that are detected in the sample in the following way:  $\text{Dry-weight \% cannabinoid} = \text{wet-weight \% cannabinoid} / (1 - \% \text{ moisture} / 100)$ .

(4) For each analyzed sample from a marijuana-derived product batch, a laboratory shall report the following information in the COA:

(A) The concentration, to 3 significant figures, in milligrams per gram (mg/g) of the cannabinoids listed in (1) of this subsection.

(B) If the labeled content of any one cannabinoid is expressed as a total concentration of the cannabinoid, the laboratory shall calculate the total cannabinoid concentration as follows:  $\text{Total cannabinoid concentration (mg/g)} = (\text{cannabinoid acid form concentration (mg/g)} \times 0.877) + \text{cannabinoid concentration (mg/g)}$ .

(C) For the purposes of cannabinoid potency testing of marijuana-derived products, the laboratory shall report whether the sample "passed" or "failed" cannabinoid potency testing. A sample passes potency testing if the concentration of THC or CBD does not exceed the labeled potency of THC or CBD, plus or minus 15 percent. A sample fails potency testing if the concentration of THC or CBD exceeds the labeled potency of THC or CBD, plus or minus 15 percent.

(5) If the sample fails cannabinoid testing, the batch from which the sample was collected fails cannabinoid testing and shall not be released for retail sale and shall be destroyed in accordance with OAC 310:681-5-10.

**(b) Water activity and moisture content.**

(1) The laboratory shall analyze a sample of usable marijuana to determine the level of water activity and the percentage of moisture content.

(2) A marijuana sample shall be deemed to have passed water activity testing if the water activity does not exceed 0.65 Aw. The laboratory shall report the result of the water activity test, to two significant figures, on the COA and indicate "pass" or "fail" on the COA.

(3) A marijuana sample shall be deemed to have passed moisture content testing if the moisture content does not exceed 15.0%. The laboratory shall report the result of the moisture content test to the nearest tenth of one percent, by weight, of the dry sample on the COA and indicate "pass" or "fail" on the COA.

(4) If a sample fails water activity and/or moisture content testing, the batch from which the sample was collected may be returned to the grower or person holding title for further drying and curing unless prohibited by these regulations, and then re-tested or used to make a cannabinoid concentrate or extract.

**(c) Residual pesticides.**

(1) **Testing required.** The laboratory shall analyze a sample of marijuana or marijuana-derived product to determine whether residual pesticides are present.

(2) **Reporting to three significant figures.** The laboratory shall report the result of the residual pesticides testing, to three significant figures, in unit parts per million(ppm) on the COA and indicate "pass" or "fail" on the COA.

(3) **Threshold for passing score.** A sample shall be deemed to have passed the residual pesticides testing if the level of any residual pesticide does not exceed the indicated action levels listed in Appendix A, Table 1.

(4) **Test Failure.** If a sample fails residual pesticides testing, the batch from which the sample was collected fails pesticides testing and shall not be released for retail sale.

**(5) Temporary residual pesticide testing requirements.**

(A) Notwithstanding these rules, if the Department finds there is insufficient laboratory capacity for the testing of residual pesticides, the Department may permit randomly chosen samples from batches of usable marijuana to be tested for residual pesticides by a licensed laboratory rather than requiring every batch of usable marijuana from a harvest lot to be tested for residual pesticides.

(B) The Department must ensure samples from at least one batch of every harvest lot are tested for residual pesticides.

(C) If any one of the randomly chosen samples from a batch or harvest lot fails a residual pesticide test every batch from the harvest lot must be tested for residual pesticides.

(D) If the randomly chosen samples from batches of usable marijuana that are tested for residual pesticides all pass, the entire harvest lot is considered to have passed residual pesticide testing and may be transferred or sold.

**(d) Heavy metals.**

(1) The laboratory shall analyze a sample of marijuana or marijuana-derived product to determine whether heavy metals are present.

(2) The laboratory shall report the result of the heavy metals test, to three significant figures, in micrograms per gram ( $\mu\text{g/g}$ ) on the COA and indicate "pass" or "fail" on the COA.

(3) A sample shall be deemed to have passed the heavy metals testing if the presence of heavy metals does not exceed the action levels listed in Appendix A, Table 2.

(4) If a sample fails heavy metals testing, the batch from which the sample was collected fails heavy metals testing and shall not be released for retail sale.

**(e) Microbiological impurities.**

(1) The laboratory shall analyze a sample of marijuana or marijuana-derived product to determine whether microbial impurities are present.

(2) The laboratory shall report the result of the microbial impurities testing by indicating "pass" or "fail" on the COA.

(3) A sample shall be deemed to have passed the microbial impurities testing if all of the following conditions are met:

(A) Shiga toxin-producing *Escherichia coli* is not detected in 1 gram;

(B) *Salmonella* spp. is not detected in 1 gram.

(4) If a sample fails microbial impurities testing, the batch from which the sample was collected fails microbial impurities testing and shall not be released for retail sale.

**(f) Foreign materials.**

(1) The laboratory shall analyze a sample of marijuana or marijuana-derived to determine whether foreign material is present. This analysis must occur using a microscope at 10X to 40X magnification.

(2) The laboratory shall report the result of the foreign material test by indicating "pass" or "fail" on the COA.

(3) The laboratory shall perform foreign material testing on the total primary sample prior to sample homogenization.

(4) When the laboratory performs foreign material testing, at minimum, the laboratory shall do all of the following:

(A) Examine both the exterior and interior of the marijuana sample; and

(B) Examine the exterior of the marijuana product sample.

(5) A sample shall be deemed to have passed the foreign material testing if the presence of foreign material does not exceed:

(A) 1/4 of the total sample area covered by sand, soil, cinders, or dirt;

(B) 1/4 of the total sample area covered by mold;

(C) 1 insect fragment, 1 rodent hair, 1 human hair, or 1 count of mammalian excreta per 3.0 grams; or

(D) 1/4 of the total sample area covered by an embedded foreign material.

(6) If a sample fails foreign material testing, the batch from which the sample was collected fails foreign material testing. A batch of useable marijuana that fails foreign material testing must not be released for retail sale, unless it can be remediated and successfully pass re-testing. Failed batches or marijuana-derived products must be destroyed.

**(g) Residual solvents and processing chemicals.**

(1) The laboratory shall analyze a sample of marijuana-derived product to determine whether residual solvents or processing chemicals are present.

(2) The laboratory shall report the result of the residual solvents and processing chemicals testing, to three significant figures, in unit micrograms per gram ( $\mu\text{g/g}$ ) on the COA and indicate "pass" or "fail" on the COA.

(3) A sample shall be deemed to have passed the residual solvents and processing chemicals testing if both of the following conditions are met:

(A) The presence of any residual solvent or processing chemical listed in Category I in Appendix A, Table 3, is not detected, and

(B) The presence of any residual solvent or processing chemical listed in Category II in Appendix A, Table 3 does not exceed the indicated action levels.



(4) If a sample fails residual solvents and processing chemicals testing the batch from which the sample was collected fails residual solvents and processing chemicals testing. Batches that fail residual solvents and processing chemicals testing may be remediated using procedures that would reduce the concentration of solvents and then re-tested. Otherwise batches that fail residual solvents and processing chemicals testing must be destroyed.

#### **310:681-8-4. Sampling requirements and procedures**

##### **(a) General requirements.**

(1) Only appropriately trained individuals employed by the laboratory performing the analyses of samples may collect samples; these individuals are called "Samplers".

(2) Samplers must:

(A) Follow the laboratory's approved sampling policies and procedures; uncontrolled copies of sampling policies and procedures shall be available to samplers in the field;

(B) Follow chain of custody procedures;

(C) Apply for and receive a Transportation license pursuant to Subchapter 3.

(3) Laboratory personnel may collect samples at the facility of the grower or processor or a grower or processor may transport batches of marijuana or marijuana-derived products to a laboratory for the sampling.

(4) The laboratory may obtain and analyze samples only from batches in final form.

(5) The laboratory shall collect both a primary sample and a field duplicate sample from each batch. The primary sample and field duplicate sample shall be stored and analyzed separately. The field duplicate sample is used for quality control purposes only.

(6) The laboratory shall ensure that the sample is transported and subsequently stored at the laboratory in a manner that prevents degradation, contamination, and tampering. If the marijuana or marijuana-derived product specifies on the label how the product shall be stored, the laboratory shall store the sample as indicated on the label.

(7) The sampler shall use a sample field log to record the following information for each sampled batch:

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

(B) Sampler's name(s) and title(s);

- (C) Date and time sampling started and ended;
  - (D) Grower's or processor's name, address, and license number;
  - (E) Batch number of the batch from which the sample was obtained;
  - (F) Sample matrix;
  - (G) Total batch size, by weight or unit count;
  - (H) Total weight or unit count of the primary sample;
  - (I) Total weight or unit count of the field duplicate sample;
  - (J) The unique sample identification number for each sample; and
  - (K) Sampling conditions or problems encountered during the sampling process, if any.
- (8) The laboratory shall complete a chain of custody form for each sample that the laboratory collects and analyzes.
- (9) A laboratory must maintain the documentation required in these rules for at least two (2) years and must provide that information to the Department upon request.
- (b) **Sampling standard operating procedures.** The laboratory shall develop and implement written sampling policies and procedures that are appropriate for each test method and each type of matrix to be tested and that are consistent with these regulations. Sampling procedures must describe the laboratory's method for collection, preparation, packaging, labeling, documentation, and transport of samples from each matrix type the laboratory tests. The sampling SOP shall include at least the following information:
- (1) A step-by-step guide for obtaining samples from each matrix type the laboratory samples;
  - (2) Accepted test sample types;
  - (3) Minimum test sample size;
  - (4) Recommended test sample containers;
  - (5) Test sample labeling;
  - (6) Transport and storage conditions, such as refrigeration, as appropriate to protect the physical and chemical integrity of the sample;

(7) Other requirements, such as use of preservatives, inert gas, or other measures designed to protect sample integrity;

(8) Chain-of-custody documentation for each sample;

(9) Statements that the sampler must:

(A) Follow the laboratory's sampling SOP;

(B) Ensure that the sampling area is free of contaminants;

(C) Sanitize sampling tools and equipment between each batch or use disposable sampling tools;

(D) Wear the following items during the entire sampling process:

(i) Disposable protective coveralls or disposable lab coat or apron;

(ii) Disposable, powder-free, nitrile gloves;

(iii) Filtering dust mask;

(iv) Safety goggles;

(v) Hair net.

(E) The sampler shall change gloves between each batch;

(F) Weigh samples to within 0.1 gram of accuracy using a calibrated balance;

(G) Collect both a primary and a field duplicate sample from each batch;

(H) Place the sample in a container capable of preventing degradation or contamination and seal the sample container with tamper evident material;

(I) Assign a unique sample identifier to both the primary and field duplicate samples;

(J) Record on the sample field log the conditions under which the sample is transported and stored;

(K) Follow chain of custody protocols; and

(L) Complete the sample field log, which shall include:

(i) Laboratory's name and license number;

- (ii) Sampler's name and title and the names of others onsite;
- (iii) Date and time sampling began;
- (iv) Distributor's name, address, and license number;
- (v) Name, business address, and license number of the person who transports the samples to the laboratory;
- (vi) Sample matrix;
- (vii) Requested analyses;
- (viii) Total composite sample weight or count;
- (ix) Date and time each sample was obtained;
- (x) Total batch size, by weight or count;
- (xi) Problems encountered and corrective actions taken;
- (xii) For each sample, the weight or count of each sample, the unique sample identification number, and the location within the batch from which the sample was taken;
- (xiii) Any other observations from sampling, including major inconsistencies in the medical marijuana goods' color, size, or smell;
- (xiv) Sampling conditions, including temperature; and
- (xv) Batch or lot number of the matrix.

(10) The sampling SOP shall be signed and dated by the laboratory director and shall include the revision dates and authors. The laboratory director's signature denotes approval of the plan.

(11) The laboratory shall retain a controlled copy of the sampling SOP on the laboratory premises and ensure that the sampling SOP is accessible to the sampler in the field during sampling.

**(c) Sampling and sample size.**

**(1) Usable marijuana.**

(A) Usable marijuana may only be sampled after it is cured.

(B) A grower must separate each harvest lot into no larger than 10-pound batches.

(C) A grower may combine batches for purposes of having a batch sampled for testing if each batch is intended for use by a processor to make a cannabinoid concentrate or extract and each harvest lot was:

(i) Cultivated utilizing the same growing practices and grown in close proximity on the licensed or registered premises;

(ii) Harvested at the same time; and

(iii) If cured prior to sampling, cured under uniform conditions.

(D) The sampler shall obtain both a primary sample and a field duplicate sample from each harvest batch. The field duplicate sample shall be collected contemporaneous to, and in the same manner as, the primary sample.

(E) The primary sample and field duplicate sample must each weigh a minimum of 0.5% of the total harvest batch weight. A sampler may collect greater than 0.5% of a harvest batch per primary sample and field duplicate sample if necessary to perform the required testing or to ensure that the samples obtained are representative.

(F) Multiple sample increments (i.e., portions of a batch that, together with other increments, constitute the sample) shall be obtained from random and varying locations (both vertically and horizontally) within an unpacked harvest batch depending on the batch size, as per table 4 in Appendix A. Where practical, increments should be of equal weight, and if the batch is stored in multiple containers, equal number of increments should be obtained from each container.

(G) The sampler shall collect a minimum of 7 and not more than 9 sample increments from each harvest batch. Table 4 in Appendix A shows the number of increments required for the primary sample, by batch size.

(H) The sampler may collect more increments if doing so is required because of the analytical method or laboratory-specific procedures or to ensure that a sufficient quantity of material is available for all required tests. The sampler may collect only the amount necessary to conduct the required and requested testing.

## **(2) Cannabinoid concentrates, extracts and products.**

(A) Marijuana-derived products may only be sampled in their final form.

(B) A processor must separate each marijuana-derived product lot into batches containing no more than 10 pounds.

(C) A grower or processor must assign each batch a unique batch number and that unique batch number must be:

(i) Documented and maintained in the grower's or processor's facility records for at least two (2) years and available to the Department upon request;

(ii) Provided to the individual responsible for taking samples;

(iii) Included on the batch label; and

(iv) Unique and may not be reused.

(D) The sampler shall obtain both a primary sample and a field duplicate sample from each harvest batch. The field duplicate sample shall be collected contemporaneous to, and in the same manner as, the primary sample.

(E) Enough samples from a batch must be taken to ensure the required attributes in the batch to be tested are homogenous and consistent with the laboratory's sampling policies and procedures.

(F) Multiple sample increments shall be obtained from random and varying locations (both vertically and horizontally) within a product batch depending on the batch size, as shown in Table 5 in Appendix A. If batches are packaged, each increment consists of one pre-packaged unit.

(G) The sampler may collect a greater number of increments if required because of an analytical method or laboratory-specific procedures or to ensure that a sufficient quantity of material is available for all required tests. The sampler may only collect the amount necessary to conduct the required and requested testing.

(d) **Grower and processor requirements for labeling and recordkeeping.** Following samples being taken from a harvest or process lot batch, growers and processors shall:

(1) Label the batch with the following information:

(A) The grower or processor licensee number;

(B) The harvest or process lot unique identification number;

(C) The name and accreditation number of the laboratory that took samples and the name and accreditation number of the laboratory responsible for the testing, if different;

(D) The test batch or sample unique identification numbers supplied by the sampler;

(E) The date the samples were taken; and

(F) In bold, capital letters, no smaller than 12-point font, "PRODUCT NOT TESTED."

(2) Store and secure the batch at the grower's or processor's premises in a manner that prevents the product from being tampered with or transferred prior to test results being reported.

(3) Be able to easily locate a batch stored and secured and provide that location to the Department or a testing laboratory upon request.

(A) If the samples pass testing, the product may be sold or transferred.

(B) If the samples do not pass testing, licensee shall comply with the requirements of 310:681-8-6 (relating to post-testing procedures).

(e) **Chain of custody (COC) protocol.**

(1) The laboratory shall develop and implement a COC protocol to ensure accurate documentation of the transport, handling, storage, and destruction of samples.

(2) The COC protocol shall require the use of a COC form that contains, at minimum, the following information:

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

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

(C) Unique sample identifier;

(D) Date and time of the sample collection;

(E) Printed and signed name(s) of the grower(s) or processor(s);

(F) Printed and signed name(s) of the sampler(s); and

(G) Printed and signed name(s) of the testing laboratory employee that received the sample.

(3) Each time the sample changes custody between licensees, is transported, or is destroyed, the date, time, and the names and signatures of persons involved in these activities shall be recorded on the COC form.

**(f) Receipt of test samples.**

(1) The laboratory may accept and analyze only samples from a grower or processor for which there is an accompanying COC form.

(2) The laboratory shall not analyze a sample obtained from a grower or distributor, and the batch from which the sample was obtained may not be released for retail sale, if any of the following occur:

(A) The sample is received at the laboratory without the requisite COC form;

(B) The tamper evident material is broken prior to the sample being received at the laboratory; or

(C) There is evidence of sample comingling, contamination, degradation, or a related occurrence rendering the sample unusable for analytical testing when the sample is received at the laboratory.

(3) The laboratory shall record the receipt of every test sample, including at a minimum the following information:

(A) The name and contact information of the licensed grower or producer that was the source of the sample;

(B) An appropriately specific description of the sample;

(C) Whether it is an initial or remediated sample;

(D) The date of receipt of the sample;

(E) A statement of the quantity (weight, volume, number, or other amount) of the sample; and

(F) A unique sample identifier for the sample.

**310:681-8-5. Laboratory analyses**

(a) **Standard operating procedures.** The laboratory shall develop, implement, and maintain written standard operating procedures (SOP) for the following laboratory processes:

(1) **Sample preparation.** Sample preparation SOP(s) shall address the following:

(A) Sample homogenization;

(B) Handling and storage;

(C) Preservation; and



(D) Hold time.

(2) **Test methods.** Each test method SOP shall address the following:

(A) Test method name;

(B) Applicable analytes and matrices;

(C) Method sensitivity;

(D) Potential interferences with the analysis, if any;

(E) Analytical instruments used for testing;

(F) Types, frequency, and acceptance criteria for quality control samples;

(G) Types, frequency, and acceptance criteria for calibration standards;

(H) Procedure for analyzing analytical batch samples;

(I) Calculation of results, if any; and

(J) Reagent, solution, standards, and reference material preparation, if any.

(3) **Review, approve and sign.** The supervisory or management laboratory employee shall review, approve, sign, and date each SOP and each revision thereto.

(4) **SOP on premises and accessible.** The laboratory shall keep each SOP at the laboratory premises and ensure that each SOP is accessible to laboratory employees during operating hours.

(5) **SOP available for inspection on request.** The laboratory shall make each SOP available for inspection by the Department upon request, as well as any other SOPs associated with the licensee's certificate of accreditation.

(b) **Test methods.**

(1) The laboratory shall develop, implement, and validate test methods for the analyses of samples as required under this section.

(2) To the extent practicable, the laboratory test methods shall comport with the most recent version of the following guidelines, which are incorporated herein by reference:

(A) US Food and Drug Administration's Bacterial Analytical Manual, 2016;

(B) US Food and Drug Administration's Guidelines for the Validation of Chemical Methods for the FDA FVM Program, 2nd Edition, 2015;

(C) AOAC International's Official Methods of Analysis for Contaminant Testing of AOAC International, 20th Edition, 2016; or

(D) United States Pharmacopeia and the National Formulary's Methods of Analysis for Contaminant Testing, 2016.

**(c) Validation of test methods.**

(1) The laboratory may use a standard, non-standard, amplified, or modified test method or a method that is designed or developed by the laboratory to validate the methods for analyses of samples.

(2) The laboratory shall follow the most recent version of the following guidelines to validate test methods:

(A) Microbial analyses: the US Food and Drug Administration's *Guidelines for the Validation of Methods for the Detection of Microbial Pathogens in Foods and Feeds*, 2nd Edition, 2015.

(B) Chemical analyses: the US Food and Drug Administration's *Guidelines for the Validation of Chemical Methods for the FDA FVM Program*, 2nd Edition, 2015.

(3) The laboratory shall include and address the criteria below when validating test methods:

(A) Microbial analyses criteria in Table 6 of Appendix A;

(B) Chemical analyses (as relevant):

(i) Accuracy;

(ii) Precision (within run, between run, between day);

(iii) Limit of detection;

(iv) Limit of quantitation;

(v) Linearity and analytic measurement range;

(vi) Reportable range;

(vii) Sensitivity and specificity;

(viii) Limit of detection and limit of quantitation;

(ix) Recovery;

(x) Other data quality parameters as relevant.

(4) If available, the laboratory shall use marijuana reference materials or certified reference materials to validate test methods.

(d) **Required testing.** A laboratory shall test each sample for the following:

(1) Cannabinoids;

(2) Foreign materials;

(3) Heavy metals;

(4) Microbial impurities;

(5) Moisture content and water activity (usable marijuana only);

(6) Residual pesticides;

(7) Residual solvents and processing chemicals (marijuana-derived products only).

(e) **Analyses.** A licensed laboratory shall:

(1) Utilize analytical methods that are appropriate for the purpose of testing of marijuana and marijuana-derived products;

(2) Require analysts to demonstrate proficiency in the performance of the analytical methods used;

(3) Maintain written procedures for the analytical method used for the analysis of each test sample;

(4) Ensure that no deviations from approved protocols or standard operating procedures are made during any analytical process without proper authorization and documentation; and

(5) Use only primary standards or secondary standards for quantitative analyses.

(f) **Recording of analytical data.**

(1) A laboratory shall ensure that all data generated during the testing of a test sample, except data generated by automated data collection systems, is recorded directly, promptly, and legibly in ink. All

data shall be annotated with the date of entry and signed or initialed by the person recording the data. Any change in entries shall be made so as not to obscure the original entry, shall indicate the reason for such change, and shall be dated and signed or initialed at the time of the change.

(2) In automated data collection systems, the individual responsible for direct data input shall be identified at the time of data input. Any change in automated data entries shall be made so as not to void or delete the original entry, shall indicate the reason for change, shall be dated, and shall identify the responsible individual.

(3) For each final result reported, a laboratory shall verify that:

(A) Any calculations or other data processing steps were performed correctly;

(B) The data meet any data quality requirements such as for accuracy, precision, linearity, etc.;

(C) Any reference standards used were of the appropriate purity and within their expiration or requalification dates;

(D) Any volumetric solutions were properly standardized before use; and

(E) Any test or measuring equipment used has been properly tested, verified, and calibrated, and is within its verification or calibration period.

(g) **Sample handling, storage and disposal.** A laboratory shall establish sample handling procedures for the tracking of test samples through the analytical process (by weight, volume, number, or other appropriate measure) to prevent diversion.

(1) The laboratory shall store each test sample under the appropriate conditions to protect the physical and chemical integrity of the sample.

(2) Analyzed test samples consisting of marijuana or marijuana-derived product shall be appropriately segregated, controlled, and held in a controlled access area pending destruction or other disposal.

(3) Any portion of a marijuana or marijuana-derived test sample that is not destroyed during analysis shall be:

(A) Returned to the licensed individual or entity that provided the sample;

(B) Transported to a state or local law enforcement office; or

(C) Destroyed in a manner that prevents unauthorized use as documented in Section 310:681-5-10 (relating to medical marijuana waste disposal). Such destruction shall be documented and witnessed

by at least two employees, one of whom shall be supervisory or managerial personnel; except that if video surveillance is used, only one employee is required.

**(h) Data reporting.**

(1) The laboratory shall generate a certificate of analysis (COA) only for each primary sample that the laboratory analyzes.

(2) The laboratory shall issue the COA to the requester within 2 business days after technical and administrative review of analysis has been completed.

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

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

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

(C) The description of the type or form of the test sample (leaf, flower, powder, oil, specific edible product, etc.) and its total primary sample weight in grams, reported to three significant figures;

(D) The unique sample identifier;

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

(F) Sample history, including the date collected, the date received by the laboratory, and the date(s) of sample analyses and corresponding testing results, including units of measure where applicable;

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

(H) The reporting limit for each analyt tested;

(I) Any compounds detected during the analyses of the sample that are not among the targeted analytes and are unknown, unidentified, tentatively identified or known and injurious to human health if consumed, if any; and

(J) The identity of the supervisory or management personnel who reviewed and verified the data and results and ensured that data quality, calibration, and other applicable requirements were met.

(4) The laboratory shall report test results for each primary sample on the COA as follows:

(A) When reporting quantitative results for each analyte, the laboratory shall use the appropriate units of measurement as required under this Chapter;

(B) When reporting qualitative results for each analyte, the laboratory shall indicate "pass" or "fail";

(C) When reporting results for each test method, the laboratory shall indicate "pass" or "fail";

(D) When reporting results for any analytes that were detected below the analytical method LOQ, indicate "

(E) When reporting results for any analytes that were not detected or detected below the LOD, indicate "ND";

(F) Indicate "NT" for any test that the laboratory did not perform; and

(G) A sample containing synthetic cannabinoids shall be reported as "failed".

(5) The Department may initiate an investigation upon receipt of a report of tentatively identified compounds from a laboratory and may require a processor or grower to submit samples for additional testing, including testing for analytes that are not required by these rules, at the licensee's expense.

(i) **Retention of testing records.** The laboratory shall retain all results of laboratory tests conducted on marijuana or marijuana-derived products for a period of at least seven (7) years and shall make them available to the Department upon the Department's request.

### **310:681-8-6. Post-testing procedures**

#### **(a) Post-testing sample retention.**

(1) The laboratory shall retain the reserve sample, consisting of any portion of a sample that was not used in the testing process. The reserve sample shall be kept, at minimum, for 45 business days after the analyses, at which time it must be destroyed and denatured to the point the material is rendered unrecognizable.

(2) The laboratory shall securely store the reserve sample in a manner that prohibits sample degradation, contamination, and tampering.

(3) The laboratory shall provide the reserve sample to the Department upon request.

#### **(b) Remediation and retesting, general.**

(1) If a sample fails a test or a reanalysis under OAC 310:681-8-5(d) (relating to required testing), the batch:

(A) May be remediated or sterilized in accordance with this rule; or

(B) If it is not or cannot be remediated or sterilized under this rule, it must be destroyed in a manner specified by the Department.

(2) A harvest or product batch that has been additionally processed after a failed testing must be re-tested and successfully pass all the analyses required under this Chapter.

(3) No remediated harvest or product batches may be sold or transported until re-tested and successful passage of all analyses required under this section.

(4) Growers and processors may remediate failed harvest or product batches providing the remediation method does not impart any toxic or deleterious substance to the usable marijuana or marijuana-derived products.

(A) Remediation solvents or methods used on marijuana or marijuana-derived products must be disclosed to the testing laboratory, processor or dispensary to which the remediated harvest or batch is transferred, or consumer upon request.

(B) The entire failed harvest or product batch must be remediated using the same remediation technique.

(5) Growers and processors must, as applicable:

(A) Have detailed procedures for sterilization processes to remove microbiological contaminants and foreign materials, and for reducing the concentration of solvents.

(B) Prior to retesting, provide to the testing laboratory a document specifying how the product was remediated. This document shall be retained by the laboratory together with other testing documentation;

(C) Document all re-sampling, re-testing, sterilization, remediation and/or destruction of marijuana or marijuana-derived products that fail laboratory testing under these rules.

(6) A harvest batch or product batch may only be remediated twice, unless otherwise stated in 310:681-8-6 (b)-(f). If the batch fails after the second remediation attempt, the entire batch shall not be released for retail sale.

(7) If a harvest batch or product batch fails after undergoing attempted remediation or sterilization as permitted under this rule, the batch must be destroyed in a manner approved by the Department.

(8) At the request of the grower or processor, the Department may authorize a re-test to validate a failed test result on a case-by-case basis. All costs of the re-test will be borne by the grower or the processor requesting the re-test. Cannabinoid re-testing will generally not be authorized.

(9) Growers and processors must inform a laboratory prior to samples being taken that the batch has failed a test and is being re-tested after undergoing remediation or sterilization.

(10) A harvest batch or product batch that fails testing because of non-conformance with the labeled content may be re-labeled to conform with the labeled content.

**(c) Remediation and retesting, microbiological impurities testing.**

(1) If a sample from a batch of usable marijuana fails microbiological contaminant testing, the batch may be used to make a cannabinoid concentrate or extract if the processing method effectively sterilizes the batch, such as a method using a hydrocarbon-based solvent or a CO<sub>2</sub> closed loop system.

(2) If a sample from a batch of a cannabinoid concentrate or extract fails microbiological contaminant testing, the batch may be further processed, if the processing method effectively sterilizes the batch, such as a method using a hydrocarbon-based solvent or a CO<sub>2</sub> closed-loop system.

(3) A batch that is sterilized in accordance with subsection (1) or (2) of this subsection must be sampled and tested in accordance with these rules and must be tested, if not otherwise required for that product, for microbiological contaminants, residual solvents and processing chemicals and residual pesticides.

(4) A batch that fails microbiological contaminant testing after undergoing a sterilization process in accordance with subsection (1) or (2) of this Section must be destroyed.

**(d) Remediation and retesting, residual solvent and processing chemicals testing.**

(1) If a sample from a batch fails residual solvent and processing chemicals testing, the batch may be remediated using procedures that would reduce the concentration of solvents to less than the action level.

(2) A batch that is remediated in accordance with (1) of this subsection must be sampled and tested in accordance with these rules and must be tested if not otherwise required for that product under these rules, for solvents and pesticides.

(3) A batch that fails residual solvent and processing chemicals testing and is not remediated or is remediated and fails testing must be destroyed in a manner specified by the Department.

**(e) Remediation and retesting, moisture content and water activity testing.**



(1) If a sample from a batch of usable marijuana fails moisture content and water activity testing, the batch from which the sample was taken may:

(A) Be used to make a cannabinoid concentrate or extract; or

(B) Continue to dry or cure.

(2) A batch that undergoes additional drying or curing as described in (1) of this subsection must be sampled and tested in accordance with these rules.

**(f) Remediation and retesting, foreign materials testing.**

(1) If a sample from a batch of usable marijuana fails foreign materials testing, the batch from which the sample was taken may be remediated to reduce the amount of foreign materials to below action levels.

(2) A batch that undergoes remediation as described in (1) of this subsection must be sampled and tested in accordance with these rules.

**(g) Remediation and retesting, residual pesticide testing.**

(1) If a sample from a batch fails residual pesticide testing, the batch may not be remediated and must be destroyed in a manner approved by the Department.

(2) The Department must report to the Oklahoma Department of Agriculture all test results showing samples failing residual pesticide testing.

**(h) Remediation and retesting, heavy metals testing.**

(1) If a sample from a batch fails heavy metals testing, the batch may not be remediated and must be destroyed in a manner approved by the Department.

(2) The Department must report to the Oklahoma Department of Agriculture all test results showing samples failing heavy metals testing.

**(i) Remediation and retesting, heavy metals testing.** If a sample from a batch fails mycotoxins testing, the batch may not be remediated and must be destroyed in a manner approved by the Department.

**(j) Remediation and retesting, cannabinoid testing.**

(1) Usable marijuana that fails cannabinoid testing under 310:681-8-3(a) may be repackaged in a manner that enables the item to meet the standard in 310:681-8-3(a).

(2) Usable marijuana that is repackaged in accordance with this Section must be sampled and tested in accordance with these rules.

**310:681-8-7. Laboratory quality assurance and quality control**

(a) **Laboratory quality assurance (LQA) program.** The laboratory shall develop and implement an LQA program to assure the reliability and validity of the analytical data produced by the laboratory.

(1) The LQA program shall, at minimum, include a written LQA manual that addresses the following:

(A) Quality control procedures;

(B) Laboratory organization and employee training and responsibilities;

(C) LQA objectives for measurement data;

(D) Traceability of data and analytical results;

(E) Instrument maintenance, calibration procedures, and frequency;

(F) Performance and system audits;

(G) Steps to change processes when necessary;

(H) Record retention;

(I) Test procedure standardization; and

(J) Method validation.

(2) A supervisory or management laboratory employee shall annually review, amend if necessary, and approve the LQA program and manual when:

(A) The LQA program and manual are created;

(B) There is a change in methods, laboratory equipment, or the supervisory or management laboratory employee overseeing the LQA program.

(b) **Laboratory quality control samples.**

(1) The laboratory shall use laboratory quality control (LQC) samples in the performance of each analysis according to the specifications in this section.

(2) The laboratory shall analyze LQC samples in the same manner as the laboratory analyzes samples of marijuana and marijuana-derived products.

(3) The laboratory shall use negative and positive controls for microbial testing.

(4) The laboratory shall prepare and analyze at least one LQC sample for each analytical batch within each set of 20 samples for the following LQC samples:

(A) Method blank;

(B) Continuing calibration verification (CCV);

(C) Laboratory replicate sample; and

(D) Matrix spike sample or matrix spike duplicate sample.

(5) If the result of the analyses is outside the specified acceptance criteria in Appendix A, Table 7, the laboratory shall determine the cause and take steps to remedy the problem until the result is within the specified acceptance criteria.

(6) The laboratory shall generate a LQC sample report for each analytical batch that includes LQC parameters, measurements, analysis date, and matrix.

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

(1) Reagents, solutions, and reference standards shall be:

(A) Secured in accordance with the laboratory's storage policies; labeled to indicate identity, date received or prepared, and expiration or requalification date; and, where applicable, concentration or purity, storage requirements, and date opened;

(B) Stored under appropriate conditions to minimize degradation or deterioration of the material; and

(C) Used only within the item's expiration or requalification date.

(2) Deteriorated or outdated reagents and solutions shall be properly disposed, in compliance with all federal, state and local regulations.

(3) The laboratory may acquire commercial reference standards for cannabinoids and other chemicals or contaminants, for the exclusive purpose of conducting testing for which the laboratory is approved. The laboratory may elect to produce reference standards in-house (internally). When internally produced, the laboratory shall utilize standard analytical techniques to document the purity and

concentration of the internally produced reference standards. The laboratory is authorized to obtain marijuana or marijuana-derived product from a licensed non-profit producer for this purpose.

(4) The laboratory shall obtain or, for internally-produced standards, shall create a certificate of analysis (COA) for each lot of reference standard. Each COA shall be kept on-file and the lot number of the reference standard used shall be recorded in the documentation for each analysis, as applicable.

**(d) Equipment.**

(1) Equipment used for the analysis of test samples shall be adequately inspected, cleaned, and maintained. Equipment used for the generation or measurement of data shall be adequately tested and calibrated on an appropriate schedule, as applicable.

(2) Laboratory operations shall document procedures setting forth in sufficient detail the methods and schedules to be used in the routine inspection, cleaning, maintenance, testing, and calibration of equipment, and shall specify, as appropriate, remedial action to be taken in the event of failure or malfunction of equipment. The procedures shall designate the personnel responsible for the performance of each operation.

(3) Records shall be maintained of all inspection, maintenance, testing, and calibrating operations. These records shall include the date of the operation, the person who performed it, the written procedure used, and any deviations from the written procedure. Records shall be kept of non-routine repairs performed on equipment as a result of failure and malfunction. Such records shall document the nature of the repair, how and when the need for the repair was discovered, and any remedial action taken in response to the repair.

(4) Computer systems used for the analysis of samples, retention of data, sample tracking, calibration scheduling, management of reference standards, or other critical laboratory management functions shall ensure that electronic records, electronic signatures, and handwritten signatures executed to electronic records are trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.

**(e) Data storage.**

(1) The laboratory shall ensure that all raw data, documentation, protocols, and final reports associated with analysis of a test sample are retained for at least seven (7) years from the date of completion of analysis.

(2) The laboratory shall designate an individual as responsible for records maintenance. Only authorized personnel may access the maintained records.

(3) The laboratory shall maintain the records identified in this section:

(A) In a manner that allows retrieval, as needed;

(B) Under conditions of storage that minimize deterioration throughout the retention period; and

(C) In a manner that prevents unauthorized alteration.

(f) **Materials to be maintained on premises.** The laboratory shall maintain on its premises, and shall promptly present to the Department upon request:

(1) Personnel documentation including, but not limited to employment records, job descriptions, education, and training requirements of the laboratory, and documentation of education and training provided to staff for the purpose of performance of assigned functions;

(2) Requirements concerning laboratory operations, business licensing, and security procedures;

(3) Standards for receipt, handling, and disposition of samples of usable marijuana;

(4) Equipment information detailing the type of equipment used, inspection standards and practices, testing and calibration schedules and records, and standards for cleaning and maintenance of equipment;

(5) Reagents, solutions, and reference standards including, but not limited to standards for labeling, storage, expiration, and re-qualification dates and records;

(6) Reference standards, acquired or internally produced, including the certificate of analysis;

(7) Sample analysis procedures including, but not limited to procedures for the use of only primary or secondary standards for quantitative analyses;

(8) Documentation demonstrating that the analytical methods used by the laboratory are appropriate for their intended purpose; that staff is proficient in the process; and that deviations from approved standards of practice do not occur without proper authorization;

(9) Standards for data recording, review, storage, and reporting that include, but are not limited to standards to ensure that:

(A) Data are recorded in a manner consistent with this rule, and that they are reviewed to verify that applicable standards of practice, equipment calibration, and reference standards were applied before reporting;

(B) All data, including raw data, documentation, protocols, and reports are retained in accordance with the requirements of this rule; and

(C) Reports are the property of the business or individual who provided the sample, and reports meet the requirements of this rule.

(10) Safety data sheets for all chemicals used are readily accessible to laboratory staff; and

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

**(g) Proficiency testing.**

(1) **Prior to approval and at frequency to be determined.** The laboratory shall be subject to proficiency testing (PT) by the Department or its designee prior to approval, and thereafter at a frequency and at times to be determined by the Department or its designee.

(2) **Cooperation.** The laboratory shall cooperate with the Department or its designee for purposes of conducting PT. The Department or its designee may require submission of marijuana and marijuana-derived product samples from licensed non-profit producers for purposes of PT.

**(3) Failure of PT.**

(A) If the Department determines on the basis of a PT that the laboratory has not satisfactorily identified the presence, quantity, or other relevant factor(s) pertaining to a given analyte, the Department may deny the application in whole or in part, require additional tests, or require remedial actions to be taken by the laboratory.

(B) If the Department determines on the basis of a PT that the laboratory has not satisfactorily identified the presence, quantity, or other relevant factor(s) pertaining to a given analyte, the Department may withdraw approval of the laboratory in whole or in part, require additional tests, or require remedial actions to be taken by the laboratory.

(h) **Inspection of the laboratory and records.** A licensed laboratory shall be subject to inspection(s), at times determined by the Department, in accordance with the provisions of this rule. The Department may require the inspection of premises, equipment, and written materials to determine compliance with this rule, and to determine compliance with the application submissions of the laboratory applicant or laboratory, including but not limited to standard operating procedures and standards for testing.

(i) **Department access to materials and premises.** The laboratory shall promptly provide the Department or the Department's designee access to a report of a test, and any underlying data, that is conducted on a sample at the request of grower or processor. The laboratory shall also provide access to the Department or the Department's designee to laboratory premises, and to any material or information requested by the Department, for the purpose of determining compliance with the requirements of this rule.

**APPENDIX A.Supporting Tables for Subchapter 8 (Relating to Testing Standards for Marijuana)**  
**[NEW]**