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

"Unofficial Version"

SUBCHAPTER 1. GENERAL PROVISIONS

310:681-1-4. Definitions

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

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

"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 or processed, packaged, and labeled during a specified time period according to a single manufacturing, packaging, and labeling protocol.

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

"Cannabinoid" means any of the diverse chemical compounds that can act on cannabinoid receptors in cells and alter neurotransmitter release in the brain, including phytocannabinoids that are produced naturally by marijuana and some other plants.

"Clone" means a non-flowering plant cut from a mother plant that is no taller than eight inches and is capable of developing into a new plant.

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

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

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

"Complete(d) Application" means a document prepared in accordance with 63 O.S. § 420 et seq., these rules, and the forms and instructions provided by the Department, including any supporting documentation required by the Department and the license fee.

"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 processer licensee or grower licensee and sell medical marijuana only to qualified patients, or their parents or legal guardian(s) if applicable, and caregivers.

"Disqualifying Criminal 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.

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

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

"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.

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

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

"Licensee" means any natural born person or entity that holds a marijuana license provided for in this Chapter, excluding inmates of any local, county, state, or federal correctional facility or jail.

"Lot" means the food produced during a period of time indicated by a specific code.

"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 that 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" or "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 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" or "Resident" means an individual who resides in the State of Oklahoma and can provide proof of residency as required by 63 O.S. § 420 et seq. and OAC 310:681-1-6.

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

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

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

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

"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.

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

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

"Private School" means an elementary, middle, or high school maintained by private individuals, religious organizations, or corporations, funded, at least in part, by fees or tuition, and open only to pupils selected and admitted based on religious affiliations or other particular qualifications.

"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, process, package, sell to, and deliver medical marijuana products to a dispensary licensee or other processor licensee; and may manufacture marijuana received from a qualified patient into a medical marijuana concentrate, for a fee.

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

"Retailer" means, as used in Title 63 O.S. § 420 et seq., a dispensary.

"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.

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

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

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

SUBCHAPTER 5. COMMERCIAL ESTABLISHMENTS

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

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

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

(1) The sale, offer to sell, dispense or release into commerce of any food or confection under a name, label, or brand when the name, label, or brand either precisely or by slang term or popular usage, is the name, label, or brand of marijuana is not prohibited.

(2) Marijuana used in food shall be considered an additive, a component, and/or an edible substance.

(3) Marijuana shall not be considered a deleterious, poisonous, or nonnutritive substance, and the use of marijuana, alone, in food shall not make such food adulterated or misbranded.

(c) **Updated law.** In the event the Oklahoma Board of Health or the Commissioner of Health amends OAC 310:257 or OAC 310:260, adopts new food safety rules, or incorporates into Oklahoma law updated federal food safety standards, including Title 21 of the Code of Federal Regulations, licensed processors shall comply with such rules to the extent they are applicable and do not conflict with 63 O.S. § 420A et seq. or these rules.

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

(e) **Labeling and packaging.** Labels and packages for food containing marijuana shall comply with all applicable requirements in existing Oklahoma law, rules, and regulations, and any laws incorporated therein by reference, to the extent they do not conflict with 63 O.S. § 420A.

(1) Title 21, part 101 of the Code of Federal Regulations ("CFR"), as of August 22, 2018, is hereby incorporated by reference into this Section to the extent it is applicable and does not conflict with 63 O.S. § 420A et seq.

(2) Existing requirements for principal display panels or information panels include:

(A) Name and address of the business;

(B) Name of the food;

(C) Net quantity or weight of contents;

(D) Ingredients list;

(E) Food allergen information;

(F) Nutrition labeling, if required under 21 CFR § 101.9;

(3) In addition, principal display panels or information panels must contain:

(A) List of cannabis ingredients;

(B) The batch of marijuana;

(C) The strain of marijuana (optional);

(D) THC dosage in milligrams per unit; and

(E) The lot code.

(4) Nutrient content, health, qualified health and structure/function claims must comply with the Food and Drug Administration ("FDA") Food Labeling Guide.

(5) Packaging must contain the statement, "For accidental ingestion call 1-800-222-1222."

(6) All packages and individually-packaged product units, including but not limited to those from bulk packaging, must

contain the Oklahoma uniform symbol in clear and plain sight. The Oklahoma uniform symbol must be printed at least one-half inch by one-half inch in size in color.

(7) In order to comply with OAC 310:681-7-1(4) and this Section, a label must contain a warning that states, "Women should not use marijuana or medical marijuana products during pregnancy because of the risk of birth defects or while breastfeeding."

(f) **Recommended HACCP.** A Hazard Analysis and Critical Control Plan ("HACCP"), as set forth under Title 21, Part 120 of the Code of Federal Regulations, shall be recognized as a standardized best practice to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable. Processors are encouraged to adopt a HACCP to help ensure compliance with existing Oklahoma food safety laws, particularly OAC 310:260-3-6.

(g) **Required testing procedures.** In light of the medical nature of marijuana authorized under 63 O.S. § 420A et seq. and to ensure the suitability and safety for human consumption of food products containing medical marijuana, processors are required to test food products containing medical marijuana for microbials, solvent and chemical residue, metals, pesticide residue, potency, and contaminants and filth in accordance with the following standards and thresholds.

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

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

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

(4) **Microbiological testing.**

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

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

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

(D) Test reports shall include method reference.

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

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

(i) Acetone < 1,000 ppm

(ii) Benzene < 2 ppm

(iii) Butanes/ Heptanes < 1,000 ppm

(iv) Hexane < 60 ppm

(v) Isopropyl Alcohol < 1,000 ppm

(vi) Pentane < 1,000 ppm

(vii) Propane < 1,000 ppm

(viii) Toluene < 180 ppm

(ix) Total Xylenes (m, p, o-xylenes) < 430 ppm

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

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

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

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

(6) **Metals.**

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

(B) Test results shall meet the following thresholds:

(i) Lead – max limit < 1ppm

(ii) Arsenic – max limit < 0.4 ppm

(iii) Cadmium – max limit < 0.44 ppm

(iv) Mercury – max limit < 0.2 ppm

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

(7) **Pesticide residue.**

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

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

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

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

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

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

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

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

(h) **Private homes; Living or sleeping quarters.**

(1) A private home, a room used as living or sleeping quarters, or an area directly opening into a room used as living or sleeping quarters may not be used for conducting processing operations.

(2) Living or sleeping quarters located on the premises of a processor such as those provided for lodging registration clerks or resident managers shall be separated from rooms and areas used for food establishment operations by complete partitioning and solid self-closing doors.