

ADMINISTRATIVE RULES TITLE 15—MISSISSIPPI STATE DEPARTMENT OF HEALTH PART 22—MEDICAL CANNABIS PROGRAM Subparts 1-11

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Subpart 1 GENERAL PROVISIONS

- 1.1 Legal Authority.
- 1.1.1 This regulation has been promulgated under the authority of and pursuant to Miss. Code Ann. §§ 41-137-1 41-137-67.
- **Definitions.** The following terms shall have the meanings <u>indicated</u> hereinafter respectively ascribed to them as they relate to licensed medical cannabis establishments participating in for purposes of the Mississippi State Department of Health's the Mississippi Medical Cannabis Program <u>rules and regulations</u>.
- 1.2.1 Accreditation The term "accreditation" means being currently deemed as technically competent under ISO/IEC 17025:2017 by an international mutual recognition arrangement signatory that has been found to meet ISO/IEC 17011, Conformity Assessment-Requirements for accreditation bodies accrediting conformity assessment bodies.
- 1.2.2 Accreditation Body — The term "accreditation body" means an impartial nonprofit organization that operates in conformance with the International Organization Standardization (ISO)/International Electrotechnical for Commission (IEC) standard 17011 and is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) for Testing.
- 1.2.3 **Acquire** The term "acquire" means coming to possess cannabis by means of any legal source in compliance with the Mississippi Medical Cannabis Act (the Act) and any rules promulgated under the Act.
- 1.2.4 Additive The term "additive" means any non-cannabis derived substance added to regulated cannabis and/or cannabis products to achieve a specific technical and/or functional purpose during processing, storage, or packaging. Additives may be direct or indirect. Direct additives are used to impart specific technological or functional qualities. Indirect additives are not intentionally added but may be present in trace amounts as a result of processing, packaging, shipping, or storage. Botanically Derived Compounds which have been isolated or enriched and subsequently added back into cannabis products are additives.

1.2.5 Adverse Health Event – The term "adverse health event" means any untoward health condition or occurrence associated with the use of medical cannabis—this could include any unfavorable and unintended sign (including a hospitalization, emergency department visit, medical visit, abnormal laboratory finding, outbreak, death [non-motor vehicle]), symptom, or disease temporally associated with the use of a cannabis product, and may include concerns or reports on the quality, labeling, or possible adverse reactions to a specific cannabis product produced by a licensee.

1.2.6 **Adverse Weather Event** – The term "adverse weather event" means:

- A. <u>Damaging weather, which involves a drought, a freeze, hail, excessive moisture, excessive wind, or a tornado; or</u>
- B. An adverse natural occurrence, which involves an earthquake, wildfire, or flood.
- 1.2.7 **Advertising** The terms "advertising" and "advertisement" shall mean all representations disseminated in any manner or by any means, other than labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of medical cannabis. Advertising does not include labeling as required by the regulations of the Medical Cannabis Program.
- 1.2.8 **Affiliate** The term "affiliate" means any entity effectively controlling or controlled by another entity or associated with other entities under common ownership or control, including a parent or subsidiary.
- 1.2.9 Allergen The term "allergen" means a major food allergen as defined in 21 U.S.C § 321(qq).
- 1.2.10 Allowable Amount of Medical Cannabis The term "allowable amount of medical cannabis" means an amount not to exceed the maximum amount of Mississippi Medical Cannabis Equivalency Units ("MMCEU").

- 1.2.11 Analytical Batch The term "analytical batch" means a set of no more than twenty (20) samples that are prepared together for the same type of analysis, are sequentially analyzed using the same instrument calibration curve, and have common analytical quality control requirements. The batch shall include testing samples as well as all applicable quality control samples, to include one method blank, duplicate laboratory fortified blanks, and duplicate matrix spikes, as required by the analytical method.
- 1.2.12 **Batch** The term "batch" means, with regard to usable medical cannabis, a homogenous, identified quantity of usable medical cannabis, no greater than twenty-five pounds (25lbs), that is harvested during a specified time period from a specified cultivation area, and with regard to oils, vapors and waxes derived from usable medical cannabis, means an identified quantity that is uniform, that is intended to meet specifications for identity, strength, and composition, and that is)d, packaged and labeled during a specified time period according to a single manufacturing, packaging and labeling protocol.
- 1.2.13 **Batch Number** The term "batch number" means a unique numeric or alphanumeric identifier assigned to a batch by a cultivation or processing facility entity when the batch is first planted. The batch number for plant batches shall contain the strain name and date created. The batch number for harvest batches shall contain the strain name and date harvested. The batch number for production batches shall contain the item name and date produced. In the event that multiple batches of the same product or item are created on the same date, a unique suffix shall be added such as a numeric or alphabetical character. (e.g., 1, 2, 3, a, b, c, etc.).
- 1.2.14 **Biosecurity Measures** The term "biosecurity measures" means practices to protect growing operations from unwanted pests, pathogens, molds, and other such contaminants or risks things (inclusive of people) that could a set of preventative measures designed to reduce the risk of transmission of infectious diseases in crops, quarantined pests, invasive alien species, and living modified organisms that could impact the safety of cannabis and cannabis products.
- 1.2.15 <u>Botanically Derived Compounds</u> The term "botanically derived compounds" means organic chemicals that typically have a high vapor pressure at room temperature and are likely to be dispersed into the air. Botanically

Derived Compounds include, but are not limited to terpenes, terpenoids, ketones, esters, and other molecules which are naturally occurring in plants and are used to affect the flavor and aroma of cannabis products. Synthetic cannabinoids are not botanically derived compounds and are prohibited.

- 1.2.16 **Brand** The term "brand" shall mean a name, term, design or symbol or any other feature that identifies one seller's goods or services as distinct from those of other sellers. For the purposes of these regulations, a company logo is considered a brand.
- 1.2.17 **Branding** The term "branding" shall mean the process of giving a meaning to a specific medical cannabis establishment's business by publicizing the business's name and logo.
- 1.2.18 **Cannabinoid Extract** The term "cannabinoid extract" means a substance obtained by separating cannabinoids from cannabis by any of the following methods:
 - A. A chemical extraction process using a hydrocarbon-based solvent; or
 - B. A chemical extraction process using the hydrocarbon-based solvent carbon dioxide if the process uses high heat or pressure.
- 1.2.19 Cannabis The term "cannabis" means all parts of the plant of the genus cannabis, the flower, the seeds thereof, the resin extracted from any part of the plant and every compound, manufacture, salt, derivative, mixture or preparation of the plant, its seeds or its resin, including whole plant extracts. Such term shall not mean 1) industrial hemp as defined in this Part per Miss. Code § 41-137-25(22) nor 2) cannabis-derived products approved by the federal Food and Drug Administration under Section 505 of the Federal Food, Drug, and Cosmetic Act.
- 1.2.20 **Cannabis Container** The term "cannabis container" means an individual locked and secure container in which an originating medical cannabis establishment places cannabis and/or cannabis products for transport to a receiving medical cannabis establishment.

- 1.2.21 Cannabis Cultivation Facility Entity The term "cannabis cultivation facility entity" means a business entity licensed and registered by the Mississippi Department of Health that acquires, grows, cultivates, and harvests medical cannabis in an indoor, enclosed, locked, and secure area. The terms "cannabis cultivator", "cultivator", or "micro-cultivator" also have the same meaning.
- 1.2.22 **Cannabis Disposal Entity** The term "cannabis disposal entity" means a business licensed and registered by the Mississippi Department of Health that is involved in the commercial disposal or destruction of medical cannabis. These entities may also be known as "waste disposal entities".
- 1.2.23 <u>Cannabis Facility</u> The term "cannabis facility" or "facility" means a permanent structure in a fixed location where a medical cannabis establishment operates or conducts business.
- 1.2.24 Cannabis Processing Facility Entity The term "cannabis processing facility entity" means a business entity that is licensed and registered by the Mississippi Department of Health that: acquires or intends to acquire cannabis from a cannabis cultivation facility entity or other cannabis processing facility entity; possesses cannabis with the intent to manufacture a cannabis product; manufactures or intends to manufacture a cannabis product from unprocessed cannabis or a cannabis extract; and sells or intends to sell a cannabis product to a medical cannabis transportation entity, cannabis testing facility entity or cannabis research facility entity. These entities may also be known as "processing facility entities", "processors", or "cannabis processors".
- 1.2.25 Cannabis Products The term "cannabis products" means eannabis flower, concentrated cannabis, cannabis extracts and products that are infused with cannabis or an extract thereof and are intended for use or consumption by humans. The term includes, without limitation, edible cannabis products, beverages, topical products, ointments, oils, tinctures and suppositories that contain tetrahydrocannabinol (THC) and/or cannabidiol (CBD) except those products excluded from control under Miss. Code §§ Sections 41-25-113 and 41-25-136 of the MS Code. The term medical cannabis products may also be used with the same meaning.

- 1.2.26 Cannabis Research Facility Entity The term "cannabis research facility entity" or "research facility—entity" means a research facility—entity at any university or college in this state or an independent entity licensed and registered by the Mississippi Department of Health pursuant to this chapter that acquires cannabis from cannabis cultivation facility—entities and cannabis processing facility—entities in order to research cannabis, develop best practices for specific medical conditions, develop medicines and provide commercial access for medical use.
- 1.2.27 **Cannabis Testing Facility Entity** The term "cannabis testing facility entity" or "testing facility entity" means an independent entity licensed and registered by the Mississippi Department of Health that analyzes the safety and potency of cannabis.
- 1.2.28 **Cannabis Waste** The term "cannabis waste" means:
 - A. Unused, surplus, returned or out-of-date cannabis; recalled cannabis; unused cannabis; plant debris of the plant of the genus cannabis, including dead plants and all unused plant parts, except the term shall not include seeds, roots, stems, stalks and fan leaves unusable sugar leaves, unusable flower, unusable bud, or any other unusable plant material containing trichomes or having a delta-9 tetrahydrocannabinol (THC) concentration greater than three-tenths of one percent (0.3%) on a dry weight basis;
 - B. All product which is deemed to fail laboratory testing and cannot be remediated or decontaminated;
 - C. All products and inventory from medical cannabis establishments that have gone out of business and/or are unable to legally transfer or sell cannabis and/or cannabis products and inventory to another medical cannabis establishment; or
 - D. Products and inventory from medical cannabis establishments that may be destroyed and/or rendered unrecognizable and unusable through disposal as a result of Department corrective and/or administrative actions.
 - E. All cannabis waste must be disposed of by licensed disposal entity.
- 1.2.29 **Canopy** The term "canopy" means the total surface area within a cultivation area that is dedicated to the cultivation of flowering cannabis plants. The surface area of the plant canopy <u>must-shall</u> be calculated in square feet. Measurement

must shall include all of the area within the boundaries where the cultivation of the flowering cannabis plant occurs. If the surface area of the canopy consists of noncontiguous areas, each component area must shall be separated by identifiable boundaries. If a tiered or shelving system is used in the cultivation area, the surface of each tier or shelf must shall be included in the calculation. Calculation of the area of the plant canopy should not include:

- A. The areas within the cultivation area that are used to cultivate immature cannabis plants and seedlings prior to flowering; and,
- B. The areas within the cultivation area that are used to support mature cannabis plants.
- 1.2.30 <u>Commercial Cannabis Activity</u> The term "commercial cannabis activity" includes the cultivation, possession, manufacture, distribution, processing, storing, laboratory testing, packaging, labeling, transportation, delivery, or sale of cannabis or cannabis products as authorized by the Mississippi Medical Cannabis Act or this Part.
- 1.2.31 **Cardholder** The term "cardholder" means a registered qualifying patient or a registered designated caregiver who has been issued and possesses a valid registration identification card by the Mississippi State Department of Health.
- 1.2.32 <u>Certificate of Analysis The term "certificate of analysis" means the report prepared for the party requesting testing and the Department about the analytical testing performed and results obtained by the cannabis testing facility. This term may be abbreviated as "COA".</u>
- 1.2.33 **CFR** The abbreviation "CFR" means the Code of Federal Regulations, the compilation of the general and permanent rules published in the Federal Register by the executive departments and agencies of the federal government which is published by the U.S. Government Printing Office. Citations in this Chapter to the CFR refer sequentially to the Title, Part and Section numbers.
- 1.2.34 **Child Resistant Packaging** The term "child-resistant packaging" means packaging that is:
 - A. Designed or constructed to be significantly difficult for children under five

- (5) years of age to open and not difficult for normal adults to use properly as defined by 16 CFR § 1700.15 (1555) and 16 CFR § 1700.20 (1555) to the extent that such laws, rules, regulations do not conflict with the MS Medical Cannabis Act; and
- B. Resealable to maintain its child-resistant effectiveness for multiple openings by the patient for any product intended for more than a single use or containing multiple servings.

Chronic Pain The term "chronic pain" means a pain state in which the cause of the pain cannot be removed or otherwise treated, and which in the generally accepted course of medical practice, no relief or cure of the cause of the pain is possible, or none has been found after reasonable efforts by a practitioner.

- 1.2.35 **Church** The term "church" means a permanent building primarily and regularly used as a place of religious worship.
- 1.2.36 **Clone** The term "clone" means a non-flowering plant cut from a mother plant that is capable of developing into a new plant but has shown no signs of flowering.
- 1.2.37 Concentrate The term "concentrate" means a product derived from medical cannabis that is kief, hashish, bubble hash, oil, wax, or other product, produced by extracting cannabinoids from the plant through the use of: a substance obtained by separating cannabinoids from cannabis by any of the following methods:
 - A. A mechanical extraction process;
 - B. A chemical extraction process using a nonhydrocarbon-based or other solvent, such as water, vegetable glycerin, vegetable oils, animal fats, foodgrade ethanol or steam distillation; or
 - C. A chemical extraction process using carbon dioxide, provided that the process does not involve the use of high heat or pressure.
- 1.2.38 <u>Compliance Test Sample The term "compliance test sample" includes a package derived from a harvest batch package or production batch intended for compliance testing by a licensed cannabis testing entity.</u>

- 1.2.39 Contaminant The term "contaminant" means an unacceptable level of an unwanted or objectionable substance, toxin, pollution or foreign material that causes impurity in a product. Contaminants include, but are not limited to, pesticides, microbiology, filth, heavy metals and residual chemical solvents.
- 1.2.40 **Daycare** The term "daycare" means a child-care facility, as defined by Miss. Code § 43-20-5.
- 1.2.41 **Demonstration of Capability** The term "demonstration of capability" means an examination, provided by a medical cannabis testing laboratory, undertaken by an analyst to determine whether he or she is able to correctly, accurately, and repeatedly perform a specific analysis or analyze a specific measurement.
- 1.2.42 **Department** The term "Department" means the Mississippi State Department of Health.
- 1.2.43 **Designated Caregiver** The term "designated caregiver" means a person, at least 21 years of age, who has agreed to assist no more than five (5) registered qualifying patients with their medical use of medical cannabis. A designated caregiver may also be referred to as a "caregiver".
- 1.2.44 **Designated Caregiver Entity** The term "designated caregiver entity" means a health care facility or facility providing residential care services or day services that has agreed to assist registered qualifying patients with their medical use of medical cannabis. A designated caregiver entity may also be referred to as a "caregiver entity".
- 1.2.45 **Dispense** The term "dispense" means the retail selling of medical cannabis or medical cannabis products that are packaged and labeled in accordance with the law to a licensed patient, the licensed patient's parent(s) or legal guardian(s) if the licensed patient is a minor, or a licensed caregiver.

- 1.2.46 **Dispose** The term "dispose" or "disposal" means the final disposition of medical cannabis waste by either a process which renders the waste unusable and unrecognizable through physical destruction or a recycling process.
- 1.2.47 **Disqualifying Felony Offense** The term "disqualifying felony offense" means:
 - A. A conviction for a crime of violence, as defined in Section 97-3-2 Mississippi Code of 1972, as amended, or
 - B. A conviction for a crime that was defined as a violent crime in the law of the jurisdiction in which the offense was committed, and that was classified as a felony in the jurisdiction where the person was convicted; or
 - C. A a-conviction for a violation of a state or federal controlled substances law that was classified as a felony in the jurisdiction where the person was convicted, including the service of any term of probation, incarceration or supervised release within the previous five (5) years and the offender has not committed another similar offense since the conviction A disqualifying felony offense shall not include a conviction that consisted of conduct for which the Mississippi Medical Cannabis Act would likely have prevented the conviction but for the fact that the conduct occurred before the effective date of the Medical Cannabis Act.
- 1.2.48 **D.O.** <u>— The term "D.O."</u> means a Doctor of Osteopathy. Also includes DO as an abbreviation.
- 1.2.49 **Economic Interest** The term "economic interest" means holding an ownership interest as a sole proprietor, partner, member, limited partner, member holding at least a ten percent (10%) equity or similar interest, stockholder owning at least ten percent (10%) of available stock, or as any other type of interest that entitles the individual or entity to regular payments for amounts based on a percentage of revenue derived from the cultivation of cannabis or cannabis products by a cannabis cultivation facility licensed medical cannabis establishment's business operations as defined by the Mississippi Medical Cannabis Act.
- 1.2.50 **Edible Cannabis Products** The term "edible cannabis products" means products that:

- A. Contain or are infused with cannabis or an extract thereof;
- B. Are intended for human consumption by oral ingestion; and,
- C. Are presented in the form of foodstuffs, beverages, extracts, oils, tinctures, lozenges and other similar products.
- 1.2.51 **Enclosed** The term "enclosed" means surrounded by roof and walls permanently in place.

Facility means the physical structure associated with a license.

- 1.2.52 **Final Form** The term "final form" means retail-ready cannabis or cannabis products that are in the form in which the cannabis or cannabis product will be consumed or used.
- 1.2.53 **Flowering** The term "flowering" means the reproductive state of cannabis in which the plant is in a light cycle intended to stimulate the production of flowers, trichromes, and cannabinoid characteristics of cannabis. There are physical signs of flower or budding out of the nodes of the stem.
- 1.2.54 **Harvest Batch** The term "harvest batch" means a specifically identified quantity of cannabis (no greater than twenty five (25) lbs.) that is uniform in strain, cultivated using the same practices, harvested at the same time at the same location and cured under the same conditions. Harvest batches converted into production batches are not required by the Department to be tested prior to processing, unless the cannabis processing facility requests that of the cannabis cultivation facility supplying the batch.
- 1.2.55 Harvest Batch Package The term "harvest batch package" means a package derived from a harvest batch that is restricted by volume to twenty-five pounds (25 lbs) or less of cannabis for testing purposes. If a finished harvest batch (bud/flower, shake/trim) is larger than twenty-five pounds (25 lbs), the harvest batch shall be separated into harvest batch packages for purposes of compliance testing. Harvest batch packages sent only to processors, for extraction, are not required by the Department to be tested prior to processing, unless the cannabis processing facility requests that of the cannabis cultivation entity supplying the

batch. There may be multiple harvest batches for the same strain on the same date.

- 1.2.56 Homogeneity The term "homogeneity" means the amount of cannabinoids within a cannabis product being consistent and reasonably equally dispersed throughout the cannabis product, including each portion of the cannabis product.
- 1.2.57 <u>Homogenization The term "homogenization" means the process by which the components of a sample are broken apart into particles that are equal in size and evenly distributed.</u>
- 1.2.57 <u>Identification Badge The term "identification badge" means a physical badge issued by a licensed medical cannabis establishment to each employee, volunteer, and visitor who has access to the licensee's premises, for purposes of verifying each such person's identity and status.</u>
- 1.2.58 **Immature Cannabis Plants** The term "immature cannabis plants" means seedlings or nonflowering cannabis plants. There are no demonstrated signs of flowering.
- 1.2.59 **Inclusivity** The term "inclusivity" means, related to microbiological method validation, the sensitivity of the test method. It evaluates the ability of the test method to detect a wide range of target organisms by a defined relatedness.
- 1.2.60 Indoor Cannabis Cultivation The term "indoor cannabis cultivation" means production of plants in a completely enclosed and secure facility with a sealed, controlled environment that prevents unfiltered air exchange with the outdoors, provides control of environmental conditions such as humidity, temperature, light, carbon dioxide levels, and either requires use of artificial light exclusively or a rate above twenty-five (25) watts per square foot. Condition changes outside of the cultivation facility shall not alter or significantly affect environmental conditions inside the facility.

- 1.2.61 Industrial Hemp The term "industrial hemp" means a plant of the genus Cannabis and any part of the plant, whether growing or not, containing a delta-9 tetrahydrocannabinol (THC) concentration of no more than three-tenths of one percent (0.3%) on a dry weight basis as set forth in the 2018 Farm Bill, Public Law No. 115-334.
- 1.2.62 <u>Infused Pre-Roll</u> The term "infused pre-roll" means a medical cannabis product produced by rolling, filling, or stuffing harvested medical cannabis flower, shake, and/or trim with regulated cannabis concentrate(s) into paper, leaves, or an equivalent wrapper and is intended for consumption by inhalation.
- 1.2.63 Infused Cannabis Product The term "infused cannabis product" means a cannabis product that includes one or more concentrate(s) along with other materials or ingredients, and includes without limitation, Aany oil, wax, ointment, salve, tincture, capsule, suppository, dermal patch, cartridge or other product containing a medical cannabis concentrate or usable cannabis that has been processed so that the dried leaves and flowers are integrated into other material. The term "infused cannabis product" Ddoes not include an edible cannabis product.
- 1.2.64 <u>Infusion</u> The term "infusion" means a process by which cannabis concentrates are directly incorporated into a product formulation to produce a cannabis product.
- 1.2.65 <u>Ingredient</u> The term "ingredient" means any non-cannabis derived substance that is added to cannabis products to achieve a desired effect. The term includes all additives as defined in this Part.
- 1.2.66 <u>Inhalable Compound Concentrate Products The term "inhalable compound concentrate product" means a cannabis product created by combining one or more marijuana products with marijuana (i.e., marijuana flower, kief) into a final form which is intended for inhalation.</u>
- 1.2.67 **Initial Display of Competency** The term "initial display of competency" means an examination, provided by a cannabis testing laboratory, undertaken

by an analyst to determine whether he or she is able to correctly, accurately, and repeatedly perform a specific analysis or analyze a specific measurement.

- 1.2.68 Kief The term "kief" means the resinous, crystal-like trichomes that have been physically separated from the cannabis plant that results in a higher concentration of cannabinoids.
- 1.2.69 **Label** The term "label" means display of written, printed or graphic matter on the immediate container of any product containing cannabis.
- 1.2.70 **Laboratory Control Sample** (LCS) The term "laboratory control sample (LCS)" means a blank matrix to which known concentrations of each of the target method analytes are added. The spiked concentration must shall be within the calibration range of the method. The LCS must shall be carried through the entire sample preparation process and must shall be analyzed in the same manner as a representative sample. The LCS must shall be made from a standard that is not from the same vendor, or from the same lot if only one vendor is available, that is used for the calibration curve.
- 1.2.71 **Laboratory Replicate Sample** The term "laboratory replicate sample" means a sub-sample taken of the representative sample used for laboratory quality control purposes to demonstrate reproducibility. It is prepared and analyzed in the identical manner as the representative sample. The results from replicate analyses are used to evaluate analytical precision.
- 1.2.72 **Limit of Detection (LOD)** The term "limit of detection (LOD)" means the lowest quantity of a substance or analyte that can be distinguished from the absence of that substance within a stated confidence limit.
- 1.2.73 **Limit of Quantitation (LOQ)** The term "limit of quantitation (LOQ)" means the minimum concentration of an analyte in a specific matrix that can be reliably quantified while also meeting predefined goals for bias and imprecision. The LOQ can be no lower than the lowest calibration standard used in the analysis.

- 1.2.74 **Linear Regression** The term "linear regression" means the determination, in analytical chemistry, of the best linear equation for calibration data to generate a calibration curve. The concentrate of an analyte in a sample can then be determined by comparing a measurement of the unknown to the calibration curve. A linear regression uses the following equation: y = mx + b; where m = slope, b = intercept.
- 1.2.75 **Locked Storage Container** The term "locked storage container" means a secure storage/packing/loading container that may contain multiple individual cannabis containers for transport. A locked storage container is a fixed part of the vehicles used for transportation and is inaccessible to the driver during transport.

Lot The term "lot" means an identified quantity of a batch, that is uniform and intended to meet specification for identity, strength, and composition; or in the case of a vapor, oil or wax derived from cannabis, an identified quantity produced in a specified time period in a manner that is uniform and intended to meet specifications for identify identity, strength, and composition.

- 1.2.76 <u>Manicure Batch</u> The term "manicure batch" means a specifically-identified quantity of cannabis harvested from plants that have not yet been cut down in a primary harvest batch.
- 1.2.77 **Manufacture** The term "manufacture" means to compound, blend, extract, infuse or otherwise make or prepare cannabis and/or cannabis products. The term "manufacture" includes the following processes:
 - A. Extraction;
 - B. Infusion;
 - C. "Post-extraction processing" or "post-processing," which means a process by which one or more active cannabinoids in cannabis concentrate are further concentrated either by chemical or physical means.

The term "manufacture" does not include the following:

- A. The preparation of raw pre-rolls by a licensed cultivator
- B. The collection of the resinous trichomes that are dislodged or sifted from the cannabis plant incidental to cultivation activities by a licensed cultivator.

The terms "manufacturing" or "process" may also be used with the same meaning.

- 1.2.78 **Marketing** The term "marketing" shall mean the activity, set of institutions, and processes for creating, communicating, delivering, and exchanging offerings that have value for customers, clients, partners, and society at large. The term also includes all representations disseminated in any manner or by any means, other than labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of medical cannabis.
- 1.2.79 **Matrix** The term "matrix" means the substances that are present in a sample except for the analyte(s) of interest.
- 1.2.80 **Matrix Spike Sample (MS)** The term "matrix spike sample (MS)" means a portion of an actual sample that is first spiked with a known quantity of target analytes, and then carried through the entire sample preparation and analysis process. The sample from which the portion to be spiked was taken must shall be analyzed separately to determine endogenous background analyte concentrations. The MS is corrected for background concentrations and used to determine whether or not the sample matrix affects the sample results.
- 1.2.81 **Matrix Spike Duplicate (MSD)** The term "matrix spike duplicate (MSD)" means second portion of actual sample used to prepare the MS that is spiked and processed in the same manner as the MS. The MS and MSD are used together to measure the precision of the methodology.
- 1.2.82 **Mature Cannabis Plant** The term "mature cannabis plant" means a cannabis plant that is flowering.
- 1.2.83 **M.D.** The term "M.D." means a Doctor of Medicine. Also includes M.D. as an abbreviation.
- 1.2.84 MDOR The term "MDOR" means the Mississippi Department of Revenue, the agency which that has the responsibility of licensing and regulating cannabis dispensaries.

- 1.2.85 Media The term "media" shall mean the communication channels through which we disseminate news, movies, education, promotional messages, and other data. It includes, but is not limited to, physical and online newspapers and magazines, television, radio, billboards, telephone, internet, fax, social media and billboards.
- 1.2.84 **Medical Cannabis** The term "medical cannabis" means cannabis and cannabis products and edible cannabis that are intended to be used by registered qualifying patients as provided in this chapter the Act.
- 1.2.86 **Medical Cannabis Establishments** The term "medical cannabis establishments" shall mean a cannabis cultivation facility entity, cannabis processing facility entity, cannabis testing facility entity, cannabis transportation entity, cannabis disposal entity, cannabis research facility entity licensed and registered by MS State Department of Health (the Department) or Mississippi Department of Revenue (MDOR). Medical Cannabis Establishments may also be known as licensed entities, licensees, or establishments.
- 1.2.87 Medical Cannabis Establishment AgentRepresentative The term "medical establishment representative" means an owner holding a 10% or greater economic interest, officer, board member, employee, volunteer or agent of a medical cannabis establishment. This term also includes independent contractors who perform services for a medical cannabis establishment if the establishment controls what will be done and how it will be done, including independent contractors and volunteers. Control can include, but isn't limited to, instructions on how work is to be done, direction on equipment to use to perform work, and training on required policies and procedures of the licensed business establishment. All medical cannabis establishment agents must possess a work permit.

"Medical Cannabis Establishment Employee" means anyone who performs services for the medical cannabis establishment if the establishment controls what will be done and how it will be done, including independent contractors and volunteers. Control can include, but isn't limited to, instructions on how work is to be done, direction on equipment to use to perform work, and training on required policies and procedures of the

medical cannabis establishment.

- 1.2.88 **Medical Cannabis Dispensary** The term "medical cannabis dispensary" means an entity licensed and registered with the MS Department of Revenue that acquires, possesses, stores, transfers, sells, supplies, or dispenses medical cannabis, equipment used for medical cannabis, or related supplies and educational material to cardholders. The terms "dispensary" and "cannabis dispensary" also have the same meaning.
- 1.2.89 **Medical Cannabis Transportation Entity** The term "medical cannabis transportation entity" or "cannabis transportation entity" means an entity licensed and registered with the Mississippi State Department of Health that acquires, possesses, stores, transfers, and transports cannabis and/or cannabis products to other medical cannabis establishments licensed by the Mississippi State Department of Health and/or Mississippi Department of Revenue. The term "transporter" may also be utilized to describe these entities.
- 1.2.90 **Method Blank** The term "method blank" means an analyte free matrix to which all reagents are added in the same volumes or proportions as used in the sample preparation and is processed in exactly the same manner as the samples.
- 1.2.91 **Micro-cultivation Facility** The term "micro-cultivation facilities entity" means an entity licensed and registered with the Mississippi State Department of Health that produces (e.g., acquires, grows, cultivates, and harvests) medical cannabis in an indoor, enclosed, locked, and secure area. Micro-cultivation facilities entities are owned by individuals who have been residents of the State Mississippi for three consecutive years prior to date of application to the Department and entities with equity ownership held by individuals who have been residents of the State of Mississippi for three consecutive years prior to the date of application to the Department.
- 1.2.92 **Micro-processing Facilities** Entity The term "micro-processing facilities entity" means an entity licensed and registered with the Mississippi State Department of Health that acquires, grows, cultivates, and harvests medical cannabis in an indoor, enclosed, locked, and secure area manufactures cannabis products from unprocessed cannabis. Micro-processing facilities entities are

owned by individuals who have been residents of the State Mississippi for three consecutive years prior to date of application to the Department and entities with equity ownership held by individuals who have been residents of the State of Mississippi for three consecutive years prior to the date of application to the Department.

- 1.2.93 **Mississippi Medical Cannabis Act** The term "Mississippi Medical Cannabis Act" means Senate Bill 2095 passed during the 2022 Regular Session of the Mississippi Legislature and signed by the Governor and any reference to the codified section of the MS Code. The term "the Act" may also be utilized to reference the Mississippi Medical Cannabis Act.
- 1.2.94 **MMCEU** The term "MMCEU" means Mississippi Medical Cannabis Equivalency Unit. One unit of MMCEU shall be considered equal to:
 - A. Three and one-half (3.5) grams of medical cannabis flower;
 - B. One (1) gram of medical cannabis concentrate; or,
 - C. One hundred (100) milligrams of THC in an infused product.
- 1.2.95 **Modification** The term "modification" means changes in structures, processes or activities at a cannabis cultivation facility that will alter the functions of cultivation structures, systems, and/or changes in the physical footprint of the cultivation facility.
- 1.2.96 **Moisture Content** The term "moisture content" means the percentage of water in a sample, by weight.
- 1.2.97 Non-cannabis Waste -The term "non-cannabis waste" means the seeds, roots, stems, stalks and fan leaves (not containing trichomes), that do not contain THC.
- 1.2.98 **Owner** The term "owner" means, except where the context otherwise requires, a direct beneficial owner, including, but not limited to, all persons or entities as follows:
 - A. All shareholders with at least a 10% equity in a corporate entity;

- B. All partners of a general partnership;
- C. All general partners and all limited partners that own an interest in a limited partnership;
- D. All members that own an interest in a limited liability company;
- E. All beneficiaries that hold a beneficial interest in a trust and all trustees of a trust;
- F. All persons or entities that own interest in a joint venture;
- G. All persons or entities that own an interest in an association;
- H. The owners of any other type of legal entity; and,
- I. Any other person holding an interest or convertible note in any entity which that owns, operates, or manages a medical cannabis establishment.
- 1.2.99 **Package** The terms "package" or "packaging" means any container or wrapper that a medical cannabis establishment may use for enclosing or containing cannabis and/or cannabis products, except that "package" or "packaging" shall not include any carry-out bag or other similar container. Packaging is not considered processing.
- 1.2.100 **Percent Recovery** The term "percent recovery" means the percentage of a measured concentration relative to the added (spiked) concentration in a reference material or matrix spike sample. A laboratory shall calculate the percent recovery by dividing the sample result by the expected result then multiplying the quotient by 100.
- 1.2.101 **Permanent** The term "permanent" means a structure that is fixed in place.
- 1.2.102 **Pesticide** The term "pesticide" means any substance or mixture of substances (organic or conventional) intended for preventing, destroying, repelling, or mitigating any pest, or any substance or mixture of substances intended for use as a plant regulator, defoliant or desiccant. "Pesticide" shall not include any article that is a "new animal drug" as designated by the United States Food and Drug Administration.

- 1.2.103 **Physical Plant** The term "physical plant" means the necessary infrastructure used in the operations and maintenance of a cannabis cultivation facility. In addition to the buildings and facilities in which <u>commercial</u> cannabis <u>related</u> activities <u>are confined</u>, the physical plant also includes the mechanical systems (lighting, ventilation, plumbing, heating and cooling, etc.) <u>necessary</u> to support operations. The actual cannabis plant(s) are not included in this definition.
- 1.2.104 Plant Batch The term "plant batch' is a batch of identical immature plants logged into the seed-to-sale system as a group on the date received as clones or planted, whichever is earliest, and prior to maturing to the vegetative phase of growth.
- 1.2.105 **Plant Growth Regulator Cannabis** The term "plant growth regulator cannabis" shall mean a cannabis plant whose growth and structure has been modified using plant growth hormones. A cannabis processing facility shall not process and/or manufacture plant growth regulator cannabis.

Plant Waste The term "plant waste" includes the seeds, roots, stems, stalks and fan leaves (not containing trichomes), that do not contain THC that shall be rendered unrecognizable via composting and disposal of by the cultivation licensees while under direct video surveillance. Products and inventory from medical cannabis establishments that may be destroyed and/or rendered unrecognizable and unusable through disposal as a result of Department corrective and/or administrative actions.

1.2.106 **Practitioner** — The term "practitioner" means a physician (MD/DO), certified nurse practitioner, physician assistant or optometrist who is licensed to prescribe medicine under the licensing requirements of their his/her respective occupational boards and the laws of this state. In relation to a nonresident cardholder, the term means a physician (MD/DO), certified nurse practitioner, physician assistant or optometrist who is licensed to prescribe medicine under the requirements of their his/her respective occupational boards and under the laws of the state or territory in which the nonresident patient resides. For registered qualifying patients who are minors, "practitioner" shall mean a physician (MD/DO) who is licensed to prescribe medicine under the licensing requirements of their his/her respective occupational boards and the laws of this state.

1.2.107 **Principal Officer** — The term "principal officer" means persons who have ultimate responsibility for implementing the decisions of the cannabis testing facility entity and, include but are not limited to, the Chief Executive Officer, Chief Administrative Officer, and Chief Financial Officer, as applicable.

Process Lot <u>The term "process lot"</u> means any amount of cannabinoid concentrate or extract of the same type and processed at the same time using the same extraction methods, standard operating procedures and from the same batch of batches harvested medical cannabis.

- 1.2.108 Production Batch The term "production batch" means a specifically-identifiable quantity of cannabis products (e.g., cannabinoid concentrate or extract, infused, edible, or topical) that are processed in one production cycle using either the same extraction methods, manufacturing methods, or formula and the same standard operating procedures. Production batches shall be utilized: (1) each time a product changes form physically or chemically; (2) each time a product changes item category; (3) when multiple item categories are combined; and/or (4) anytime an additive, lipid, flavoring, or terpene is added to any cannabis product. Production batches identify when a cannabis product undergoes processing from item category to another and the new product requires a new set of compliance tests in final form.
- 1.2.109 **Proficiency Test** The term "proficiency test" means an evaluation of a laboratory's performance against pre-established criteria by means of interlaboratory comparisons of test measurements.
- 1.2.110 **Proficiency Test Sample** The term "proficiency test sample" means a sample that is prepared by a party independent of the testing laboratory with the ISO/IEC 17043 accreditation, where the concentration and identity of an analyte is known to the independent party but is unknown to the testing laboratory and testing laboratory employees.
- 1.2.111 **Program** The term "program" means the Mississippi Medical Cannabis Program.

- 1.2.112 **Provisional License** The term "provisional license" means a license issued by the Mississippi State Department of Health when a temporary condition of non-compliance with the regulations contained in this Part exists. A provisional license shall be issued only if the Mississippi State Department of Health is satisfied that preparations are being made to qualify for a regular license and that the health and safety of patients and the public will not be endangered. Business activities and operations can be limited by the Department for this licensure category.
- 1.2.113 **Public Place** The term "public place" means a church or any area to which the general public is invited or in which the general public is permitted, regardless of the ownership of the area, and any area owned or controlled by a municipality, county, state or federal government, including, but not limited to, streets, sidewalks or other forms of public transportation. Such term shall not mean a private residential dwelling.
- 1.2.114 Raw Pre-Roll The term "raw pre-roll" means a medical cannabis product that is produced by rolling, filling, or stuffing harvested cannabis flower, shake, and/or trim into paper, leaves or an equivalent wrapper and is intended for consumption by inhalation.
- 1.2.115 **Registry Identification Card** The term "registry identification card" means a document issued by the Department that identifies a person as a registered qualifying patient, nonresident registered qualifying patient or registered designated caregiver.
- 1.2.116 **Regular License** The term "regular license" means a license issued by the Mississippi State Department of Health when there is evidence of compliance with all applicable rules and regulations in this Part and components of the Mississippi Medical Cannabis Act.
- 1.2.117 Research and Development Testing The term "research and development (R&D) testing" means optional testing performed before final compliance testing.

- 1.2.118 **Residency** The term "residency" means a person's dwelling where a person typically stays or stays more often than other locations. Residency may be determined by the Department with submission of two (2) of the following: Mississippi Tax Return Form 80-105; ownership, lease or rental documents for primary residence; utility bills (electric, water, gas bills) for primary residence; and/or vehicle registration.
- 1.2.119 **Revocation** The term "revocation" means the Department's final decision to revoke a license in accordance with Mississippi law.
- 1.2.120 **Restricted Area** The term "restricted area" means a building, room or other contiguous area upon the permitted premises where cannabis is grown, cultivated, harvested, stored, weighed, packaged, processed for sale or sold (to other medical cannabis establishments, not directly to an individual), under control of the licensed cannabis cultivator.
- 1.2.121 Sanitize The term "sanitize" means to adequately treat cleaned equipment, containers, utensils, or any other cleaned contact surface by a process that is effective in destroying vegetative cells of pathogens, and in substantially reducing numbers of other microorganisms, but without adversely affecting the product or its safety for the end-user/consumer.
- 1.2.122 **School** The term "school" means an institution for the teaching of children, consisting of a physical location, whether owned or leased, including instructional staff members and students, and which is in session each school year. This definition shall include, but not be limited to, public, private, church and parochial programs for kindergarten, elementary, junior high and high schools. Such term shall not mean a home instruction program.
- 1.2.123 Scope of Practice The term "scope of practice" means the defined parameters of various duties, services or activities that may be provided or performed by a certified nurse practitioner as authorized under Miss. Code. §§ 73-15-5 and 73-15-20, by an optometrist as authorized under § 73-19-1, by a physician as authorized under § 73-25-33, or by a physician assistant under § 73-26-5, and rules and regulations adopted by the respective licensing boards for those practitioners.

- 1.2.124 **Secure** The term "secure" means protected from danger or risk.
- 1.2.125 **Seedling** The term "seedling" means a cannabis plant that has no flowers.
- 1.2.126 **Seed-to-Sale System** The term "seed-to-sale system" means the specialized inventory management system utilized throughout the medical cannabis program that allows for the tracking of cannabis from early life cycle until final sale to a qualified patient or caregiver or disposal/destruction by <u>a</u> cannabis disposal entity.
- 1.2.127 **THC** The terms "THC" or "Tetrahydrocannabinol" mean any and all forms of tetrahydrocannabinol that are contained naturally in the cannabis plant, as well as synthesized forms of THC and derived variations, derivatives, isomers and allotropes that have similar molecular and physiological characteristics of tetrahydrocannabinol, including, but not limited to, THCA, THC Delta 5, THC Delta 8, THC Delta 10 and THC Delta 6.
- 1.2.128 <u>Tincture</u> The term "tincture" means a liquid edible cannabis product with a concentration of greater than 1 mg of THC per ounce of liquid.
- 1.2.129 <u>Topical Cannabis Product</u> The term "topical cannabis product" means a <u>THC-infused product intended for external application to human body surfaces and/or absorption through the skin, does not cross the blood-brain barrier and is not intended for consumption by oral ingestion.</u>
- 1.2.130 Total CBD The term "Total CBD" means the sum of CBD and CBDA. Total CBD is calculated using the following equation: Total CBD = CBD + (CBDA*0.877).
- 1.2.131 Total THC The term "Total THC" means the sum of THC and THCA. Total THC is calculated using the following equation: Total THC = delta-9 THC + (THCA*0.877).

- 1.2.132 <u>Total Yeast and Mold Count (TYMC)</u> The term "Total Yeast and Mold Count (TYMC)" means the total combined yeast and mold count in standardized planting methodologies and is usually expressed in number of colony forming units (CFU).
- 1.2.133 **Unique Identification Number** The term "unique identification number" means a unique number generated by the seed-to-sale system and assigned to all usable medical cannabis for the purpose of tracking cannabis from early life cycle until final sale to a qualified patient or caregiver or disposal/destruction by a cannabis disposal entity.
- 1.2.134 **Unusable and Unrecognizable** The term "unusable and unrecognizable" means that anything that containsing THC must-shall be destroyed to prevent THC-containing material(s) from being accessed or consumed.
- 1.2.135 **Usable Medical Cannabis** The term "usable medical cannabis" means any medical cannabis product that has completed all required growing/processing steps, is in final form and is intended for sale or distribution and intended for use or consumption by qualifying patients as defined in the Mississippi Medical Cannabis Act. The term "retail-ready medical cannabis" may also be used.
- 1.2.136 **Validation** The term "validation" means the confirmation by examination and objective evidence that the requirements for a specific intended use or analytical method are fulfilled.
- 1.2.137 **Variance** The term "variance" means a Department granted exception to the rules contained in this Part.
- 1.2.138 **Water Activity** The term "water activity" means the measure of the quantity of water in a product that is available and therefore capable of supporting bacteria, yeasts, and fungi and which is reported in units a_w.
- 1.2.139 **Work Permit** The term "work permit" means the official document issued by the Department that authorizes a person to <u>function as</u> a Medical Cannabis Establishment Representative Employee of a Medical Cannabis

Establishment regulated by the Department. All medical cannabis establishment agents must also possess a work permit.

- 1.2.140 **Written Certification** The term "written certification" means a form approved by the Department, signed and dated by a practitioner, certifying that a person has a debilitating medical condition. This written certification may also be referred to as a "practitioner certification".
 - **Severability.** The provisions of this Part are severable. If a court of competent jurisdiction declares any section, subsection, paragraph, or provision unconstitutional or invalid, the validity of the remaining provisions shall not be affected.

Source: Miss. Code Ann. §§ 41-137-1 – 41-137-67.

Subpart 2 Practitioners, Certification, Registration Cards & Caregivers

- 2.1 Types of Medical Cannabis Registries & Fee Types Associated with Registry-and-Associated Fees
- 2.1.1 The following types of medical cannabis registry and registry identification cards (may also be referred to as identification cards or patient cards) will be issued, in a form and manner set by the Department, upon satisfaction of all application criteria:
 - A. Registered Qualifying Patient Identification Card;
 - B. Nonresident Qualifying Patient Identification Card (i.e., temporary patient card or nonresident cardholder); and,
 - C. Registered Designated Caregiver Identification Card.
 - D. Practitioner Registration.
- 2.1.2 At a minimum, identification cards issued by the Department will identify:
 - A. Type of card;
 - B. Valid dates of the card;
 - C. Legal name of the cardholder;
 - D. Date of birth of the cardholder:

- E. Photograph (passport style headshot) of the cardholder;
- F. Unique identification number;
- G. MMCEU limits allotment and limitations; and,
- H. How the card may be verified.
- 2.1.3 The initial fees for Registered Qualifying Patient Identification Card are as follows:
 - A. The standard nonrefundable fee is \$25.00.
 - B. The nonrefundable fee for a 100% disabled veteran or disabled first responder is waived. A disabled veteran or disabled first responder may prove their disability by providing written documentation to the Department from the Social Security Disability Office or documentation that attests the applicant is a 100% disabled veteran as determined by the U.S. Department of Veteran Affairs.
 - C. The nonrefundable fee for a Mississippi Medicaid participant shall be \$15.00. Medicaid status will be verified at the time of application.
 - D. All fees are nonrefundable. Fees must shall be paid in the manner set forth by the Department at the time of application.
- 2.1.4 The renewal fees for Registered Qualifying Patient Identification Cards are as follows:
 - A. The standard nonrefundable fee is \$25.00.
 - B. The nonrefundable fee for a 100% disabled veteran or disabled first responder is waived. A disabled veteran or disabled first responder may prove their disability by providing written documentation to the Department from the Social Security Disability Office or documentation that attests the applicant is a 100% disabled veteran as determined by the U.S. Department of Veteran Affairs.
 - C. The nonrefundable fee for a Mississippi Medicaid participant shall be \$15.00. Medicaid status will be verified at the time of renewal.
 - D. All renewal fees are nonrefundable. Fees must shall be paid in the manner set forth by the Department at the time of renewal.

- 2.1.5 The initial nonrefundable fees for a Designated Caregiver Registry Identification Card are as follows:
 - A. The standard initial nonrefundable fee is \$25.00.
 - B. The designated caregiver criminal background check nonrefundable fee is \$37.00 to be paid to MSDH the Department for conducting the required background checks.
 - C. All fees are nonrefundable. Fees must shall be paid in the manner set forth by the Department at the time of application.
- 2.1.6 The annual renewal nonrefundable fees for a Designated Caregiver Registry Identification Card are as follows:
 - A. The standard-initial nonrefundable fee is \$25.00.
 - B. The designated caregiver criminal background check nonrefundable fee is \$37.00.
 - C. All fees are nonrefundable. Fees must shall be paid in the manner set forth by the Department at the time of application.
- 2.1.7 Both initial and renewal fees for all medical cannabis identification cards may be waived by the Department in the event of extenuating circumstances approved by the Department.
- 2.2 Registered Qualifying Patient Identification Cards.
- 2.2.1 Registered Qualifying Patient Identification Cards will only be issued by the Department when all application and practitioner certification criteria is are met. Upon issuance of the identification card, the applicant is recognized as a qualified patient, or cardholder, of the medical cannabis program.
- 2.2.2 Registered Qualifying Patient Identification Cards issued by the Department are valid for one (1) year from the date of issuance unless a lesser timeframe is otherwise imposed through the written certification or circumstances determined by the Department.

2.2.3 Utilizing the same process outlined in Rule 2.4.1-2.3.1, Qualified Patients may apply for renewal of their identification card no later than one (1) year from the date of issuance or last renewal of the identification card.

For purposes of renewal, a registered practitioner may conduct a registered cardholder's recertification assessment via telehealth if he/she previously evaluated the registered cardholder in-person.

- When there <u>is</u> a change in the cardholder's name, address, designated caregiver, or if the registered qualifying patient ceases to have his or her diagnosed debilitating medical condition (as determined by the practitioner issuing the patient's written certification) that qualified him/her for the medical cannabis program, the patient is responsible for notifying the Department within twenty (20) calendar days of the change. If the patient is unable to make these notifications, the patient's registered designated caregiver with the program or legal representative shall make these notifications to the Department of on behalf of the patient in the same required timeframes as stated above in this Rule.
- 2.2.5 Reporting of changes required in Rule 2.3.4-2.2.4 must shall be done in a format required by the Department.
- 2.2.6 Registered Qualifying Patient Identification Cards may be denied or revoked for the following:
 - A. The cardholder provided false or incomplete information to the Department during application or renewal;
 - B. The cardholder uses his/her card to obtain medical cannabis or medical cannabis products for another individual; and/or,
 - C. The certifying practitioner has terminated the written certification.
- 2.2.7 In addition to Rule 2.3.6-2.2.6, if the cardholder is under the age of eighteen (18), the Registered Qualifying Patient Identification Card may be denied or revoked if the custodial parent or legal guardian with responsibility for health care decisions doesn't provide written consent to the patient's use of medical cannabis, agree to serve as the patient's designated caregiver; and control the acquisition, dosage and frequency of use of the patient's medical cannabis.

2.3 Application to Participate in the Medical Cannabis Program as a Registered Qualifying Patient

- 2.3.1 To obtain a Registered Qualifying Patient Identification Card, an applicant must shall submit (in a form and manner determined by the Department) the following information:
 - A. Full legal name and any aliases, such as a nickname (e.g., Bill as a nickname for William);
 - B. Date of birth;
 - C. Current physical address;
 - D. Current mailing address;
 - E. Current telephone number and/or email address;
 - F. Identification issued by the State of MS (driver's license, or state-issued ID card issued by the Mississippi Ddepartment of Mmotor Vvehicles);
 - G. Current photograph, meeting the following requirements:
 - 1. clear, color photograph of the head and top of shoulders (headshot);
 - 2. be an image in a .jpg, .png, or .gif digital image format;
 - 3. be taken in the last six months to reflect the applicant's appearance;
 - 4. be taken in front of a plain white or off-white background;
 - 5. be-taken in full-face view directly facing the camera at eye level with nothing obscuring the face;
 - 6. must shall not be digitally enhanced to change the appearance of the applicant (e.g., use of "filters").:
 - H. Written certification (as set forth by the Department);
 - I. Identification card nonrefundable fee (see Rules 2.2.3-2.1.3 and 2.2.4-2.1.4);
 - J. An attestation, signed and dated by the applicant, that the information provided is true and correct;
 - K. An attestation, signed and dated by the applicant, pledging not to divert medical cannabis or medical cannabis products to any individual or entity; and,
 - L. Any other information that may be required by the Department.

- 2.3.2 To obtain a Qualified Patient Identification Card for a Minor (under the age of 18), a legal guardian or custodial parent with responsibility for health care decisions, on behalf of the minor applicant, must shall submit (in a form and manner determined by the Department) the following information:
 - A. The full legal name and aliases, such as a nickname (e.g., Bill as a nickname for William) of the minor applicant;
 - B. The minor applicant's date of birth;
 - C. A copy of the minor applicant's birth certificate;
 - D. A copy of any court orders pertaining to custody of the minor applicant (including, but not limited to custody order through chancery or youth court);
 - E. The minor applicant's current physical address;
 - F. Proof of minor's residency in the State of Mississippi provided by the custodial parent and/ or legal guardian (See Rule 2.4.1 for sources required);
 - G. The minor applicant's telephone number and/or email address if the applicant has a telephone number and/or email address and that telephone number and/or email address is different from one provided by the applicant's parent(s) or legal guardian(s);
 - H. The full legal name(s) of the minor applicant's parent(s) or legal guardian(s);
 - I. The date(s) of birth of the minor applicant's parent(s) or legal guardian(s);
 - J. The current physical address(es) of the minor applicant's parent(s) or legal guardian(s);
 - K. The current telephone number(s) and/or email address(es) of the minor applicant's parent(s) or legal guardian(s);
 - L. Identification issued by the State of MS (if applicable based on minor applicant) MS (driver's license, or state issued ID card issued by the Mississippi Ddepartment of Mmotor Vvehicles);
 - M. Current photograph of minor applicant:
 - 1. clear, color photograph of the head and top of shoulders (headshot);
 - 2. be an image in a .jpg, .png, or .gif digital image format
 - 3. be taken in the last six months to reflect the applicant's appearance;
 - 4. be taken in front of a plain white or off-white background;
 - 5. be taken in full-face view directly facing the camera at eye level with

- nothing obscuring the face;
- 6. must shall not be digitally enhanced to change the appearance of the applicant (e.g., use of "filters");
- N. Written certifications (as set forth by the Department);
- O. Identification card <u>nonrefundable</u> fee (see Rules 2.2.3 2.1.3 and 2.2.4 2.1.4);
- P. An attestation that the information provided is true and correct;
- Q. Parental or legal guardian consent for the minor to participate in the medical cannabis program;
- R. An attestation, signed and dated by the applicant and parent(s)/legal guardian(s), pledging not to divert medical cannabis or medical cannabis products to any individual or entity; and,
- S. Any other information that may be required by the Department.
- 2.3.3 To obtain a Registered Qualifying Patient Identification Card for an individual age eighteen (18) to twenty-five (25), an applicant shall submit (in a form and manner determined by the Department) the following information:
 - A. Full legal name and any aliases, such as a nickname (e.g., Bill as a nickname for William);
 - B. Date of birth;
 - C. Current physical address;
 - D. Current mailing address;
 - E. Current telephone number and/or email address;
 - F. <u>Identification issued by the State of MS (driver's license or ID card issued by the Mississippi Department of Motor Vehicles);</u>
 - G. Current photograph, meeting the following requirements:
 - 1. clear, color photograph of the head and top of shoulders (headshot);
 - 2. in a .jpg, .png, or .gif digital image format;
 - 3. taken in the last six months to reflect the applicant's appearance;
 - 4. taken in front of a plain white or off-white background;
 - 5. taken in full-face view directly facing the camera at eye level with nothing obscuring the face;
 - 6. shall not be digitally enhanced to change the appearance of the applicant

(e.g., use of "filters").;

- H. Written certification shall meet the following conditions:
 - i. The debilitating condition is confirmed by two practitioners from separate practices after an in-person consultation (this is not required if the person is homebound or had an identification card before the age of 18); and,
 - ii. One of the practitioners shall be a physician (MD/DO).
- I. Identification card nonrefundable fee (see Rules 2.1.3 and 2.1.4);
- J. An attestation, signed and dated by the applicant, that the information provided is true and correct;
- K. An attestation, signed and dated by the applicant, pledging not to divert medical cannabis or medical cannabis products to any individual or entity; and,
- L. Any other information that may be required by the Department.
- 2.3.4 The following limitations apply to resident cardholders:
 - A. A resident card is valid for a maximum of one (1) year from the date of issuance of the card;
 - B. A maximum of six (6) MMCEUs of medical cannabis in a week can be dispensed to a resident cardholder;
 - C. A maximum of twenty-four (24) MMCEUs of medical cannabis in a thirty (30) day period can be dispensed to a resident cardholder; and
 - D. A maximum of twenty-eight (28) MMCEUs is the possession limit for resident cardholders.

2.4 Nonresident Qualifying Patients (i.e., Nonresident Cardholders).

- 2.4.1 In order to participate in the program as a nonresident cardholder the following conditions must shall be met:
 - A. The individual has been diagnosed with a debilitating medical condition by a practitioner (licensed to prescribe medicine under the respective occupational board of the state of residence) in his or her respective state of residence;
 - B. The individual is not a resident of the State of Mississippi or has been a

- resident of the State of Mississippi for less than 45 days;
- C. The individual has an active identification card for the use of medical cannabis in his/her state of residence; and,
- D. The individual has met the application criteria in Rule 2.5.2 2.4.2 below.
- 2.4.2 To obtain a Nonresident Qualifying Patient Identification Card, an applicant must shall submit (in a form and manner determined by the Department) the following information:
 - A. Full legal name and any aliases, such as a nickname (e.g., Bill as a nickname for William);
 - B. Date of birth;
 - C. Current physical address and mailing address;
 - D. Current telephone number and/or email address;
 - E. Identification issued by the applicant's state of residence (driver's license, or state-issued ID card issued by the department of motor vehicles);
 - F. Current photograph
 - 1. clear, color photograph of the head and top of shoulders (headshot);
 - 2. be an image in a .jpg, .png, or .gif digital image format;
 - 3. be taken in the last six months to reflect the applicant's appearance;
 - 4. be taken in front of a plain white or off-white background;
 - 5. be taken in full-face view directly facing the camera at eye level with nothing obscuring the face;
 - 6. must shall not be digitally enhanced to change the appearance of the applicant (e.g., use of "filters");
 - G. Proof of active (current) participation in the medical cannabis program of the individual's state of residence (as set forth by the Department); consisting of the following:
 - 1. A practitioner's statement confirming that the patient has a debilitating medical condition; and
 - 2. <u>Documentation demonstrating that the nonresident cardholder is allowed to possess medical cannabis or cannabis preparations in the jurisdiction where he or she resides;</u>

- H. Identification card nonrefundable fee of \$75.00;
- I. An attestation, signed and dated by the applicant, that the information provided is true and correct;
- J. An attestation, signed and dated by the applicant, pledging not to divert medical cannabis or medical cannabis products to any individual or entity; and,
- K. Any other information that may be required by the Department.
- 2.4.3 In compliance with Rule 2.5.2 2.4.2 above, an individual seeking to participate in the program as a nonresident cardholder may apply to receive his/her nonresident identification card up to thirty (30) days before arriving in Mississippi.
- 2.4.4 The following limitations apply to nonresident cardholders:
 - A. A nonresident card is valid for a maximum of two (2) may be approved by the Department and issued to a nonresident cardholder twice during any 365-day period, for a maximum each period of fifteen (15) day period consecutive days in a 365-day year from the date of issuance of the card;
 - B. The first consecutive fifteen (15) day period is the initial approval period;
 - C. The second consecutive fifteen (15) day period is the renewal approval period;
 - D. A maximum of six (6) MMCEUs of medical cannabis in a can shall be dispensed per week to a nonresident cardholder;
 - E. A maximum of twelve (12) MMCEUs of medical cannabis ean shall be dispensed to a nonresident cardholder in a consecutive fifteen (15) day period; and
 - F. A<u>The</u> maximum possession limit for nonresident cardholders <u>shall be</u> is fourteen (14) MMCEUs.

2.5 Registered Designated Caregiver Identification Cards.

2.5.1 Registered Designated Caregiver Identification Cards will only be issued by the Department when all application criteria are met. Upon issuance of the identification designated caregiver card, the applicant is recognized as a designated caregiver to a qualified patient or patients (inclusive of nonresident

patients) of the medical cannabis program. The Department will not issue a designated caregiver identification card before the Department issues the designated caregiver's qualifying patient's identification card.

- 2.5.2 Caregiver applicants are prohibited from having a disqualifying felony offense.
- 2.5.3 Caregivers must-shall be at least twenty-one (21) years of age unless the person is the parent or legal guardian of each the qualifyinged patient cardholder that the designated caregiver he/she assists.
- 2.5.4 Registered Designated Caregiver Identification Cards issued by the Department are valid for one (1) year from the date of issuance or lesser timeframe if assisting a nonresident patient.
- 2.5.5 Utilizing the same process outlined in Rule 2.5.2 2.4.2, Caregivers may apply for renewal of their identification card no later than one (1) year from the date of issuance or last renewal of the Caregiver Identification Card.
- 2.5.6 Caregiver Identification Cards may be suspended or revoked for the following:
 - A. The caregiver provided false information to the Department;
 - B. The caregiver uses his/her card to obtain medical cannabis for an individual who has not designated them as their caregiver or who is not a qualified patient; and/or,
 - C. The caregiver uses the medical cannabis of the patient for whom he/she is providing care.
- 2.6 Application to Participate in the Medical Cannabis Program as a Caregiver.
- 2.6.1 To obtain a Registered Designated Caregiver Identification Card, an applicant must shall submit (in a form and manner determined by the Department) the following information:
 - A. Full legal name and any aliases, such as a nickname (e.g., "Bill" as a nickname for "William");

- B. Date of birth;
- C. Current physical address and mailing address;
- D. Current telephone number and/or email address;
- E. Identification issued by the State of Mississippi (driver's license, or state-issued ID card issued by the Mississippi Delepartment of Memotor V-vehicles);
- F. Current photograph, meeting the following requirements:
 - 1. clear, color photograph of the head and top of shoulders (headshot);
 - 2. be an image in a .jpg, .png, or .gif digital image format no larger than 3 mb in size;
 - 3. be taken in the last six months to reflect the applicant's appearance;
 - 4. be-taken in front of a plain white or off-white background;
 - 5. be taken in full-face view directly facing the camera at eye level with nothing obscuring the face;
 - 6. must shall not be digitally enhanced to change the appearance of the applicant (e.g., use of "filters").
- G. Name(s), date(s) of birth, and identification number(s) (if available at the time of application) of the patient(s) they will be providing to whom services to are being provided;
- H. Identification card nonrefundable fee of \$25.00;
- Fingerprints on a fingerprint card or a live scan fingerprint to be submitted to <u>the Department to</u> conduct a <u>state and federal</u> criminal <u>records background</u> check;
- J. Authorization to conduct state and federal criminal records checks:
- K. Caregiver criminal background check nonrefundable fee of \$37.00 paid at the time of application to complete the required background check;
- L. An attestation that the information provided is true and correct;
- M. An attestation, signed and dated by the applicant, pledging not to divert medical cannabis or medical cannabis products to any individual or entity; and,
- N. Designation of Caregiver Form; and,
- O. Any other documentation required by the Department such as an acknowledgement of caregiver responsibilities.

2.6.2 In the event that an applicant is applying to become a registered designated caregiver for a qualified patient who is a minor and the caregiver applicant is not the patient's parent and/or legal guardian, the caregiver applicant must-shall also submit authorization from the patient's parent and/or legal guardian to serve in a caregiver capacity. The form of the authorization may be determined by the Department.

2.7 Application to Obtain a Caregiver Entity Identification Card.

- 2.7.1 The following entities, licensed by the applicable state authority, may facilitate the use of medical cannabis by a qualified patient after registering with the Department as a Caregiver Entity:
 - A. Hospitals;
 - B. Hospice Programs;
 - C. Assisted Living Programs;
 - D. ICF/IDD Institutions:
 - E. Nursing Homes;
 - F. Personal Care Homes;
 - G. Adult day care facilities; and
 - H. Adult foster care facilities.
- 2.7.2 To register as a Caregiver Entity, the facility/program shall submit, in a form and manner determined by the Department, the following information:
 - A. The name, address, and telephone number of the facility/program, as well as the contact information for a primary contact person at that facility/program;
 - B. A copy of the facility/program's current facility license; and,
 - C. An attestation that the information provided is true and correct and must shall be signed and dated by an authorized signatory of the facility/program.
- 2.7.3 The Caregiver Entity shall update the Department with any changes to the facility/program's primary contact person within three (3) business days of the change and shall file a copy of their license(s) each time that license is renewed or updated.

- 2.7.4 A Caregiver Entity identification card shall remain valid unless or until the facility's/program's state license or certification (whichever is applicable) is no longer valid or the registration with the medical cannabis program is suspended, revoked, or restricted by the Department.
- 2.7.5 The Department shall provide a single identification card to a Caregiver Entity. The Caregiver Entity will be notified by the Department of each qualifying patient's designation of that entity as his/her caregiver.
- 2.7.6 <u>Individual</u> caregivers in recognized employed by registered Caregiver Entities are subject to all other Caregiver requirements included in this Part.
- 2.8 Practitioner Certification for Registered Qualifying Patients (Mississippi Residents of MS)
- 2.8.1 A practitioner's written certification (in a manner set forth the by the Department) is required for a person, residing in the State of Mississippi, to apply to become a qualified patient of the Medical Cannabis Program.
- 2.8.2 The purpose of the practitioner certification is to determine and certify that a person suffers from a debilitating medical condition for which the use of medical cannabis may mitigate the symptoms and/or effects.
- 2.8.3 Before issuing a Practitioner Certification for an individual seeking to participate in the medical cannabis program, a Practitioner must shall:
 - A. Have a bona fide practitioner-patient relationship within his/her scope of practice with the individual;
 - B. Examine the individual in person in Mississippi Conduct a physical examination of the individual patient appropriate to confirm the qualifying medical condition. Such examination shall be conducted in person by the practitioner within the state of Mississippi in a clinical setting that allows for complete patient privacy as specified within the parameters of the Health Insurance Portability and Accountability Act; and, at minimum includes,

- 1. <u>Assessment of vital signs (blood pressure, pulse oxygenation, heart rate, respiratory rate, weight, temperature);</u>
- 2. Review of Systems,
- 3. Medication reconciliation;
- 4. Review of MPMP data;
- 5. Complete medical history; and,
- 6. <u>Medical lab tests and screenings (i.e urine drug screen, pregnancy test, blood work)</u> as clinically appropriate; and,
- C. Determine that the individual suffers from a Debilitating Medical Condition for which the use of medical cannabis may mitigate the symptoms and/or the effects.
- 2.8.4 A bona fide practitioner-patient relationship must shall include the following:
 - A. A treatment or consulting relationship between the practitioner and the individual seeking the practitioner certification;
 - B. Assessment of the individual's medical history and current medical condition A practitioner certification is included in the individual's medical record;
 - C. <u>Availability of Tthe practitioner is available</u> to provide follow-up care and treatment, <u>including but not limited to the development of a treatment plan</u>, for the individual seeking certification; and,
 - D. Communication, as appropriate, with the individual's treating healthcare providers and signed, dated authorization to release healthcare information from each such treating and/or diagnosing medical provider;
 - E. In the event of a consulting relationship, records procured directly from treating/diagnosing medical practitioner(s); and,
 - F. Any other requirements related to the practitioner's scope of practice put in place by the practitioner's respective occupational/licensing board or the Department.
- 2.8.5 A practitioner certification is valid for twelve (12) months from the date of issueance unless a shorter timeframe is specified by the certifying practitioner.

- 2.8.6 A practitioner certification <u>must_shall</u> not exceed the allowable amount of medical cannabis. A practitioner can place restrictions on the allowable amount of medical cannabis by stating the maximum amount of medical cannabis and/or the method(s) of administration permissible <u>via on</u> the practitioner certification.
- 2.8.7 A practitioner is not required to shall not issue a written certification for andy individual with whom he/she does not have a bona fide practitioner-patient relationship.
- 2.8.8 A practitioner <u>registered to provide written certifications to qualifying patients</u> for the purpose of enrollment in the <u>Program issuing a written certification</u> is prohibited from being a medical cannabis dispensary <u>agentrepresentative</u> or employee.
- 2.8.9 A certification issued for an individual between the ages of eighteen (18) and to twenty-five (25) years old shall must meet the following conditions:
 - A. The debilitating condition is confirmed by two practitioners from separate practices after an in-person consultation (this isn't required if the person is homebound or had an identification card before the age of 18); and,
 - B. One of the practitioners must shall be a physician (MD/DO).
- 2.8.10 A certification issued for a minor (under the age of 18) may only be issued by a physician (MD/DO).
- 2.8.11 A registered practitioner is prohibited from the following:
 - A. Referring patients to a specific medical cannabis establishment;
 - B. Referring patients to a specific caregiver;
 - C. Advertising in medical cannabis establishments; and,
 - D. Issuing <u>a written certification for a qualifying patient</u> while holding a financial interest in any medical cannabis establishment.
- 2.8.12 Prior to issuing a written certification for a qualifying patient for the purpose of enrollment in the Program, a registered practitioner shall:

- A. Determine in his/her professional medical judgment that the patient suffers from a qualifying medical condition, and, if so determined, provide the patient with a certification of that diagnosis;
- B. Advise the qualifying patient, designated caregiver, and/or parent(s), legal guardian(s), or spouse acting as caregiver(s) of the existence of any nonprofit patient support groups or organizations; and,
- C. Provide explanatory information to the qualifying patient regarding the possible risks, benefits, and side effects of medical cannabis and disclose the experimental nature of therapeutic use of medical cannabis.
- 2.8.13 After issuing a written certification to a qualifying patient for purposes of enrollment in the Program, a registered practitioner shall:
 - A. Be available to provide continuing treatment and follow-up care to the qualifying relationship;
 - B. Maintain health records to support certification of the qualifying patient that include, at minimum, his/her name, date(s) of visit and treatment(s), case history as it relates to the qualifying condition, results of any diagnostic test(s) and examination as they relate to the qualifying condition, the diagnosis resulting from examination, and current medications. Such records shall be maintained for a minimum period of seven (7) years from the date of the certification or last appointment but need not be maintained separately from the practitioner's established records for the ongoing medical relationship with the respective patient;
 - C. Make available to the Department, upon request, for viewing and inspection the individual's health records including but not limited to those supporting the certification of his/her qualifying medical condition, to ensure compliance with the Act.
- 2.8.14 After a registered practitioner issues a written certification to a qualifying patient, he/she may assist that patient in applying for a registry identification card via the Department's Licensing Portal.

2.9 Practitioner Registration.

2.9.1 Practitioners-<u>shall register annually with the Department</u> to participatinge in the medical cannabis program with the intent of <u>for purposes of</u> issuing practitioner

<u>written</u> certifications <u>on behalf of qualifying patients</u> <u>must register annually with</u> the Department in order to issue certifications for the medical cannabis program.

- 2.9.2 The collaborating physician (MD/DO), for both physician assistants and certified nurse practitioners, must-shall be registered with the Department in order for the physician assistant or nurse practitioner in collaboration with that physician (MD/DO) to subsequently register with the Department.
- 2.9.3 In order to register with the Department, the practitioner (i.e., applicant) must shall submit the following information in a manner set byto the Department:
 - A. Evidence of unrestricted licensure in Mississippi by the Mississippi State Board of Medical Licensure; Mississippi State Board of Nursing; or Mississippi State Board of Optometry;
 - B. Issue date and expiration date of licensure in Mississippi;
 - C. Area of specialty;
 - D. Physical address of practice;
 - E. Current telephone number and email address;
 - F. Evidence of completion of continuing medical education approved by the Department;
 - G. A waiver, signed and dated by the practitioner, allowing, and authorizing the Department to fully communicate with the Mississippi State Board of Medical Licensure, Mississippi State Board of Nursing; or Mississippi State Board of Optometry and receive licensure information; and,
 - H. If applicable, a disclosure that the applicant An attestation that the applicant has a no direct or indirect familial or financial relationship with or interest in any licensed entity participating in the medical cannabis program establishment.
- 2.9.4 Practitioner Registration may be suspended or revoked for the following:
 - A. The practitioner provided false information to the Department; and/or
 - B. The practitioner is the subject of disciplinary action from the Mississippi State Board of Medical Licensure, Mississippi State Board of Nursing, or Mississippi State Board of Optometry.

2.10 Requirements of Practitioners Participating in the Medical Cannabis Program.

- 2.10.1 Practitioners must shall complete eight (8) hours of initial training related to the use of medical cannabis in order to enroll in the program. Annual training in the amount of five (5) hours related to the use of medical cannabis must shall also be completed in order to annually renew participation in the program. All training must shall be approved by the Department. Failure to meet these training requirements will negatively impact a practitioner's ability to participate in the Program.
- 2.10.2 Practitioners are prohibited from sharing office space with a medical cannabis establishment.
- 2.10.3 Participation in the program does not negate the authority of the Mississippi State Board of Medical Licensure, Mississippi State Board of Nursing or Mississippi State Board of Optometry to investigate practitioners and freely communicate with the Department should those instances occur. Additionally, pPractitioners registered with the Program agree to the additional regulatory requirements related to the MS Medical Cannabis Act and the rules contained in this Part. Practitioners participating in the Program agree that MSDH is authorized to freely communicate with the practitioner's professional licensing board if violations are alleged.
- 2.10.4 Practitioners must shall utilize the Prescription Monitoring Program in order to complete an assessment of the patient prior to issuing an initial or renewal written certification qualifying his/her condition for the medical cannabis program.
- 2.10.5 All patients must shall be advised of their freedom of choice as to the medical cannabis dispensary they wish to utilize. Evidence of this must shall be maintained in the patient's medical record.
- 2.10.6 In addition to the requirements set forth in this Part, practitioners must shall also follow the rules, regulations, and policies set forth by the Mississippi State Board of Medical Licensure, Mississippi State Board of Nursing, or the

Mississippi State Board of Optometry in order to maintain an unrestricted license from the respective licensing boards.

- 2.10.7 A certifying practitioner may determine that a patient no longer meets the requirements related to a debilitating medical condition; no longer believes that the patient receives therapeutic benefit from the use of medical cannabis; or does not believe the patient is using the medical cannabis for medical purposes. The practitioner must-shall notify the Department of that determination and intent to terminate the physician certification. Termination of physician certification renders the patient identification card null and void.
- 2.10.8 Notification of termination of practitioner certification to the Department and patient must shall include, but isn't limited to:
 - A. The practitioner's identification number issued by the MS Medical Cannabis Program;
 - B. The patient's identification number issued by the MS Medical Cannabis Program;
 - C. The reason the certification is being revoked;
 - D. The date of revocation;
 - E. The signature of the practitioner;
 - F. The date of notification to the Department;
 - G. The date of notification to the patient; and,
 - H. The official letterhead and/or email account of the practitioner.

2.11 Advertising Restrictions for Registered Practitioners.

- 2.11.1 Advertising for cannabis certification(s) shall be professional in nature and may not be designed in such a way as to suggest that patients will obtain certification regardless of their condition or compliance with the requirements of the Act, or in any way that entices minors.
- 2.11.2 <u>A practitioner or affiliated clinic/entity shall not publish or cause to be published any advertisement that:</u>

- A. Contains false or misleading statements about medical cannabis or about the Program;
- B. Uses colloquial terms to refer to medical cannabis, including but not limited to pot, weed, dope or grass;
- C. States or implies the health care practitioner is endorsed by the Department or by the Program, including use of the Department's Medical Cannabis Program logo;
- <u>D.</u> <u>Includes images of cannabis in its plant or leaf form or of cannabis-smoking paraphernalia; or </u>
- E. Contains medical symbols that could reasonably be confused with symbols of established medical associations or groups.
- 2.11.3 Registered Practitioners authorized by the Department pursuant to this Part or entities acting on their behalf, are prohibited from advertising and marketing in any media, including but not limited to:
 - A. <u>Broadcast or electronic media:</u>
 - 1. Radio
 - 2. Television
 - 3. Unsolicited internet pop-up advertising
 - 4. Social media
 - B. Print media:
 - 1. Newspaper
 - C. Other forms:
 - 1. Mass text/messaging communications
 - 2. Mass email communications
 - 3. <u>Medical cannabis or medical cannabis products shall not be displayed in windows or public view.</u>
 - 4. Advertisement in any manner that can be viewable or otherwise perceived as a public space, including, but not limited to, adopt a highway signs, and electronic interstate signs.
 - 5. <u>Solicited/paid patient and/or caregiver reviews/ testimonies/</u> endorsements.

A practitioner found by the Department to have violated this Part is prohibited from certifying that patients have a qualifying medical condition for purposes of patient participation in the Program. The Department's decision that a practitioner has violated this subdivision is a final decision of the Department.

Source: Miss. Code Ann. §§ 41-137-1 – 41-137-67.

Subpart 3 Medical Cannabis Establishment Licenses, Background Checks, & Work Permits

- 3.1 Application for Medical Cannabis Establishment License.
- 3.1.1 An application and all complete required documentation must be submitted to the Department using its required format and/or system shall be completed by the applicant and submitted to the Department using the Department's Online Licensing Portal.
- 3.1.2 At a minimum, an application for licensure as a medical cannabis establishment must shall include the following:
 - A. The names and other required information for all individuals and legal entities who are applicants;
 - B. The proposed physical location of the cannabis cultivation facility;
 - C. A map or sketch of the premises proposed for licensure, including the defined boundaries of the premises and a scaled floorplan sketch of all enclosed areas with clear identification of the main entrance, walls, all areas of ingress and egress, and all limited access areas. This map must-shall provide accurate measurements that allow the Department, at a minimum, to determine the precise main entrance location in reference to the rest of the premises. This map must-shall also clearly identify the distinct areas utilized for cultivation commercial cannabis activities (i.e., growing, harvesting, <a href="drivation-
 - D. If the application is based on proposed construction not completed at the time of application, the applicant must shall submit construction plans for the proposed building which will be the basis for the application investigation.

These plans must shall, at a minimum, provide accurate measurements that allow the Department to determine the precise main entrance location in reference to the rest of the building. If the application is based on an existing building, photos of the interior, exterior and the surrounding property should be submitted at the time of application;

- E. An operating plan that demonstrates the following at a minimum:
 - 1. The applicant's organization chart;
 - 2. Job descriptions and minimum qualifications for each position;
 - 3. An explanation of whether the applicant has experience operating businesses in highly-regulated industries, including but not limited to the cannabis industry under the laws of Mississippi or any other state or jurisdiction within the United States;
 - 4. Employee training plan; and
 - 5. Hours of operation.
- F. Standard Operating Procedures that demonstrate at a minimum how the applicant's proposed premises and business will comply with applicable laws and rules regarding:
 - 1. Security;
 - 2. Employment practices adhering to state and federal law;
 - 3. Record-keeping systems;
 - 4. Hours of operation;
 - 5. Preventing diversion of cannabis and/or cannabis products;
 - 6. Types and quantities of cannabis products that will be produced at the cannabis cultivation facility;
 - 7. Methods of cultivation or processing planting, harvesting, drying and storage of cannabis and/or cannabis products, as applicable based on category of license applied for;
 - 8. Inventory control and tracking;
 - 9. Procedures for proper labeling and packaging;
 - Transportation of cannabis and/or cannabis products (additional licensure in this Part is required), as applicable based on category of license applied for;

- 11. Disposal of plant waste under direct video surveillance and cannabis waste (additional licensure in this Part is required), as applicable based on category of license applied for Waste disposal; and,
- 12. Recall of cannabis and/or cannabis products;
- G. If the municipality or county where the proposed cannabis cultivation facility will be located has enacted zoning restrictions, a sworn attestation by the applicant certifying that the proposed cannabis cultivation facility is in compliance with the restrictions;
- H. If the municipality or county where the proposed cannabis cultivation facility will be located requires a local registration, license, or permit, then the applicant must shall include a copy of such registration, license or permit issued to the applicant with the application submitted to the Department. If construction is still underway at the time of application, then the applicant shall include a signed attestation containing the following information:
 - 1. A list of all local requirements not yet obtained;
 - 2. Anticipated dates that the applicant will obtain each location registration, license and/or permit;
 - 3. An attestation that acknowledges that the applicant is aware of the outstanding need for local registrations, licenses and/or permits and will provide delinquent documents within 10 business days of their receipt as a condition of licensure;
- I. The names and other required information for all individuals persons, entities or affiliated entities who directly or indirectly own ten percent (10%) or more of the medical cannabis establishment applicant and legal entities (inclusive of the ownership of those entities) with an economic interest in the proposed cannabis cultivation facility entity;
- J. If the applicant is a business entity, the names and other required information for each principal officer and board member of the medical cannabis establishment applying for licensure;
- K. Fingerprint cards or electronic fingerprints collected by a live scan (or like) vendor for any person who directly or indirectly owns ten percent (10%) or more of the medical cannabis establishment applicant applicant's individual owners and/or individuals/entities with economic interest in order to perform a criminal background check to determine whether a disqualifying felony offense is present. The signed and notarized Background Check Affidavit for each applicant should be submitted at the time of application. Other means of accomplishing and documenting required background checks may be

- approved by the Department, in collaboration with the MS Department of Public Safety; and,
- L. Other information that may be required by the Department.
- 3.1.3 All information and documents required by the Department including but not limited to the following must shall accompany an application for registration and licensing as a cannabis testing facility entity:
 - A. Initial applications for regular and/or provisional licensing as a cannabis testing entity shall require:
 - 1. The legal name of the prospective cannabis testing facility entity;
 - 2. The physical address of the prospective cannabis testing entity's facility, which shall not be within one thousand (1,000) feet of the nearest property boundary line of a school, church, or child care facility which exists or has acquired necessary real property for the operation of such facility before the date of the cannabis testing facility application unless the proposed entity has received approval from the school, church or child care facility and received the applicable waiver from the entity that licenses or accredits any such school or child care facility, provided that the main point of entry of the cannabis testing facility is not located within five hundred (500) feet of the nearest property boundary line of any school, church or child care facility;
 - 3. The name of each owner, principal officer, board member, and lab director of the proposed cannabis testing facility entity;
 - 4. An attestation that the information provided to the Department to apply for a cannabis testing facility entity registration and license is true and correct;
 - 5. The signatures of the owners of the cannabis testing facility entity and the technical laboratory director and the date each signed;
 - 6. For each owner:
 - a. An attestation signed and dated by the owner that the owner has not been convicted of an excluded felony offense;
 - b. An attestation signed and dated by the owner that the owner does not have a direct or indirect familial or financial relationship with or interest in a cannabis dispensary, cannabis cultivation facility entity, cannabis processing facility entity, cannabis transportation entity,

- cannabis disposal entity or cannabis research facility entity;
- c. An attestation signed and dated by the owner pledging not to divert cannabis to any individual who or entity that is not allowed to possess cannabis; and,
- 7. Verification for each principal officer or board member that they are at least 21 years of age.
- 8. Verification for each principal officer or board member that they are at least 21 years of age;
- 9. A valid certificate of accreditation, issued by an accreditation body, as defined in this Chapter, that attests to the laboratory's competence to perform testing, including all the required analytes for the relevant test methods:
 - a. Cannabinoids;
 - b. Heavy metals;
 - c. Microbial impurities;
 - d. Mycotoxins;
 - e. Residual pesticides;
 - f. Residual solvents and processing chemicals;
 - g. Terpenoids (if performed); and,
 - h. Foreign Material;
- 10. A copy of the cannabis testing facility's most recent assessment by the laboratory's accreditation body, the laboratory's responses to any findings of non-compliance with standards or recommendations, and the corrective actions taken by the laboratory to address the findings or recommendations;
- 11. Laboratory standard operating procedures for all testing methods;
- 12. Laboratory test method verification and validation documentation for all testing methods, including final data reports approved by the laboratory director, validation material package inserts and all supporting data including instrument raw data and calculation tools;
- 13. Laboratory standard operating procedures for security measures;
- 14. Laboratory standard operating procedures for the sampling of cannabis or cannabis products;

- 15. Laboratory standard operating procedures for the transportation of cannabis or cannabis products;
- 16. Laboratory standard operating procedures for the reporting of test results for cannabis or cannabis products;
- 17. Laboratory standard operating procedures for the disposal of samples, digestates, leachates and extracts or other sample preparation products;
- 18. Copy of an approved waste disposal license issued under this Chapter or an executed contract with an approved waste disposal licensee issued under this Chapter;
- 19. Testing staff initial <u>and/or ongoing</u> demonstration of capability for all applicable tests.
- 20. All completed proficiency testing. For new applications, a testing entity shall successfully analyze one set of proficiency testing samples for all required analytes prior to being licensed.
- B. <u>In addition to the above, applications for renewal of a cannabis testing entity</u> license shall also include:
 - A valid certificate of accreditation, issued by an accreditation body, as defined in this Chapter Part, that attests to the laboratory's competence to perform testing, including all the required analytes for the relevant test methods:
 - a. Cannabinoids;
 - b. Heavy metals;
 - c. Microbial impurities;
 - d. Mycotoxins;
 - e. Residual pesticides;
 - f. Residual solvents and processing chemicals;
 - g. Foreign Material;
 - h. Terpenoids, if performed.
 - 2. A copy of the cannabis testing facility entity's most recent assessment by the laboratory's accreditation body, the laboratory's responses to any findings of non-compliance with standards or recommendations, and the corrective actions taken by the laboratory to address the findings or recommendations;
 - 3. Any new or updated <u>Ll</u>aboratory standard operating procedures for all

testing methods;

- 4. Any new or updated Laboratory test method verification and validation documentation for all testing methods, including final data reports approved by the laboratory director, validation material package inserts and all supporting data including instrument raw data and calculation tools;
- 5. <u>Any new or updated</u> <u>Ll</u>aboratory standard operating procedures for security measures;
- 6. <u>Any new or updated</u> <u>Ll</u>aboratory standard operating procedures for the sampling of cannabis or cannabis products;
- 7. <u>Any new or updated</u> <u>Ll</u>aboratory standard operating procedures for the transportation of cannabis or cannabis products;
- 8. <u>Any new or updated Ll</u>aboratory standard operating procedures for the reporting of test results for cannabis or cannabis products;
- 9. <u>Any new or updated</u> <u>Ll</u>aboratory standard operating procedures for the disposal of samples, digestates, leachates and extracts or other sample preparation products; <u>and</u>,
- 10. Copy of an approved waste disposal license issued under this Chapter or an executed contract with an approved waste disposal licensee issued under this Chapter;
- 11. Testing staff initial demonstration of capability for all applicable tests.
- 3.1.4 The Department will review an application <u>for licensure</u> to determine if it is complete. An application will not be considered complete if the applicant does not provide all information required by the application form, the full application and license fees have not been paid, or all of the additional information required under these rules is not submitted. If items are missing/require correction/require additional information, the Department will send notification to the applicant that the application has been returned for action and provide a description of the <u>requisite</u> information. The applicant will need to resubmit an amended application and/or supporting documents for a license if the application is returned for action.
- 3.1.5 Upon review, the Department may return an application for action, an applicant will have three opportunities for correction. If an applicant is unable to present a

complete and correct application, as determined by the Department, after these three attempts, the application will be denied.

Upon denial, if the entity chooses to apply again, a new application and supporting documents meeting the requirements in of this Subchapter and Subchapter 3 of this Chapter Part must-shall be submitted.

3.1.6 Once all required information is received and the fees have been paid, the Department will send notification to the applicant that it has received a completed application. Once the application has been deemed complete, the Department will review the application and issue a determination within thirty (30) days of receiving the completed application. Applications will be processed in the order in which a completed application is filed by the applicant. Review will be initiated based on the order in which a complete application is filed; however, the duration of the review will depend upon the information provided by the applicant.

3.2 Categories and Fees.

- 3.2.1 <u>Categories of Medical Cannabis Establishment Licenses. The following categories of medical cannabis establishment licenses may be issued by the Department consistent with the Mississippi Medical Cannabis Act:</u>
 - A. Cannabis Cultivation License. Establishments licensed as cannabis cultivation facilities/entities or micro-cultivation facilities may engage in the following commercial cannabis activities: acquisition and possession of medical cannabis, production of cannabis (e.g., grow, cultivate, harvest, dry, cure, trim) in accordance with the rules contained in this Part; storage of cannabis and/or raw pre-roll cannabis products; packaging and labeling of cannabis and/or cannabis products; production of raw pre-roll cannabis products, the sale of cannabis and raw pre-roll cannabis products to medical cannabis establishments authorized by this Part or medical cannabis dispensaries licensed by MDOR. Additionally, establishments licensed as micro-cultivation facilities/entities shall meet the ownership requirement established in Miss. Code § 41-137-35(12).
 - B. Cannabis Processing License. Establishments licensed as cannabis processing facilities/entities or micro-processing facilities may engage in the following commercial cannabis activities: acquisition of cannabis from licensed cultivation and/or micro-cultivation facilities/entities; possession of cannabis with the intent to manufacture cannabis products; manufacture of

- cannabis products from unprocessed cannabis and/or a cannabis extract; storage of cannabis and/or cannabis products, packaging and labeling of cannabis and/or cannabis products, the sale of cannabis products to medical cannabis establishments authorized by this Part or medical cannabis dispensaries licensed by MDOR. Additionally, establishments licensed as micro-processing facilities/entities shall meet the ownership requirement established in Miss. Code § 41-137-35(12).
- C. Cannabis Transportation License. Establishments licensed as cannabis transportation entities may engage in the transportation (e.g., transfer, distribution) and storage of cannabis and/or cannabis products to other licensed medical cannabis establishments authorized by this Part and/or medical cannabis dispensaries licensed by MDOR.
- D. <u>Cannabis Disposal License</u>. <u>Establishments licensed as cannabis disposal entities may engage in the following commercial cannabis activities: disposal or destruction of medical cannabis, cannabis products, and/or cannabis waste.</u>
- E. Cannabis Testing Facility License. Establishments licensed as medical cannabis testing facilities/entities may engage in the following commercial cannabis activities: collection and transportation of medical cannabis test samples, testing of medical cannabis test samples for purposes of analyzing the safety and potency of cannabis and cannabis products.
- F. Cannabis Research License. Establishments licensed as medical cannabis research facilities/entities may engage in the following commercial cannabis activities: acquisition of cannabis or cannabis products from licensed cannabis cultivation facilities and licensed cannabis processing facilities in order to research cannabis, develop best practices for specific medical conditions, develop medicines and provide commercial access for medical use.
- 3.2.2 <u>License Fees.</u> The following nonrefundable fees are required at the time of initial application and renewal:

A. Micro-cultivators.

- 1. Tier 1 (canopy of 1,000 square feet or less) one-time application fee of \$1,500.00. Annual license fee of \$2,000.00.
- 2. Tier II (canopy of more than 1,000 square feet but not more than 2,000 square feet) one-time application fee of \$2,500.00. Annual license fee of \$3,500.00.

B. Cultivators.

- 1. Tier I (canopy of not less than 2,000 square feet but not more than 5,000 square feet) one-time application fee of \$5,000.00. Annual license fee of \$15,000.00.
- 2. Tier II (canopy of not less than 5,000 square feet but not more than 15,000.00 square feet) one-time application fee of \$10,000.00. Annual license fee of \$25,000.00.
- 3. Tier III (canopy of not less than 15,000 square feet but not more than 30,000 square feet) one-time application fee of \$20,000.00. Annual license fee of \$50,000.00.
- 4. Tier IV (canopy of not less than 30,000 square feet but not more than 60,000 square feet) one time application fee of \$30,000.00. Annual license fee of \$75,000.00.
- 5. Tier V (canopy of not less than 60,000 square feet but not more than 100,000 square feet) one time application fee of \$40,000.00. Annual license fee of \$100,000.00.
- 6. Tier VI (canopy of <u>not less than</u>100,000 square feet <u>orbut no</u> more <u>than</u> <u>150,000 square feet with up to two locations</u>) one time application fee \$60,000.00. Annual license fee of \$150,000.00.

C. Micro-Processors.

- 1. Tier 1 (processes less than two thousand (2,000) pounds of dried biomass annually) one-time application fee of \$2,000.00. Annual license fee of \$3,500.00.
- 2. Tier II (processes not less than two thousand (2,000) pounds of dried biomass annually but not more than but less than three thousand (3,000) pounds of dried biomass annually) one-time application fee of \$2,500.00. Annual license fee of \$5,000.00.
- D. Processors. A cannabis processing facility that (processes no less than three thousand (3,000) pounds of dried biomass annually) one time application fee of \$15,000.00. Annual license fee of \$20,000.00.
- E. Transportation Entity. One time application fee of \$5,000.00. Annual license fee of \$7,500.00.
- F. Waste Disposal Entity. One-time application fee of \$5,000.00. Annual license fee of \$7,500.00.
- G. Testing Entity. One-time application fee of \$10,000.00. Annual license fee

of \$15,000.00.

- H. Research Entity. One-time application fee of \$10,000.00. Annual license fee of \$15,000.00.
- 3.2.3 <u>All application and license</u> Ffees must shall be paid in a manner set forth by the Department.
- 3.2.4 The one-time application fee and license fee must-shall be paid in order for the an initial application to be determined complete and move forward in the Department's review.
- 3.2.5 A fee for a status change from provisional license to regular license is not required. The application and license fees must shall be paid as stated in Rules 5.3.1 5.3.3 3.2.2.
- 3.2.6 Should fees be returned to the Department as insufficient; the Department will cease the application review process. The applicant will be notified of the activity and the application will be denied at that time. If a license has been issued when the Department is notified of insufficient funds associated with the payment of fee, the medical cannabis establishment will be notified, and its license will be suspended until the fee payments are remedied. Remediation of the insufficient funds must-shall occur within thirty (30) days.

3.3. Background Checks.

3.3.1 Fingerprinting and criminal history record checks are required for anyone proposed as an owner, officer, director, board member and/or anyone-person with an economic interest of ten percent (10%) or more of-in a medical cannabis establishment.

3.4 Licensure: Regular and Provisional

3.4.1 A license, issued by the Department, shall be obtained for each <u>medical</u> cannabis <u>cultivation business/entity establishment</u> prior to the commencement of any <u>commercial cannabis</u> cultivation activities <u>related to authorized by this Part and the Mississippi Medical Cannabis Act</u>. Activities outside of the authority granted

to medical cannabis establishments by virtue of these rules, licensure and registration with the Department and the Mississippi Medical Cannabis Act may be considered suspected illegal activities and reported to proper authorities as such.

- 3.4.2 All <u>operational medical</u> cannabis <u>testing facilities establishments must-shall</u> be currently licensed and registered by the Department and adhere to all regulations set forth by the Department.
- 3.4.3 To be licensed and registered by the Department, cannabis testing facilities entities must shall be accredited as defined in this Chapter Part.
- 3.4.4 To be licensed and registered by the Department, cannabis testing facilities entities must shall test at least one analyte required by the Department.
- 3.4.5 To maintain an active license and registration certificate, cannabis testing facilities entities must-shall maintain accreditation, as defined in this ChapterPart.
- 3.4.6 Any loss of accreditation status by a cannabis testing <u>facility entity</u> will result in immediate revocation of the license and registration of the cannabis testing facility.
- 3.4.7 Any cannabis testing facility entity that has a license and registration revoked for failure to maintain accreditation, as defined in this Chapter Part, may file a written petition to the Department to reinstate the cannabis testing facilities' registration and entity's license once the cannabis testing facility entity submits proof of accreditation, as defined in the Chapter this Part. A reinstatement of registration or a license is required prior to the cannabis testing facility entity resuming cannabis testing operations.
- 3.4.8 A medical cannabis establishment shall not be within 1,000 feet of the nearest property boundary line of a school, church or child care facility which exists or has acquired necessary real property for the operation of such facility before the date of the medical cannabis establishment application unless the entity has received approval from the school, church or child care facility and received the

applicable waiver from their licensing agency, provided that the main point of entry of the cannabis establishment is not located within five hundred (500) feet of the nearest property boundary line of any school, church or child care facility.

3.4.9 Regular Licensure. A license shall be issued for the specific business/entity identified on the application, and is valid only for the owner, premises and name designated on the application and Department issued license and the location for which it is issued.

Upon issuance of a license, the licensee may begin operations; provided that it may not commence cultivating, producing or dispensing cannabis or cannabis products until it receives a written notice authorizing commencement from the Department, following the Department's initial inspection to determine compliance with this Part.

- 3.4.10 Provisional Licensure. Within its discretion, the Department may issue a provisional license when a temporary condition of non-compliance with the regulations contained in this Part exists. A provisional license shall be issued only if the Department is satisfied that preparations are being made to qualify for a regular license and that the health and safety of patients and the public will not be endangered. The Department identifies opportunities for diversion, such as a lack of plant/package tags and insufficient security measures, as dangers to the health and safety of patients and the public.
- 3.4.11 A provisional license may be issued when the following conditions exist:
 - A. Prior to the medical cannabis establishment's start date of operations and subsequent to meeting the licensure requirements for the development of all required standard operating procedures. The license issued under this provision shall be valid until the issuance of a regular license but shall generally not exceed four (4) months following date of issuance, whichever may be sooner.
 - B. When a temporary issue of non-compliance with these regulations exists that does not endanger the health and safety of patients and the public (at the discretion of the Department). The license issued under this provision shall be valid until the issues of non-compliance are remedied and evidence of compliance is submitted to the Department. The license issued under this provision shall be valid until the issuance of a regular license but shall generally not exceed four (4) months following date of issuance, whichever

may be sooner.

- 3.4.12 Upon acceptance of the <u>a</u> license issued by the Department to operate as a medical cannabis establishment pursuant to this Part and the Medical Cannabis Act, the license holder licensee shall:
 - A. Post the license or permit in a location in the medical cannabis establishment that is conspicuous;
 - B. Comply with the provisions in of the Act and the rules and regulations contained in this Part;
 - C. Comply with directives of the Department including time frames for corrective actions specified in inspection reports, audit reports, notices, orders, warnings, and other directives issued by the Department in regard to the license holder's medical cannabis business or in response to community emergencies;
 - D. Be subject to the administrative, civil, injunctive, and criminal remedies authorized in law for failure to comply with these Rrules in this Part or a directive of the Department, including time frames for corrective actions specified in inspection reports, audit reports, notices, orders, warnings, and other directives; and,
 - E. Bear the financial responsibility for all compliance and inventory tracking obligations and responsibilities set forth in Mississippi statutes and these Rrules in this Part.
- 3.4.13 Cannabis cultivation <u>lL</u>icensees <u>must shall</u> register with the Mississippi Department of Revenue for tax purposes.

3.5 Oversight and Inspections.

- 3.5.1 The physical location of medical cannabis establishments, all general business (inclusive of employee records) of the establishments, all financial records of the establishments, and vehicles utilized to transport cannabis and/or cannabis products (which requires a cannabis transportation entity license) are subject to reasonable inspection by the Department.
- 3.5.2 The Department shall conduct at least one on-site inspection of all medical cannabis establishments. Inspections by the Department may be scheduled or

unannounced but generally shall occur during the reported hours of operation included in the licensee's operating plan submitted as a requisite component of the application for licensure.

- 3.5.3 Cannabis testing facilities are subject to inspection by the Department during business hours, including but not limited to, inspection of the physical cannabis testing facility, interviews of personnel, review, inspection, and audit of records and documents related to the analyses of dispensary samples to verify compliance with this Chapter Part.
- 3.5.4 Medical cannabis establishments <u>licensees</u> must <u>shall</u> cooperate with the Department during any inspections, requests to resolve complaints, requests for information/data, etc. in order to verify compliance with the rules and regulations in this Part, the Mississippi Medical Cannabis Act and any subsequent versions of the rules and regulations in this Part and the Act.
- 3.5.5 If the Department discovers what it reasonably believes to be criminal activity or other violations of Mississippi law during an inspection, the Department may refer the matter to appropriate Mississippi state or local law enforcement or regulatory authorities for further investigation.
- 3.6 Authority Relating to Inspections and Investigations; Administration of Provisions of Program.
- 3.6.1 Except for license information concerning licensed patients, the Department may share confidential information to assist other agencies in ensuring compliance with applicable laws, rules, and regulations.

3.7 Term of License.

3.7.1 Regular licenses <u>issued by the Department under this Part</u> are valid for one year from the date of issuance.

3.8 Renewal of Licensure.

3.8.1 Regular licenses <u>issued by the Department under this Part must be require annual</u> renewaled on an annual basis.

3.8.2 The Department shall send notification to each licensee of the duty to renew <u>at leastno later than sixty (60)</u> days prior to the expiration date of an active license. Notification will be to the <u>email address listed of the primary contact person designated</u> by the licensee on its application or latest renewal, as applicable.

3.8.3 License Renewal Process.

- A. A license issued under this Part may be renewed annually if the medical cannabis establishment:
 - 1. Submits to the Department a renewal application in the manner prescribed by the Department within thirty (30) days prior to the expiration date on the license that includes as applicable:
 - a. Copy of current Certificate of Good Standing from the Mississippi Secretary of State's Office;
 - b. New, updated or revised service agreements;
 - c. Any new or updated Standard Operating Procedures;
 - d. <u>Updated and/or revised diagram of the licensee's premises;</u>
 - e. Copy of licensee's current insurance policy;
 - f. Updated vehicle information (transportation and disposal licensees);
 - 2. Continues to meet all the requirements of this Part; and,
 - 3. The licensee shall s<u>S</u>ubmit<u>s</u> proof that the licensee is still<u>remains</u> in compliance with all requisite local permits and licenses.: and,
 - 4. Submits the renewal fee for the license to the Department as required in Rule 3.2.2.
- B. Before renewing a license, the Department may require further information and documentation and may conduct additional background checks to determine that the licensee continues to meet the requirements of this Part.
- C. A licensee whose license is not renewed shall cease all operations immediately upon expiration of the license, schedule a close out inspection with the Department, and destroy all cannabis and cannabis products in the licensee's possession in a manner approved by the Department.

- 3.8.4 At the time of renewal, the licensee shall ensure that all material changes to the required plans and/or standard operating procedures have been communicated in writing to the Department.
- 3.8.5 An annual inspection by the Department within sixty (60) days prior to expiration of a license issued under this Part may be required at the Department's discretion for renewal of the license.
- 3.8.6 A license may be suspended, revoked, <u>or and</u> shall not be renewed by the Department if:
 - A. Outstanding fines are owed to the Department;
 - B. An owner has been convicted of a disqualifying felony;
 - C. The medical cannabis establishment has not engaged in licensed activity at the licensed premises for a period of one (1) year or more, unless the medical cannabis establishment submits evidence of reasonable justification, including without limitation death, illness, natural disaster, or other circumstances beyond the medical cannabis establishment's control;
 - D. Renewal will result in any person having a direct or indirect ownership or economic interest of greater than ten percent 10% in more than one (1) Mississippi cannabis cultivation facility entity license; more than one (1) Mississippi cannabis processing facility entity license; and more than five (5) Mississippi cannabis dispensary licenses;
 - E. The licensed entity owes delinquent taxes. Applicants who have completed an agreed upon payment plan and/or are following an agreed upon payment plan are not considered to be delinquent;
 - F. The licensed entity no longer meets all eligibility requirements for the issuance of a cannabis cultivation medical cannabis establishment license;
 - G. The licensed entity does not meet regulatory requirements set by the Department; and/or,
 - H. The licensed entity provides of misleading, incorrect, false or fraudulent information.
- 3.8.7 The licensed entity's application for renewal of a medical cannabis establishment license may be denied after consideration by the Department of the licensee's

demonstrated history of violations of these Rrules in this Part. The number and severity of violations will be considered by the Department.

3.8.8 If the license of a medical cannabis establishment expires (by date), isn't renewed, or is suspended or revoked, operations of that establishment that are authorized by rules and regulations in this Part and the MS Medical Cannabis Act must cease as instructed by the Department.

3.9 **Procedure for Termination of License.**

- 3.9.1 <u>Licensees who permanently abandon the licensed premises or otherwise</u> permanently cease all activities relating to the operation of a medical cannabis establishment under its license, whether a result of revocation, voluntary surrender or other reasons, shall follow the following procedures for terminating the license:
 - A. Provide written notice of abandoning the licensed premises or ceasing operations at least forty-eight (48) hours in advance to the Department stating the reason for surrender of the license; name(s) and contact information of the person(s) responsible for closing of all business operations; and the address where business records will be retained.
 - B. Provide the Department with a full accounting of all cannabis plants, cannabis and cannabis products located within the licensed premises; and
 - C. <u>Destroy all cannabis plants, cannabis and cannabis products in its possession</u> as instructed by the Department.

The annual licensing fee paid at the time of application is non-refundable. No portion of the annual licensing fee shall be returned to the licensee.

3.10 Transfer of Ownership Requirements.

- 3.10.1 A licensee may transfer ownership interests, including without limitation partial ownership, only after the application for a transfer of an ownership interest has been approved by the Department.
- 3.10.2 An application for the transfer of ownership interests must in a medical cannabis establishment shall:
 - A. Be completed on forms and/or a system made available by the Department;

- B. Be submitted to the Department; and,
- C. Contain all required supplemental information provided by the person or entity seeking to assume an ownership interest, similar to that which is required in an application for a cannabis cultivation license, to demonstrate compliance with all applicable requirements for licensure, including but not limited to fingerprinting and background check requirements.
- 3.10.3 The Department may revoke or suspend a license upon discovery of any effort or attempt to transfer an ownership interest in a license without complying with the requirements of this Part.
- 3.10.4 All information and documents required by the Department, including but not limited to, the following must accompany an application for change of ownership for a cannabis testing facility registration and licensing entity:
 - A. The legal name of the cannabis testing facility entity;
 - B. The name of each principal officer and board member of the cannabis testing facility-entity;
 - C. An attestation that the information provided to the Department regarding the change of ownership for a cannabis testing <u>facility entity</u> is true and correct;
 - D. The signatures of the owners of the cannabis testing <u>facility entity</u> and the technical laboratory director and the date each signed;

E. For each owner:

- 1. An attestation signed and dated by the owner that the owner has not been convicted of an excluded felony offense;
- 2. An attestation signed and dated by the owner that the owner does not have a direct or indirect familial or financial relationship with or interest in a dispensary, cannabis cultivation facility entity, cannabis processing facility entity, cannabis dispensary, cannabis transportation entity, cannabis disposal entity or cannabis research facility entity; and
- 3. An attestation signed and dated by the owner pledging not to divert cannabis to any individual or entity that is not allowed to possess cannabis;

F. Verification for each principal officer or board member that they are at least twenty-one (21) years of age.

3.11 Work Permit Licenses.

- 3.11.1 A medical cannabis establishment <u>representative as defined in this Partemployee</u> shall be registered for and (receive) obtain a work permit license issued by the Department before the individual may work for, <u>volunteer at</u>, or maintain <u>his/her</u> ownership <u>interest of ten percent (10%) or greater</u>, whether direct or indirect, in, a medical cannabis establishment licensed and registered by the Department or MDOR as applicable.
- 3.11.2 An individual possessing a To be eligible to obtain a work permit, an individual shall must be at least twenty-one (21) years of age.
- 3.11.3 An applicant for an initial work permit or renewal of a work permit must shall complete a fingerprint-based background check of the Mississippi Central Criminal Database and the Federal Bureau of Investigation Criminal History Database and must shall not have a disqualifying felony offense.
- 3.11.4 A work permit <u>license</u> shall be valid for five (5) years from the date of issuance by the <u>Department</u>.
- 3.11.5 A medical cannabis work permit shall be the property of the <u>licensed</u> permitted individual and shall not be transferable to others-non-transferrable.
- Anyone holding a valid work permit shall <u>provide written</u> notif<u>yication to</u> the Department within ten (10) business days of a name change and complete a new application as specified in Subchapter 3 of this Chapter.
- 3.11.7 All applicants for a Work Permit and registration must shall complete the application required by the Department and include the all documentation outlined in this Subchapter set forth in this Part, pay the appropriate nonrefundable application and fingerprinting/background fees to the Department, and be registered and issued approved as a valid work permit license-

<u>holder</u> by the Department prior to <u>beginning</u> working <u>at/for</u> a medical cannabis establishment licensed <u>and registered</u> by the Department or the MDOR.

- 3.11.8 All information and documents required by the Department, including but not limited to, the following <u>must shall</u> accompany an <u>initial or renewal</u> application for a medical cannabis <u>employee</u> work permit <u>and registration</u>:
 - A. Digital Photo Current photograph, meeting the following requirements:
 - 1. In Clear, color photograph of the head and top of shoulders (headshot);
 - 2. Passport style In a .jpg, .png, or .gif digital image format;
 - 3. Taken within the last six (6) months to reflect the applicant's appearance of application;
 - 4. Taken in front of a plain white or off-white background;
 - 5. Taken in full-face view directly facing the camera <u>at eye level with</u> <u>nothing obscuring the face</u>;
 - 6. With a neutral facial expression and both eyes open;
 - 7. No hat or head covering that obscures the hair or hairline, unless worn daily for a religious purpose. Full face must shall be visible, and the head covering must shall not cast any shadows on the face;
 - 8. Shall not be digitally enhanced to change the appearance of the applicant (e.g., use of "filters");
 - 9. Other photo requirements as specified by the Department;
 - B. Copy of a current driver's license or state-issued ID card issued by the state department of motor vehicles;
 - C. Copies of all current state issued professional licenses;
 - D. Authorization for the Department to perform a criminal history records check;
 - E. An attestation that the information provided to the Department to apply for a medical cannabis establishment employee work permit and registration is true and correct;
 - F. Fees as required by the Department.
- 3.11.9 Application and Permit Fees: Initial and Renewal. The following nonrefundable

fees are due and payable at the time of initial registration for a work permit and at the time of renewal of such permit:

- A. Medical Cannabis Establishment Work Permit and registration fee of \$25.00.
- B. Fingerprinting and Department background records check fee(s) in addition to the work permit registration fee.
- C. All payments <u>must shall</u> be made through the Department's electronic payment system(s) found on the Department's website.
- 3.11.10

 All applicants renewing a Medical Cannabis Employee Work Permit registration must shall complete the application required by the Department and include the documentation outlined in this Subchapter, pay the appropriate nonrefundable fees to the Department, and be registered and issued hold a valid work permit by the Department.
- 3.11.11 Cannabis testing facilities Medical cannabis establishments shall not employ a medical cannabis establishment agent, any person who has been convicted of a disqualifying felony offense as defined in this Chapter Part.

Renewal Application and Permit Fees:

- 1. Work Permit fee \$25.00, and
- 2. Fingerprinting and Department background records check fee(s) in addition to the work permit registration fee.
- 3. All payments must be made through the Department's electronic payment system(s).
- 3.11.12 The Department may deny an application for <u>registration</u> or renewal of a work permit for any of the following reasons:
 - A. Failure to provide the information required in this Chapter Part;
 - B. Failure to meet the requirements set forth in this Chapter-Part;
 - C. Provision of misleading, incorrect, false or fraudulent information;
 - D. Failure to pay all applicable fees as required; and/or

- E. Any other grounds that serve the purposes of this Chapter Part.
- 3.11.13 If the Department denies an application for <u>registration</u> or renewal of a work permit, the Department shall notify the applicant in writing of the Department's decision, including the reason for denial.
- 3.11.14 If an individual does not complete the annual continuing education requirementsd by this Part, the Department may revoke the individual's work permit or suspend the work permit until such time as the education requirements are completed.
- 3.11.15 The Department may fine, suspend or revoke the work permit issued by the Department for a violation of this Chapter or any rules and or regulations under in this Chapter Part or any disqualifying felony offense.
- 3.11.16 If an applicant for a A medical cannabis work permit applicant or registered permit-holder a medical cannabis establishment employee wishes to appeal a aggrieved by a decision by of the Department to denying, suspending or revokeing registration of a medical cannabis employee work permit or impose ing a fine or other penalty, the applicant for a medical cannabis establishment employee work permit or the medical cannabis establishment employee permit-holder shall-may file an administrative appeal in writing with the Department within twenty (20) days of receipt of the initial notice of the decision. If an applicant for a medical cannabis establishment employee work permit or a medical cannabis establishment employee permit-holder fails to appeal the initial notice within twenty (20) days of receipt of the initial notice, the Department's decision becomes final.
- 3.11.17 The hearing decision of the Department on the denial of an application for registration or renewal of a work permit, or the revocation or suspension of a work permit, is a final decision of the Department.

Any person or entity aggrieved by a final decision of the Department under the provisions of this Chapter Part may petition for judicial review of the decision or order as provided in Section 31 of the Mississippi Medical Cannabis Act Miss. Code § 41-137-59.

Source: Miss. Code Ann. §§ 41-137-1 – 41-137-67.

Subpart 4 Operational & Recordkeeping Requirements

4.1 General.

- 4.1.1 All <u>medical cannabis establishments, including</u> cannabis testing facility laboratory operations, <u>must_shall</u> be physically located within the State of Mississippi.
- 4.1.2 Cannabis cultivation facilities—<u>Licensed medical cannabis establishments</u> may grow—produce and possess usable medical cannabis in an amount reasonably necessary to meet the demand for and needs of qualifying patients as demand and needs may be determined by the Department. At a minimum, the Department will utilize the following data sources to make such determinations: patient registry, medical cannabis establishment licensing data, and data produced by the statewide seed-to-sale system.
- 4.1.3 Cannabis processing facilities entities that process edible cannabis products must shall also comply with any and all Department regulations for Mississippi Food Manufacture and Sale with fees and inspection schedules associated with risk level 4 for the related manufactured food permit.
- 4.1.4 <u>Commencement of Operations.</u> Medical cannabis <u>establishments licensees</u> <u>shallmust</u> notify the Department (in a format approved by the Department) of their intent to commence operations for which authority is granted by the licensure status, along with the date of the commencement. Notification to the Department <u>must-shall</u> include, but is not limited to:
 - A. Verification of an operational alarm and video surveillance system meeting requirements in Rules 5.10.8-4.5.2 and 5.10.9-4.5.3;
 - B. Verification of secure locks throughout the facility;
 - C. Verification of implementation of biosecurity measures;
 - D. Verification of access controls throughout the facility;
 - E. Verification of initial inventory of cannabis and/or cannabis products;
 - F. Verification of functional operation capacity;

- G. Verification of employment records (at the time); and,
- H. Verification of connection to the state's seed-to-sale system.
- 4.1.5 A <u>medical</u> cannabis <u>eultivation</u>—licensee that fails to maintain <u>production</u> <u>operations</u> for any reason for more than six (6) months from the date of licensure after it has <u>begun production commenced business activities</u> shall be notified in writing and given thirty (30) days from the date of notification from the Department to submit a written explanation why it so failed and, if it plans on continuing to operate as a <u>cannabis cultivation</u> licensee, a description of how it will correct the problem and prevent it from occurring again.
- 4.1.6 ALicensed medical cannabis establishments shall only purchase, grow, cultivate, and use cannabis that is grown, cultivated, processed, and dispensed in this state. Any No medical cannabis that is grown, cultivated or processed in this state shall not be transported outside of this state. No cannabis product, containing THC, shall be brought into the State of Mississippi for the purpose of converting, transforming, chemically engineering, or otherwise altering it into a compound or substance which would constitute cannabis and/or a cannabis product under these Rules this Part.

As of July1, 2023cannabis for medical use shall be grown from seeds or plants obtained from a Mississippi licensed cannabis cultivation facility.

4.1.7 A cannabis cultivation facility may Licensed medical cannabis establishments shall not acquire, possess, store, grow, cultivate, or harvest, manufacture, produce, or transport cannabis or cannabis products for any person or entity other than a medical cannabis establishment those authorized by this Part.

4.2 <u>Personnel.</u>

4.2.1 An individual will not be able to shall not begin work at a medical cannabis establishment until after he or she receives obtains a work permit license issued by the Department. An individual is required to renew his or her permit every five (5) years.

- 4.2.2 <u>Medical cannabis establishments licensed under this Part by the Department</u> must shall complete a criminal history background check on each employee to verify that the employee does not have a disqualifying felony.
- 4.2.3 Every medical cannabis licensee shall ensure that any and all persons who are employed by, volunteer for, and/or engaged in activities or operations under the direction of the licensee are qualified to perform their assigned duties.
- 4.2.4 All employees of the <u>a licensed</u> medical cannabis establishment <u>must-shall</u> be entered into the state's seed-to-sale system. <u>Employees must be entered</u> within seven (7) calendar days of their start dates with the <u>employment by the medical cannabis establishment licensee</u>.
- 4.2.5 A cannabis testing facility entity shall not employ an agent or employee individual who also is employed or has ownership at any other medical cannabis establishment other than a licensed cannabis transportation entity. Further, when a cannabis testing entity owns a transport entity or any part thereof, the transport entity cannon have any ownership that creates conflict(s).
- 4.2.6 Qualified lab employees only shall collect and transport samples for testing, etc.

 Transport of non-lab samples such as retail products or products between facilities shall not occurr in the same vehicle at the same timedue to potential cross-contamination issues.
- 4.2.7 Cannabis testing <u>facilities entities</u> shall employ a full-time supervisor or management employee who <u>must-shall</u> be responsible for the following:
 - A. Overseeing and directing the scientific methods of the cannabis testing facility;
 - B. Ensuring that the cannabis testing facility achieves and maintains a cannabis testing facility quality assurance program; and
 - C. Providing ongoing and appropriate training to cannabis testing facility employees.
 - D. To be considered qualified, the supervisor or management employee must shall have at minimum:

- 1. A doctoral degree in biological, chemical, agricultural, environmental, or related sciences from an accredited college or university;
- 2. A master's degree in biological, chemical, agricultural, environmental, or related sciences from an accredited college or university, plus at least 2 years of full-time practical experience;
- 3. A bachelor's degree in biological, chemical, agricultural, environmental, or related sciences from an accredited college or university, plus at least 4 years of full-time practical experience; or
- 4. A bachelor's degree in any field from an accredited college or university, plus at least 8 years of full-time practical experience, four (4) years of which must-shall have been in a supervisory or management position.
- 4.2.8 Cannabis testing facilities entities shall employ a full-time analyst who, at minimum must-shall have:
 - A. Earned a master's degree or a bachelor's degree in biological, chemical, agricultural, environmental, or related sciences from an accredited college or university; or
 - B. Completed 2 years of college or university education that included coursework in biological, chemical, agricultural, environmental, or related sciences from an accredited college or university, plus at least 3 years of full-time practical experience; and
 - C. Demonstrated the analyst's ability to perform a preparation and/or analytical method through:
 - 1. A documented training program that includes a training checklist that is signed by the trainer and the analyst; and
 - 2. A documented attestation that the analyst has read and understands the methods Standard Operating Procedure.
 - D. Demonstrated an initial display of competency prior to analyzing any compliance sample. An initial display of competency for a method includes:
 - 1. Obtaining quality control samples from an outside source or preparing the samples using stock standards that are prepared independently from those used in instrument calibration.
 - 2. Preparing four (4) aliquots at the concentration specified, or if unspecified, to a concentration of one (1) to four (4) times the LOQ for low concentration analytes either concurrently or over a period of days.

- For higher concentration analytes (such as potency), the concentration may be greater than four (4) times the LOQ.
- 3. Analyzing the aliquots either concurrently or over a period of days.
- 4. Using all results, assess the results against established and documented method acceptance criteria
- E. Complete a continuing demonstration of competency annually thereafter for all methods performed. One of the following options must shall be performed and documented:
 - 1. Another initial Ddemonstration of competency (as described above), or
 - 2. Participation in a proficiency test study offered by an ISO/IEC 17043 proficiency test provider (if available); or
 - 3. Analysis of one (1) sample of clean matrix that is fortified with a known quantity of the target analyte, with the result compared to method acceptance criteria.
- F. If an analyst has not run a specific analysis within one calendar year, he or she must shall successfully complete an initial display of competency for this analysis and shall not run such analysis until competency has been demonstrated.
- G. If a method Standard Operating Procedure is significantly amended, an analyst must be retrained on the procedure, and the training documented.
- 4.2.9 <u>Cannabis testing facilities entities shall employ designated sample collector who, at minimum, shall have:</u>
 - 1. <u>documented attestation that the designated sample collector has read and understands the Sampling Standard Operating Procedure;</u>
 - 2. A documented sampling training program that includes principles, procedures, and policies of sampling and was provided by a qualified instructor who has demonstrated competency in performing the sampling methods referenced with all training documented on a training checklist for each sample matrix type that will be collected;
 - 3. At least 8-hours of documented field training on various sampling techniques with a qualified instructor;
 - 4. <u>Documentation of an initial demonstration of capability (IDOC) through</u> the comparison of replicate samples within a defined Relative Standard

- <u>Deviation (%RSD)</u> or the comparison of a sample collected to that of one collected by personnel with an existing IDOC within a defined RPD;
- 5. Thereafter, continuing demonstration of capability (CDOC) is required annually. The cannabis testing entity shall have a documented procedure for performing the CDOC. The cannabis testing entity shall retain documentation verifying CDOC for each designated sample collector and make this documentation available to the Department upon request; and,
- 6. If the Sampling SOP is significantly amended, all designated sample collectors shall be retrained on the procedure, and the training documented.
- 4.2.10 A cannabis testing entity must maintain a master of list of all controlled quality system documents and a signature log that includes the names, initials and signatures for all individuals who are responsible for signing or initialing any cannabis testing entity record.
- 4.2.11 Each <u>licensed</u> medical cannabis establishment is required to create an identification badge for its <u>agents representatives</u>/employees. This badge <u>must shall</u> be conspicuously worn by all <u>agents representatives</u> /employees at all times while they are on the licensed premises or during transport of cannabis and/or cannabis products. <u>Agents Representatives</u>/employees <u>must shall</u> also maintain a copy of the Department issued work permit on their person while present at a medical cannabis establishment.
- 4.2.12 Within thirty (30) calendar days of the date of hire, eultivation facilities must licensed medical cannabis establishments shall ensure all facility employees are trained in at least the following for a minimum of eight (8) hours of initial training and five (5) hours of annual training:
 - A. The rules and regulations applicable to cultivation facilities contained in this Part;
 - B. The use of security measures and controls that have been adopted by the facility for the prevention of diversion, inversion, theft, or loss of cannabis and/or cannabis products;
 - C. Proper use of the statewide seed-to-sale system;
 - D. Response to an emergency, including severe weather, fire, natural disasters,

and unauthorized intrusions; and,

E. The facility's safety and sanitation procedures.

- 4.2.13 <u>Medical cannabis licensees shall take reasonable measures and precautions to ensure the following measures for personnel:</u>
 - A. Disease control. Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of cannabis, cannabis products, components, contact surfaces, or packaging materials becoming contaminated, shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected, unless conditions such as open lesions, boils, and infected wounds are adequately covered (e.g., by an impermeable cover). Personnel shall be instructed to report such health conditions to their supervisors.
 - B. Cleanliness. All persons working in direct contact with cannabis, cannabis products, components, contact surfaces, and packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against allergen cross-contact and against contamination of cannabis or cannabis products. The methods for maintaining cleanliness include:
 - 1. Wearing outer garments suitable to the operation in a manner that protects against allergen cross-contact and against the contamination of cannabis, cannabis products, components, contact surfaces, or packaging materials;
 - 2. Maintaining adequate personal cleanliness;
 - 3. Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate handwashing facility before starting work, after each absence from the workstation, and at any other time when the hands may have become soiled or contaminated;
 - 4. Removing all unsecured jewelry and other objects that might fall into cannabis, cannabis products, components, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which cannabis, cannabis products, or components are manipulated by hand. If such hand jewelry cannot be removed, it may be covered by gloves or material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the cannabis, cannabis products,

- components, contact surfaces, or packaging materials;
- 5. <u>Maintaining gloves</u>, if they are used in handling cannabis, cannabis products, or components, in an intact, clean, and sanitary condition;
- 6. Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints;
- 7. Storing clothing or other personal belongings in areas other than where cannabis, cannabis products, or components are exposed or where equipment or utensils are washed;
- 8. Confining the following to areas other than where cannabis, cannabis products, or components may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco; and
- 9. Taking any other necessary precautions to protect against allergen cross contact and against contamination of cannabis, cannabis products, components, contact surfaces, or packaging materials with microorganisms or foreign substances (including perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin).
- C. Responsibility for ensuring compliance by individuals with the requirements of this subchapter shall be clearly assigned to supervisory personnel who have the education, training, or experience (or a combination thereof) necessary to supervise the production of clean and safe cannabis and/or cannabis products.
- 4.2.14 Cannabis cultivation 1 Licensees shall not permit the consumption of cannabis and/or cannabis products on its licensed premises or by employees during working hours.

4.2.15 Contractors and Other <u>Authorized Visitors.</u>

- A. Contractors and other authorized visitors permitted access to a licensee's premises who will not handle cannabis plants, cannabis or cannabis products, including but not limited to electricians, plumbers, engineers and alarm technicians, do not require an individual identification card issued by the licensed medical cannabis establishment.
- B. A contractor may enter a limited access area only if wearing a visitor identification badge, signed in and recorded on a visitor entry log and prevented from accessing cannabis plants, cannabis or cannabis products.

- 1. If the contractor is working in an area with immediate access to cannabis plants, cannabis or cannabis products, a licensee or employee shall supervise the contractor at all times.
- 2. If the contractor is working in an area in which locked doors, compartments or other physical security measures prevent the contractor from accessing cannabis plants, cannabis or cannabis products, a licensee or employee shall take reasonable precautions to ensure that the contractor remains in such areas and does not attempt to gain access to cannabis plants, cannabis or cannabis products.
- C. At all times while in a limited access area, the contractor shall display in a conspicuous place on their person a visitor identification badge.
 - 1. The visitor identification badge shall display an identifying mark, which may be a clearly identifiable letter, number or symbol or combination thereof.
 - 2. The visitor identification badge may be displayed on a sticker, a card on a lanyard, a card pinned to the clothing of the visitor, or by other effective means.
- D. A visitor entry log shall include, at a minimum:
 - 1. The date and time of the visitor's entry;
 - 2. The date and time of the visitor's departure;
 - 3. The full name of the visitor;
 - 4. The identifying number of the visitor's state- or federally-issued identification;
 - 5. The identifying mark on the visitor identification badge;
 - 6. The individual identification card number of the person who will accompany the contractor, if required, while the contractor is in the limited access areas of the premises; and,
 - 7. The purpose for which the contractor is accessing the limited access area[s].
- E. Any incident of noncompliance with the licensee's authorized conduct that occurred while the contractor or visitor was in a limited access area of the premises shall be reported in writing to the Department within 24 hours, including all information required by the visitor entry log.

4.3 Facility and Grounds.

- 4.3.1 A cannabis cultivation licensee Licensed medical cannabis establishments may be located in any area in a municipality or county that is zoned as agricultural or industrial or for which agricultural or industrial use is otherwise authorized or not prohibited, provided that it being there does not violate any other provision of this Part.
- 4.3.2 A cannabis cultivation licensee Licensed medical cannabis establishments may be located in any area in a municipality or county that is zoned as commercial or for which commercial use is otherwise authorized or not prohibited, provided that the municipality or county has authorized the entity to be located in such area and that it being there does not violate any other provision of this chapter. The municipality or county may authorize this by granting a variance to an existing zoning ordinance or by adopting a change in the zoning ordinance that allows for those entities to be located in specific commercial areas.
- 4.3.3 A municipality or county may require a medical cannabis establishment to obtain a local license, permit or registration to operate, and may charge a reasonable fee for the local license, permit or registration, provided that this fee is consistent with fees charged to businesses that are not involved in the cannabis industry.
- 4.3.4 No individuals may reside at the same address and/or live on the same property where a medical cannabis establishment is located. Should a prospective owner of a medical cannabis establishment reside on an adjoining property, a separate address for the medical cannabis establishment must-shall be obtained from the county (e.g., 123 County Road and 123 A County Road). The medical cannabis establishment must-shall have its own-a separate, independent address from any residential premises.
- 4.3.5 Grounds and Premises. Every licensee shall keep its facility grounds and premises in a condition that will protect against the contamination of cannabis or cannabis products. The methods for adequate maintenance of facility grounds and premises shall include:
 - A. <u>Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the facility that may constitute an attractant, breeding place, or harborage for pests;</u>

- B. <u>Maintaining roads</u>, yards, and parking lots so that they do not constitute a source of contamination in areas where cannabis, cannabis products, or components are exposed;
- C. Adequately draining areas that may contribute contamination to cannabis, cannabis products, or components by seepage, foot-borne filth, or providing a breeding place for pests;
- D. Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where cannabis, cannabis products, or components are exposed; and
- E. If the facility grounds are bordered by grounds not under the licensee's control and not maintained in the manner described in paragraphs (A) to (D), care shall be exercised in the facility by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of contamination.

4.4 Facility Construction and Design.

- 4.4.1 All <u>eultivation commercial cannabis</u> activities <u>must shall</u> take place in indoor, enclosed, locked and secure facilities <u>with no unfiltered air exchange with the outdoors and provides control of environmental conditions such as humidity, temperature, light, and odor. Condition changes outside of the facility should not alter or significantly affect environmental conditions inside the facility. Outdoor cultivation <u>is and processing of cannabis and cannabis products are prohibited.</u>
 "Home grow" of cannabis is prohibited.</u>
- 4.4.2 The licensee's facility shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for purposes of commercial cannabis activities including but not limited to the cultivation, processing, and storage of cannabis and/or cannabis products. The licensee's facility shall:
 - A. Provide adequate space for such placement of equipment and storage of materials as is necessary for maintenance, sanitary operations, and the production (e.g., cultivation, processing, storage) of safe cannabis and cannabis products;
 - B. Permit the taking of adequate precautions to reduce the potential for mix-ups and allergen cross-contact and for contamination of cannabis, cannabis products, components, contact surfaces, or packaging materials with microorganisms, chemicals, filth, and other extraneous material. The potential for allergen cross-contact and for contamination may be reduced by

adequate safety controls and operating practices and effective design, including the separation of operations in which allergen cross contact and contamination are likely to occur, by one or more of the following means: location, time, partition, air flow systems, dust control systems, enclosed systems, or other effective means;

- 4.4.3 Indoor, enclosed, and secure facilities. All <u>eultivation business operations and</u> activities <u>must shall</u> take place within a building or secure structure that meets all state and local electrical, fire, plumbing and building codes and specification(s) in addition to the following requirements:
 - A. Has a complete roof enclosure supported by connecting permanent walls, constructed of solid materials extending from the ground to the roof; that:
 - 1. Provides a sealed environment that prevents unfiltered air exchange with the outdoors;
 - 2. Provides control over the environment (i.e., temperature, humidity, light, carbon dioxide levels, etc.); and,
 - 3. Protects commercial cannabis activities from all external elements;
 - B. Is secure against unauthorized entry;
 - C. Has a foundation, slab, or equivalent base to which the floor is securely attached;
 - D. Has commercial grade door locks on all external doors that are locked at all times;
 - E. Restricts access to only authorized personnel to locked and secure areas identified with signage and daily records of entry and exit;
 - F. Plumbing is adequate to carry sufficient quantities of water to locations through the facility and convey sewage and waste from the facility without cross-contamination of potable water and waste;
 - G. Water supplies should be sufficient for cultivation commercial cannabis activities;
 - H. Toxic cleaning compounds, sanitizing agents, solvents, and pesticides must shall be identified and stored in a manner that is in accordance with applicable local, state or federal law, rule, or regulation; and,
 - I. A pest control and management plan is are implemented on the premises;
 - J. Biosecurity measures are implemented and adhered to at all times.

- 4.4.4 Licensees' facilities shall also be constructed in such a manner that:
 - A. Ensures floors, walls, and ceilings may be adequately cleaned, kept clean, and kept in good repair;
 - B. <u>Prevents drip or condensate from fixtures, ducts, and pipes from contaminating cannabis, cannabis products, components, contact surfaces, or packaging materials; and</u>
 - C. Ensures Aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating cannabis, cannabis products, components, contact surfaces, or packaging materials with clothing or personal contact;
 - D. Provides adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where cannabis, cannabis products, or components are examined, produced, packed, or stored and where equipment or utensils are cleaned;
 - E. Provides shatter-resistant light bulbs, fixtures, skylights, or other glass suspended over exposed cannabis, cannabis products, or components in any step of preparation, or otherwise protect against contamination in case of glass breakage;
 - F. Provides adequate ventilation or control equipment to minimize dust, odors, and vapors (including steam and noxious fumes) in areas where they may cause allergen cross contact or contaminate cannabis, cannabis products, or components;
 - G. Ensures fans and other air blowing equipment are located and operate in a manner that minimizes the potential for allergen cross-contact and for contaminating cannabis, cannabis products, components, contact surfaces, and packaging materials; and,
 - H. Provides adequate screening or other protection against pests.
- 4.4.5 The perimeter of all <u>licensed medical</u> cannabis <u>cultivation licensee must</u> <u>establishments shall</u> be designed and maintained to discourage theft and diversion of cannabis and/or cannabis products. In addition to any local zoning requirements, all cannabis <u>cultivation</u> licensees <u>must-shall</u>:

- A. Maintain adequate lighting to facilitate video surveillance at all times (24 hours per day/7 days per week);
- B. <u>Must hH</u>ave landscaping that <u>does not allow for a prevents the concealment</u> <u>of any person(s)</u> <u>or persons to conceal themselves</u> from sight or video surveillance;
- C. Must Shall have fencing that ensures all stages of cultivation physical barriers to secure perimeter access and points of entry onto the premises including but not limited to fencing around the grounds and driveway, that ensures all commercial cannabis activities are not visible or inaccessible to and hidden from view of the public. Fencing shall meet at least the following minimum requirements:
 - 1. <u>Constructed of nine gauge or lower metal chain link fence or another similarly secure material;</u>
 - 2. Measure at least eight feet from the ground to the top, or in the alternative, the fence may measure six feet from the ground to the top with a one-foot barbed wire arm with at least three strands along the entire fence;
 - 3. Securely anchored by steel support posts; and,
 - 4. Have ingress/egress gates that measure at least eight feet from the ground to the top of the entry gate, or in the alternative, the gate may measure six feet from the ground to the top with a one-foot barbed wire arm with at least three strands, and constructed of nine gauge or lower metal chain link fence or a similarly secure material;
- D. Post signage in a conspicuous location at each entrance of the cannabis cultivation facility that reads "PERSONS UNDER 21 YEARS OF AGE NOT PERMITTED ON THESE PREMISES"; and,
- E. Post signage in a conspicuous location at each entrance of the cannabis cultivation facility that reads "THESE PREMISES ARE UNDER CONSTANT VIDEO SURVEILLANCE".
- 4.4.6 Cannabis cultivation licensees shall maintain physical access to the <u>cannabis</u> plant(s) <u>in their possession</u> for safe and easy observation and inventory of each plant group.

Aisles <u>must-shall</u> be open and accessible so as to allow inspection of the plants by the <u>Department</u> and <u>must-shall</u> provide a safe means for access and viewing of plants if plants are located/placed on an upper rack that requires scaffolding or a ladder for viewing.

4.4.7 Separation of Functions. If a medical cannabis establishment is licensed as a cultivation facility entity and processing facility entity with both functions in the same physical space, there must-shall be physical separation between the two by connecting permanent walls, constructed of solid materials extending from the ground to the roof with separate means of entrance and exit.

4.5 Security and Surveillance.

- 4.5.1 Cannabis cultivation facilities <u>Licensees must shall</u> designate a security manager with responsibility for overall facility security to include, but not limited to: adherence to security requirements; conducting semiannual audits of security measures to identify areas of needed improvements/corrective actions; employee training on security measures and controls; and, prevention of diversion/theft of cannabis and/or cannabis products.
- 4.5.2 Alarm Systems. All eannabis cultivation licensees and locations must shall have alarm systems that meet the following:
 - A. Upon attempted—unauthorized entry, or attempted unauthorized entry, the alarm system shall transmit a signal directly to a central protection company or a law enforcement agency that has a legal authority to respond. A designated employee of the cannabis cultivation facility—licensee must-shall also be notified:
 - B. Provide continuous, uninterrupted coverage (24 hours/7 days) for all points of ingress and egress to the facility, including without limitation doorways, windows, loading areas;
 - C. Provide continuous, uninterrupted coverage (24 hours/7 days) of any room with an exterior wall, any room containing cannabis (of any type or stage of growth) and any room used for cannabis—cultivation—production operations and activities of any type;
 - D. Be equipped with failure notification systems to notify the cannabis cultivation facility licensee and law enforcement of any failure in the alarm system; and,
 - E. Have the ability to remain operational during a power outage.

- 4.5.3 Video Surveillance. All cannabis cultivation licensees and locations must shall have video surveillance that meets the following:
 - A. Provide continuous, uninterrupted coverage (24 hours/7 days) for all points of ingress and egress to the facility, including without limitation doorways, windows, loading areas, and parking areas;
 - B. Provide continuous, uninterrupted coverage (24 hours/7 days) of any room with an exterior wall, any room containing cannabis (of any type or stage of growth), and any room used for cannabis cultivation production operations and activities of any type;
 - C. Digital archiving capabilities for a minimum of (120) days;
 - D. On-site and off-site monitoring capabilities;
 - E. At least one on-site display monitor, of at least twelve inches, connected to the system at all times must-shall be available;
 - F. Have the date and time embedded on all surveillance recordings without significantly obscuring the picture; and,
 - G. Use cameras that are capable of recording in both high and low lighting conditions.
 - H. Destruction of all plant waste (as defined in this Chapter Part) must take place under direct video surveillance at all times.
 - I. Have the ability to remain operational during a power outage.
 - J. Licensing entities should undertake a vulnerability assessment of their standby power systems, to include: all system components and hazards likely to impact the facility, conduct a detailed accounting of what electrical devices are and are not supplied by the backup power, identify system that should not go down during a power outage event.
 - K. Licensees should have a backup power system/generator for backup power supply for up to a minimum of forty-eight (48) hours for portions of the facility that should be supplied with standby power during a power interruption. Licensees should have a safe and secure location for a digital back-up archiving system in the facility located in a locked and secure area to prevent any unauthorized access or theft of video/recording system monitors or video footage.

- 4.5.4 Upon request, a medical cannabis establishment must licensees shall make all information related to security alarm systems and video surveillance, monitoring, and recordings available to the Department within the timeframe requested.
- 4.5.5 Cannabis testing facilities Licensed medical cannabis establishments shall notify local law enforcement and the Department of any theft, robbery, break-in, or security breach that occurs on the laboratory's premises, no later than 10 calendar days twenty-four hours after the facilities licensee first becomes aware of the event. The description Notice to the Department shall include at minimum a description of any property that was stolen or destroyed, and the quantity of any usable cannabis that was stolen.

Standard Operating Procedures.

- 4.6.1 <u>Medical cannabis establishment licensees shall establish and maintain on-site</u> written standard operating procedures for the following:
 - A. Securit, which shall include at minimum a description of plans for the use of security personnel, including contractors; the experience or qualifications of security personnel and proposed contractors; security and surveillance features, including descriptions of any alarm systems, video surveillance systems, and access and visitor management systems, along with drawings identifying the proposed locations for surveillance cameras and other security features; plans for the storage of medical cannabis and medical cannabis products, including any safes, vaults, and climate control systems that will be utilized for this purpose;
 - B. Employment practices adhering to state and federal law;
 - C. Record-keeping;
 - D. Preventing the diversion and/or inversion of cannabis and/or cannabis products;
 - E. Types and quantities of cannabis products that will be produced at the cannabis cultivation facility (licensed cultivators, micro-cultivators, processors, and/or micro-processors);
 - F. Methods of cultivation or processing planting, harvesting, drying and storage of cannabis and/or cannabis products (licensed cultivators, micro-cultivators, processors, and/or micro-processors);
 - G. <u>Production of cannabis and cannabis products to include at minimum good</u> manufacturing practices; extraction methods, including intended use and

sourcing of extraction equipment and associated solvents or intended methods and equipment for non-solvent extraction; product formulations; processing procedures;) intended use and sourcing of all non-cannabis ingredients used in the manufacture, production, and creation of cannabis products, including methods to verify or ensure the safety and integrity of those ingredients and their potential to be or contain allergens; in-process control and quality assurance methods; and procedures for operating equipment (licensed cultivators, micro-cultivators, processors, and/or micro-processors, as applicable);

- H. Integrated Pest Management plan;
- I. Inventory control and tracking;
- J. Procedures for proper labeling and packaging;
- K. <u>Transportation of cannabis and/or cannabis products (additional licensure in this Part is required)</u>, as applicable based on category of license applied for;
- L. Waste disposal; and,
- M. Recall of cannabis and/or cannabis products.

4.6.2 Standard operating procedures shall include provisions to ensure that:

- A. <u>The selection, weighing, and measuring of ingredients and the determination of finished yield are reviewed by a second individual;</u>
- B. <u>Major equipment</u>, transfer lines, containers and tanks used for processing, holding, or filling are identified to indicate contents, batch identification, stage of processing, and control status;
- C. There are appropriate measures to prevent contamination with microorganisms, chemicals, filth, or other extraneous material:
- D. There are in-process controls to ensure product uniformity, integrity (for example, in-process batch weights), accurate fill of mixing containers, and adequacy of mixing;
- E. The theoretical yield for a production batch is compared with the actual yield;
- F. The storage and handling of packaging materials that are intended to come into direct contact with the product prevent mix-ups and microbiological or chemical contamination; and
- G. <u>Finished product packages bear permanent, meaningful, unique batch numbers.</u>

4.6.3 <u>Documentation of standard operating procedures shall be sufficient to prevent errors of interpretation and loss of information.</u>

4.7 Health and Safety Standards.

4.7.1 General.

- A. <u>Each licensee shall ensure that all cannabis and cannabis products it dispenses</u> are safe for use or consumption by registered patient cardholders.
- B. Each licensee shall comply with State and county health, safety, and sanitation laws and regulations and will be subject to unannounced inspections to confirm that no health or safety concerns are present which may contaminate the cannabis or cannabis products.
- 4.7.2 General Sanitation Requirements. All <u>cultivation medical cannabis establishment</u> licensees <u>and locations must-shall</u> maintain sanitary conditions <u>at their respective facilities and locations</u> that include the following:
 - A. Any employee who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination for whom there is a reasonable possibility of contact with cannabis and/or cannabis products shall be excluded from any operations which may be expected to result in such contamination until the condition is resolved.
 - B. Hand-washing areas that are adequate and convenient to employees. Hand washing or sanitizing areas shall include running water at a suitable temperature and a sanitary towel service or suitable drying device.
 - C. Any person working in direct contact with cannabis and/or cannabis products shall:
 - 1. Maintain adequate personal cleanliness;
 - 2. Wash hands and exposed portions of his or her arms thoroughly in an adequate hand-washing area before starting work and at any other time when the hands may have become soiled or contaminated, including but not limited to:
 - a. Any time after handling possibly soiled equipment or utensils;

- b. After leaving the initial room in which he or she was working, and before resuming work in any room, including the initial room;
- Litter and waste <u>must shall</u> be properly removed so they do not contribute to potential sources of contamination in areas where cannabis plants <u>or products</u> are located;
- 5. Floors, walls, and ceilings must shall be adequately cleaned and kept in good repair; and,
- 6. There <u>must shall</u> be adequate screen or other protection against the entry of pests.

4.7.3 <u>Sanitary Operations.</u>

- A. General maintenance. Buildings, fixtures, and other physical facilities shall be maintained in a clean and sanitary condition and shall be kept in repair adequate to prevent cannabis or cannabis products from becoming contaminated. Cleaning and sanitizing of utensils and equipment shall be conducted in a manner that protects against allergen cross-contact and against contamination of cannabis, cannabis products, components, contact surfaces, or packaging materials.
- B. Substances used in cleaning and sanitizing; storage of toxic materials.
 - A. Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures shall be free from undesirable microorganisms and shall be safe and adequate under the conditions of use. Compliance with this requirement may be verified by any effective means, including purchase of these substances under a letter of guarantee or certification or examination of these substances for contamination. Only the following toxic materials may be used or stored in a medical cannabis production center:
 - 1. Those required to maintain clean and sanitary conditions;
 - 2. Those necessary for use in laboratory testing procedures;
 - 3. Those necessary for facility and equipment maintenance and operation; and,
 - 4. Those necessary for use in the facility's operations.
- C. Toxic cleaning compounds, sanitizing agents, and pesticide chemicals shall be identified and stored in a manner that protects against contamination of cannabis, cannabis products, components, contact surfaces, or packaging

materials.

- D. Pest control. Pests shall not be allowed in any area of a production center. Guard, guide, or pest-detecting dogs may be allowed in some areas of a production center if the presence of the dogs is unlikely to result in contamination of cannabis, cannabis products, components, contact surfaces, or packaging materials. Effective measures shall be taken to exclude pests from the production and storage areas and to protect against the contamination of cannabis, cannabis products, or components on the premises by pests. The use of pesticides to control pests in the production center is permitted only under precautions and restrictions that will protect against the contamination of cannabis, cannabis products, components, contact surfaces, and packaging materials.
- E. Sanitation of contact surfaces. All contact surfaces, including utensils and contact surfaces of equipment, shall be cleaned as frequently as necessary to protect against allergen cross-contact and against contamination of cannabis, cannabis products, or components.
 - 1. Contact surfaces used for producing and storing cannabis or low-moisture cannabis products or components shall be in a clean, dry, sanitary condition before use. When the surfaces are wet cleaned, they shall, when necessary, be sanitized and thoroughly dried before subsequent use.
 - 2. In wet processing, when cleaning is necessary to protect against allergen cross contact or the introduction of microorganisms into cannabis, cannabis products, or components, all contact surfaces shall be cleaned and sanitized before use and after any interruption during which the contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and contact surfaces of the equipment shall be cleaned and sanitized as necessary.
 - 3. Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) shall be stored, handled, and disposed of in a manner that protects against allergen cross-contact and against contamination of cannabis, cannabis products, components, contact surfaces, or packaging materials.
- E. <u>Sanitation of non-contact surfaces</u>. <u>Noncontact surfaces of equipment used in the operation of a production center shall be cleaned in a manner and as frequently as necessary to protect against allergen cross-contact and against contamination of cannabis, cannabis products, components, contact surfaces,</u>

- and packaging materials.
- F. Storage and handling of cleaned portable equipment and utensils. Cleaned and sanitized portable equipment with contact surfaces and utensils shall be stored in a location and manner that protects contact surfaces from allergen cross-contact and from contamination.
- 4.7.4 <u>Sanitary Facilities and Controls. Each medical cannabis production center shall</u> be equipped with adequate sanitary facilities and accommodations including:
 - A. Water supply. The water supply shall be adequate for the operations intended and shall be derived from an adequate source. Any water that contacts cannabis, cannabis products, components, contact surfaces, or packaging materials shall be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, shall be provided in all areas where required for the production of cannabis and cannabis products, for the cleaning of equipment, utensils, and packaging materials, or for employee sanitary facilities;
 - B. <u>Plumbing. Plumbing shall be of adequate size and design and adequately</u> installed and maintained to:
 - Carry adequate quantities of water to required locations throughout the facility;
 - 2. Properly convey sewage and liquid disposable waste from the facility;
 - 3. Avoid constituting a source of contamination to cannabis, cannabis products, components, water supplies, equipment, or utensils or creating an unsanitary condition;
 - 4. Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor; and
 - 5. Provide that there is not backflow from, or cross-connection between, piping systems that discharge wastewater or sewage and piping systems that carry water for cannabis or cannabis product production;
 - B. <u>Sewage disposal. Sewage shall be disposed of into an adequate sewerage</u> system or disposed of through other adequate means;
 - C. <u>Toilet facilities</u>. <u>Licensees shall provide employees with adequate, readily accessible toilet facilities</u>. <u>Toilet facilities shall be kept clean and shall not be a potential source of contamination of cannabis, cannabis products, and the contamination of cannabis products.</u>

- components, contact surfaces, or packaging materials;
- D. Hand-washing facilities. Licensees shall provide hand-washing facilities designed to ensure that an employee's hands are not a source of contamination of cannabis, cannabis products, components, contact surfaces, or packaging materials, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature; and rubbish disposal. Rubbish shall be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of cannabis, cannabis products, components, contact surfaces, packaging materials, water supplies, and ground surfaces.
- 4.7.5 Each production area <u>designated and/or used for commercial cannabis activities</u> shall be maintained free of debris.
- 4.7.6 Potable water sources must-shall be utilized in processing/ manufacturing of cannabis and/or cannabis products.
- 4.7.7 Equipment and Utensils.
 - A. All equipment and utensils used in production and storage of cannabis or cannabis products shall be so designed and of such material and workmanship as to be adequately cleanable and shall be adequately maintained to protect against allergen cross-contact and against contamination.
 - B. Equipment and utensils shall be designed, constructed, and used appropriately to avoid the contamination of cannabis, cannabis products, or components with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.
 - C. Equipment shall be installed so as to facilitate the cleaning and maintenance of the equipment and of adjacent spaces.
 - D. Contact surfaces shall be corrosion resistant.
 - E. Contact surfaces shall be made of non-toxic materials and designed to withstand the environment of their intended use and the action of cannabis, cannabis products, and components, and, if applicable, cleaning compounds, sanitizing agents, and cleaning procedures.
 - F. Contact surfaces shall be maintained to protect cannabis, cannabis products,

- and components from allergen cross-contact and from being contaminated by any source.
- G. Seams on contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and allergen crosscontact.
- H. Equipment that is in areas where cannabis or cannabis products are produced, packed, or stored and that does not come into contact with cannabis, cannabis products, or components shall be so constructed that it can be kept in a clean and sanitary condition.
- I. Production, conveyance, and storage systems, including gravimetric, pneumatic, closed, and automated systems, shall be of a design and construction that enables them to be maintained in an appropriate clean and sanitary condition.
- J. Each freezer and cold storage compartment used to store cannabis, cannabis products, or components capable of supporting growth of microorganisms shall be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment.
- K. Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in cannabis, cannabis products, or components shall be accurate and precise and adequately maintained, and adequate in number for their designated uses.
- L. Compressed air or other gases mechanically introduced into cannabis, cannabis products, or components or used to clean contact surfaces or equipment shall be treated in such a way that cannabis, cannabis products, or components are not contaminated.
- M. Equipment and utensils used in measuring, mixing, or weighing shall be:
 - 1. Of suitable size and accuracy for measuring, mixing, and weighing operations;
 - 2. Calibrated regularly or checked according to a written standard operating procedure with results documented, where appropriate; and
 - 3. Removed from use if they are defective, do not meet recommended tolerances, or cannot be repaired and calibrated immediately.

4.8 Processes and Controls.

4.8.1 General.

- A. All operations in the production and storage of cannabis, cannabis products, and components shall be conducted in accordance with adequate sanitation principles.
- B. Appropriate quality control operations shall be employed to ensure that cannabis and cannabis products are suitable for human consumption or for topical application to the skin or hair, as applicable, and that packaging materials are safe and suitable.
- C. Overall sanitation of the facility shall be under the supervision of one or more competent individuals assigned responsibility for this function.
- D. Adequate precautions shall be taken to ensure that production procedures do not contribute to allergen cross-contact or to contamination from any source.
- E. Chemical, microbial, or extraneous-material testing procedures shall be used where necessary to identify sanitation failures or possible allergen crosscontact and contamination.
- F. All cannabis, cannabis products, components, and in-process materials that have become contaminated shall be rejected, or if appropriate and allowed under the rules in this Part, treated or processed to eliminate the contamination.

4.8.2 <u>Ingredients.</u>

- A. Ingredients shall be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into cannabis products and shall be stored under conditions that will protect against allergen cross-contact and against contamination and minimize deterioration. Ingredients shall be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying cannabis, cannabis products, or components shall be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying cannabis, cannabis products, or components if it does not cause allergen cross-contact or increase the level of contamination of the cannabis, cannabis product, or component.
- B. <u>Ingredients shall either not contain levels of microorganisms that may render</u> the cannabis product injurious to the health of humans, or they shall be treated during manufacturing operations so that they no longer contain levels that

- would cause the product to be contaminated.
- C. <u>Ingredients susceptible to contamination with aflatoxins or other natural toxins shall not be contaminated before these ingredients are incorporated into a cannabis product.</u>
- D. <u>Ingredients susceptible to contamination with pests, undesirable microorganisms, or extraneous material shall be examined and, based on examination results, shall not be contaminated before these ingredients are incorporated into a cannabis product.</u>
- E. <u>Ingredients shall be stored in bulk or in containers designed and constructed so as to protect against mix-ups, allergen cross-contact, and contamination and shall be stored at such temperature and relative humidity and in such a manner as to prevent the ingredients or cannabis product from becoming contaminated. Material scheduled for reprocessing shall be identified as such.</u>
- F. Frozen ingredients shall be kept frozen. If thawing is required prior to use, it shall be done in a manner that prevents the ingredients from becoming contaminated.
- G. <u>Liquid or dry ingredients received and stored in bulk form shall be stored in a manner that protects against allergen cross contact and against contamination.</u>
- H. <u>Ingredients that are allergens</u>, and rework that contains allergens, shall be identified and stored in a manner that prevents allergen cross-contact.
- I. Water used as an ingredient shall be:
 - 1. Of a defined quality;
 - 2. Unaffected by materials used in the water treatment equipment;
 - 3. Tested or monitored regularly to verify that it meets applicable chemical, physical, and microbiological specifications for quality; and
 - 4. <u>Supplied by a system set up to avoid stagnation and risks of contamination that is routinely cleaned and sanitized according to an appropriate standard operating procedure that ensures no biofilm build-up.</u>

4.8.3 <u>Manufacturing Operations.</u>

A. <u>Equipment</u>, utensils, and containers shall be maintained in an adequate condition through appropriate cleaning and sanitizing, as necessary. Insofar

- as necessary, equipment shall be taken apart for thorough cleaning.
- B. All cannabis and cannabis product production and storage shall be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, allergen cross-contact, contamination, and deterioration.
- C. Components that can support the rapid growth of undesirable microorganisms shall be stored at temperatures that will prevent the component from becoming contaminated during production and storage.
- D. Measures such as sterilizing, irradiating, pasteurizing, cooking, freezing, refrigerating, controlling pH, or controlling a_w that are taken to destroy or prevent the growth of undesirable microorganisms shall be adequate under the conditions of production, storage, and distribution to prevent cannabis, cannabis products, or components from being contaminated.
- E. Work-in-process and rework shall be handled in a manner that protects against allergen cross contact, contamination, and growth of undesirable microorganisms.
- F. Effective measures shall be taken to protect cannabis and cannabis products from allergen cross-contact and from contamination by ingredients, other components, or refuse. When ingredients, other components, or refuse are unprotected, they shall not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in allergen cross contact or contamination of cannabis or cannabis products. Cannabis, cannabis products, or components transported by conveyor shall be protected against allergen cross-contact and against contamination as necessary.
- G. Equipment, containers, and utensils used to convey or store cannabis, components, work-in-process, rework, or other cannabis products shall be constructed, handled, and maintained during production and storage in a manner that protects against allergen cross-contact and against contamination.
- H. Adequate measures shall be taken to protect against the inclusion of metal or other extraneous material in cannabis or cannabis products.
- I. Cannabis, cannabis products, and components that are contaminated:
 - 1. Shall be disposed of in a manner that protects against the contamination of other cannabis, cannabis products, and components; or
 - 2. <u>If the contaminated cannabis, cannabis product, or component is allowed to be reprocessed under the rules in this Part, it may be:</u>

- i. Reprocessed using a method that has been proven to be effective; or
- ii. Reprocessed and reexamined and subsequently found not to be contaminated before being incorporated into other cannabis products.
- J. All operations in the production and storage of cannabis, cannabis products, and components shall be performed so as to protect cannabis, cannabis products, and components against allergen cross-contact, contamination, and growth of undesirable microorganisms. Cannabis, cannabis products, and components shall be protected from contaminants that may drip, drain, or be drawn into them.
- K. Heat blanching, when required in the preparation of cannabis products or components capable of supporting microbial growth, shall be affected by heating the cannabis product or component to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling it or passing it to subsequent manufacturing without delay. Growth and contamination by thermophilic microorganisms in blanchers shall be minimized by the use of adequate operating temperatures and by periodic cleaning and sanitizing as necessary.
- L. Cannabis and cannabis products and components that rely principally on the control of aw for preventing the growth of undesirable microorganisms shall be processed to and maintained at a safe moisture level.
- M. Cannabis products and components that rely principally on the control of pH for preventing the growth of undesirable microorganisms shall be monitored and maintained at a pH of 4.6 or below.
- N. When ice is used in contact with cannabis, cannabis products, or components, it shall be made from water that is safe and of adequate sanitary quality.

4.9 <u>Extraction/Processing.</u>

- 4.9.1 Cannabis processing licensees may utilize chemical extraction processes using a nonhydrocarbon-based, or other solvent such as water, vegetable glycerin, vegetable oils, animal fats, steam distillation, food-grade ethanol. Nonhydrocarbon-based solvents must-shall be food grade.
- 4.9.2 Cannabis processing licensees may use chemical extraction processes using hydrocarbon-based solvents that are at least ninety-nine percent (99%) purity.

- 4.9.3 Extraction processes <u>must_shall</u> take place in an environment with proper ventilation, controlling all sources of ignition where a flammable atmosphere is, or could be, present.
- 4.9.4 Cannabis processing licensees are prohibited from using pressurized canned flammable fuel such as butane intended for use in outdoor/camp like activities, handheld torch devise, refillable cigarette letters, etc.
- 4.9.5 Cannabis processing licensees using carbon dioxide must shall have equipment and facilities approved by local fire code officials, if applicable.
- 4.9.6 Manufacturing processes using flammable gas of or flammable liquid must shall have leak or gas detection measures, or both.

4.10 Storage of Cannabis and/or Cannabis Products.

4.10.1 Storage of cannabis, cannabis products, and components shall be under conditions that will protect against allergen cross-contact and against biological, chemical (including radiological), and physical contamination of cannabis, cannabis products, or components as well as against deterioration of the cannabis, cannabis product, or component and the container.

4.11 General Recordkeeping Requirements.

- 4.11.1 Medical cannabis establishments must shall participate in and utilize the state's seed-to-sale system for inventory control and tracking purposes. All associated costs for their participation are the financial responsibility of the medical cannabis establishments.
- 4.11.2 Medical cannabis establishments are required to maintain the following for a minimum period of five (5) years:
 - A. All books and records necessary to fully account for each business transactions conducted under its license;
 - B. A copy of each transportation manifest for each transport of cannabis and/or cannabis products <u>must_shall</u> be maintained (a separate license as a cannabis transportation entity is required <u>is if</u> cannabis is being transported);

- C. Employment records;
- D. Record of all pesticides and chemical applications to cannabis and/or cannabis products; and,
- E. Records of any theft, loss, or other unaccountability of any cannabis and/or cannabis products.
- 4.11.3 Records of all pesticides and chemical applications to cannabis plants and/or cannabis products must-shall include the following:
 - A. The date of application;
 - B. The name of the individual making the application;
 - C. The product that was applied;
 - D. The section, including the square footage, that receive the application;
 - E. The amount of product that was applied; and,
 - F. A copy of the label of the product that was applied.
- 4.11.4 All records must-shall be maintained on-site or electronically (virtually) and available for Department review at the address of the licensee.
- 4.11.5 All <u>cannabis</u> plants, <u>cannabis</u> and <u>cannabis</u> products <u>must shall</u> be physically inventoried on a weekly basis and records maintained for a minimum of five (5) years. Any removal, <u>including but not limited to disposal or destruction</u>, of <u>cannabis</u> plants, <u>cannabis or cannabis products</u> <u>must shall</u> be recorded.

4.12 Employment Records.

- 4.12.1 A medical cannabis establishment must shall keep an individual employment record for all employees, including, but not limited to:
 - A. Full legal name and any nicknames;
 - B. Detailed job description;
 - C. Record of all training received or acquired by the employee;
 - D. Dates of employment;
 - E. Records of days and hours worked;

- F. Records of time worked; and,
- G. Any disciplinary actions taken.
- 4.12.2 Employment records must shall be maintained, either electronically or in hard copy, for at least five (5) years after the employee's last date of employment with the cannabis cultivation facility.
- 4.12.3 Cannabis testing facilities <u>Licensees</u> shall ensure, document, and provide to the Department upon request, documentation that each medical cannabis establishment <u>agents-representative</u>, as defined by this <u>Chapter-Part</u>, meets the requirements of the Mississippi Medical Cannabis Act, and Department regulations.

4.13 Statewide Seed-to-Sale System and Inventory Control.

- 4.13.1 Cannabis cultivation <u>IL</u>icensees <u>must-shall</u> use the Department designated seed-to-sale system directly for inventory tracking or may use an approved third-party integrator for interface into the Department designated seed-to-sale system.
- 4.13.2 Cannabis cultivation <u>L</u>icensees <u>must-shall</u> identify an employee with primary responsibility for seed-to-sale tracking (e.g., seed-to-sale system administrator).
- 4.13.3 Cannabis Cultivation Licensees must shall ensure that all reporting into the Department approved statewide seed-to-sale system is clear, accurate, and transparent.
- 4.13.4 Cannabis cultivation lLicensees shall ensure its inventories are properly tagged and labeled in any manner which is compatible with the state seed-to-sale tracking program for tracking purposes and such tags may include bar codes, RFID tags, NFC tags, or other equivalent system for assigning unique numbers to cannabis plants, products, and packages:
 - A. Tags <u>must shall</u> contain the legal name and correct license number of the <u>licensed</u> medical cannabis establishment.
 - B. Prior to a <u>cannabis</u> plant reaching a point where it is able to support the weight of a tag (8 inches in height), a tag may be securely fastened to the stalk or

- other similarly situated position approved by the Department. The tag shall remain affixed for the entire life of the plant until disposal.
- C. Cannabis <u>must shall</u> be continuously and properly tagged (individually or as packages) at all stages of <u>production, including all</u> cultivation <u>phases and/or production steps</u>.
- D. Mother plants <u>must_shall</u> be tagged before any cuttings or clones are generated therefrom. <u>Cuttings or clones taken from the mother plant for a plant batch shall be e recorded in the state seed-to-sale program as being <u>derived from that mother plant's tag.</u></u>
- E. If a tag is destroyed, stolen, or falls off of a cannabis plant <u>or package</u>, the licensee <u>must-shall</u> ensure a new tag is placed on the cannabis plant <u>or package</u> and the change is properly reflected in the State seed-to-sale system.
- F. <u>Medical cannabis establishments Licensees</u> shall not reuse any tags that have already been affixed to any cannabis plant or cannabis products.
- G. Each wholesale package of cannabis and/or cannabis products must shall have a tag during storage and transfer and may only contain one batch of cannabis and/or cannabis products. This is inclusive of packages awaiting testing.
- H. Prior to transfer, medical cannabis establishments <u>licensees</u> shall ensure that each immature plant <u>batch is assigned a package tag</u> is properly affixed with a tag if the plant was not previously tagged in accordance with these Rules seed-to-sale system protocol and the rules in this Part.
- I. <u>Medical cannabis establishments Licensees</u>' inventory <u>must shall</u> have a tag properly affixed to all cannabis and/or cannabis products during storage and transfer in one of the following manners:
 - 1. Individual units of cannabis products shall be individually affixed with a tag;
 - 2. Cannabis products may only be combined in a single wholesale package using one tag if all units are from the same production batch.
 - 3. If any cannabis and/or cannabis products are removed from a wholesale package, each individual unit or new wholesale package <u>must-shall</u> be separately tagged.
- 4.13.5 All locations related to cultivation the commercial production of cannabis and cannabis products must shall be easily distinguishable in the statewide seed-to-sale system. Locations identified in the system must shall be designed to easily

<u>and labeled</u> in accordance with the <u>licensee's</u> approved site plan <u>and in a manner</u> that identifies determine the <u>location position</u> of inventory <u>within the facility</u> at all times of the medical cannabis establishment.

Source: Miss. Code Ann. §§ 41-137-1 – 41-137-67.

Subpart 5 PRODUCT TESTING AND SAFETY

5.1 General.

- 5.1.1 Cannabis testing facilities entities shall test for cannabis-related analytes for which they are licensed and registered by the Department.
- 5.1.2 Cannabis testing <u>facilities entities</u> shall develop and implement an employee training program to ensure competency of cannabis testing <u>facility entity</u> employees for their assigned function and shall document each employee's qualifications.
- 5.1.3 A cannabis processing licensee, or any medical cannabis establishment <u>Licensees</u> shall not treat or otherwise adulterate a cannabinoid product, concentrate, cannabinoid extract, or extract with any non-cannabinoid additive that would increase potency, toxicity or addictive potential, or that would create an unsafe combination, with caffeine or other chemical that may increase carcinogenicity or cardiac effects.
- 5.1.4 All edible cannabis products must shall be homogenized to ensure uniform disbursement of cannabinoids throughout the product(s).
- 5.1.5 Cannabis cultivation Every medical cannabis establishment licensees must shall comply with the testing requirements rules and regulations for cannabis and cannabis products in this Partrelated to Cannabis Testing Facilities in Subpart 1: Cannabis Testing Facilities.

5.2 Batch Requirements.

5.2.1 A medical cannabis establishment must shall separate each harvest batch package or production batch package lot of usable medical cannabis into no larger than twenty-five pound (25 lb) batches.

- 5.2.2 Notwithstanding Rule 1.5.1-5.2.1 of this section, a medical cannabis establishment may combine harvest batches packages for purposes of having a batch sampled test sampling if each batch is intended for use by a medical cannabis establishment licensed processing entity to make a cannabinoid concentrate or extract and each harvest lot was:
 - A. Cultivated utilizing the same growing practices and grown in close proximity on the licensed or registered premises;
 - B. Harvested at the same time; and
 - C. If cured prior to sampling, cured under uniform conditions.
- 5.2.3 A medical cannabis establishment may not combine harvest lots into a batch <u>packages</u> for purposes of sampling and testing for THC or CBD.

If harvest lots are combined in accordance with Rule 1.5.2, the batch must be labeled so that it identifies the different harvest lots that were combined.

For all concentrates and extracts, a process lot is considered a batch.

- 5.2.4 A medical cannabis establishment <u>must-shall</u> assign each <u>harvest and production</u> batch a unique batch number <u>as defined in this Part</u> and that unique batch number <u>must-shall</u> be:
 - A. Documented and maintained in the cannabis cultivation facility or cannabis dispensary licensee's records for at least two years and available to the Department upon request;
 - B. Provided to the individual responsible for taking testing samples; and
 - C. Included on the batch label.
- 5.2.5 <u>Batch Production and Distribution Records.</u>
 - A. Production records shall document, for each batch of cannabis or cannabis product:
 - 1. Review of ingredient records to determine if ingredients are adequately controlled;

- 2. <u>Ingredients (name, code, batch number, quantity, etc.) added to the batch;</u>
- 3. Production steps (for example, processing, handling, transferring, holding, and filling);
- 4. <u>In-process sampling, controlling, and adjusting steps;</u>
- 5. Compliance with or deviations from standard operating procedures;
- 6. <u>Detailed description of any deviations from standard procedures, justifications</u> for the deviations, and corrective measures taken;
- 7. Any quality control review and disposition decision and follow-up required by rules in this Part;
- 8. Any remediation carried out under this Part; and,
- 9. Batch number.
- B. Distribution records shall identify, for each batch of cannabis or cannabis product:
 - 1. The product;
 - 2. The batch number;
 - 3. The retail dispensing location; and
 - 4. The date of distribution.
- C. <u>Batch production and distribution records shall be adequate to conduct an effective</u> recall.
- D. <u>Batch production and distribution records shall be established and maintained for a minimum of five (5) years.</u>

5.3 Sample Size, Handling, Storage and Disposal.

5.3.1 Usable medical cannabis may only be sampled only after it is cured, unless the usable medical cannabis is intended for sale or transfer to a medical cannabis establishment to make a cannabinoid concentrate or extract.

An employee of a licensed testing facility will obtain and analyze samples only from usable medical cannabis.

Retail-ready cannabis products shall be sampled and tested in final form in accordance with the rules in this Part.

5.3.2 Sampling must shall be conducted on-site at a the cannabis cultivation facility or dispensary processing-entity's premises.

The testing facility entity personnel shall have access to the entire batch for the purposes of sampling.

All final-form cannabis products shall be in the retail-ready packaging (i.e., sealed vaporization cartridge/pen, gummies in a carton or mylar bag, whole flower in jars, pre-rolls in tubes, bottles of tincture, etc).

5.3.3 <u>Sampling Requirements for Mandatory Testing.</u>

- A. Sampling of medical cannabis product for mandatory testing shall be done by the testing licensee at the harvest batch or production batch level. All samples must be collected, stored, and transported in a way that mitigates contamination and degradation.
- B. Sampling of each harvest batch or production batch shall be conducted with representative samples such that there is assurance that all harvest or process lots are adequately assessed for contaminants and that the cannabinoid profile is consistent throughout.
- 5.3.4 Samples taken must in total represent a minimum of 0.5 percent of the batch and consist of minimally 12 unique increments of 1gram each, with at least 50% of the sample taken homogenized for testing in compliance with the laboratory's sampling policies and procedures. The primary sample, the duplicate sample and any required replicate samples must be prepared and analyzed separately.

The maximum harvest batch package is twenty-five pounds (25 lbs). For harvest batch sampling a licensed testing entity shall take a minimum of fifteen (15) sample increments of half a gram (0.5 g) each. Additional increments may be collected to ensure that the samples obtained are representative and are sufficient to perform required testing.

- 5.3.5 For cannabis-infused products, a laboratory must The production batch for infused cannabis products (edible, non-edible liquids, non-edible solids) shall not contain more than 150,000 units. For infused and edible cannabis products, the test sample collected by a licensed testing entity for product testing shall comply with the take the following minimum number of units set forth below based upon the production batch size. Additional increments may be collected to ensure that the samples obtained are representative.
 - A. 2-3 units for a production batch of up to 100 units.

- B. 5-6 units for a production batch of 101 to 500 units.
- C. 6-9 units for a production batch of 501 to 1000 units.
- D. $\frac{8}{12}$ units for a production batch of 1001 to 5000 units.
- E. 10 15 units for a production batch of 5001 to 10,000 units.
- F. 12-20 units for a production batch 10,001 to 35,000 units.
- G. 30 units for a production batch of 35,001 to 100,000 units.
- H. 50 units for a production batch of 100,001 to 150,000 units.
- 5.3.6 For cannabinoid concentrates extracts and products, samples must in total represent a minimum of 0.3 percent of the batch and consist of enough samples from a batch must be taken to ensure that the required attributes in the batch to be tested are homogenous and consistent with the laboratory's accredited sampling policies and procedures.

For a cannabis concentrate, each sample increment taken by a licensed testing entity for product testing shall be one-quarter gram (0.25 g). The test sample collected by a licensed testing entity for product testing shall comply with the minimum number of increments set forth below based upon the production batch size. Additional increments may be collected to ensure that the samples obtained are representative.

- A. 12 increments for a production batch of 1 to 2 pounds.
- B. 15 increments for a production batch of 2.01 to 3 pounds.
- C. 18 increments for a production batch of 3.01 to 4 pounds.
- D. 23 increments for a production batch of 4.01 to 10 pounds.
- E. 30 increments for a production batch greater than 10 pounds.
- 5.3.7 A production batch of raw or infused pre-rolls shall contain no more than 150,000 units.

 The test sample collected by a licensed testing entity for product testing shall comply with the minimum number of increments relative to the batch size as set forth below.

 Additional increments may be collected at the discretion of the licensed testing entity to ensure that the samples obtained are representative. Each sample increment consists of one packaged unit.
 - A. 2 units for a production batch of up to 50 units.
 - B. 3 units for a production batch of 51 to 100 units.
 - C. 4 units for a production batch of 101 to 500 units.

- D. 8 units for a production batch of 501 to 1500 units.
- E. 12 units for a production batch of 1501 to 3000 units.
- F. 20 units for a production batch of 3001 to 10,000 units.
- G. 30 units for a production batch of 10,001 units-35,000 units.
- H. 50 units for a production batch of 35,001 units 150,000 units.
- 5.3.8 A production batch of inhalable concentrate products shall contain no more than 150,000 units. The test sample collected by a licensed testing entity for product testing shall comply with the minimum number of increments relative to the batch size as set forth below. Additional increments may be collected at the discretion of the licensed testing entity to ensure that the samples obtained are representative. Each sample increment consists of one packaged unit.
 - A. 2 units for a production batch of up to 50 units.
 - B. 3 units for a production batch of 51 to 100 units.
 - C. 4 units for a production batch of 101 to 500 units.
 - D. 8 units for a production batch of 501 to 1500 units.
 - E. 12 units for a production batch of 1501 to 3000 units.
 - F. 20 units for a production batch of 3001 to 10,000 units.
 - G. 30 units for a production batch of 10,001 units-35,000 units.
 - H. 50 units for a production batch of 35,001 units 150,000 units.
- 5.3.9 A licensed testing entity shall not do any of the following:
 - A. Desicate samples;
 - B. Pre-test samples;
 - C. Select the best or most desirable material from a batch or sample for testing; or
 - D. <u>Manipulate samples in any way that would alter the sample integrity or homogeneity of the sample.</u> All sample increments must have the same genesis.
- 5.3.10 Only <u>qualified employees/representatives of a licensed testing entity</u> sampling under these rules may take collect and transport test samples and must shall follow the testing these rules that the collect is a licensed testing entity sampling under these rules may take collect and transport test samples and must shall follow the testing

facility entity's accredited sampling and transportation policies and procedure when collecting samples for testing.

- A. A <u>licensed testing entity</u> <u>must shall</u> prepare medical cannabis sampling policies and procedures that contain all of the information necessary for collecting and transporting samples from usable medical cannabis in a manner that does not endanger the integrity of the sample for any analysis required by this rule. These policies and procedures <u>must shall</u> be appropriate to the matrix being sampled.
- B. Care <u>must-shall</u> be <u>taken</u> to avoid contamination of the non-sampled material. Sample containers <u>must-shall</u> be free of analytes of interest and appropriate for the analyses requested.
- C. A sufficient sample size must shall be taken for analysis of all requested tests and the quality control performed by the testing laboratory for these tests.
- D. A <u>licensed testing entity</u> <u>must shall</u> comply with any recording requirements for samples and subsamples in the policies and procedures and at a minimum:
 - 1. Record the location of each sample and subsample taken.
 - 2. Subsamples collected from the same batch must shall be combined into a single sample by a laboratory prior to testing.
 - 3. Subsamples and samples collected from different batches may not be combined.
 - 4. Field duplicates may not be combined with the primary samples.
 - 5. Assign a field identification number for each sample, subsample and field duplicate that have an unequivocal link to the laboratory identification number.
 - 6. Assign a unique identification number for each test batch.
 - 7. Have a documented system for uniquely identifying the samples to be tested to ensure there can be no confusion regarding the identity of such samples at any time. This system <u>must shall</u> include identification for all samples, subsamples, preservations, sample containers, tests, and subsequent extracts or digestates.
 - 8. Place the laboratory licensed testing entity identification code as a durable mark on each sample container.
 - 9. Enter a unique sample identification number into the laboratory records. This number must shall be the link that associates the sample with related laboratory activities such as sample preparation. In cases where the sample collector and analyst are the same individual, or the laboratory pre-assigns numbers to sample containers, the unique identification number may be the same as the field identification code.
- E. The cannabis must test sample(s) shall be transported in one or more sealed

- containers and not be accessible while in transit.
- F. The vehicle a testing facility employee uses to transport <u>medical cannabis test</u> samples of cannabis product <u>must shall</u> not bear markings or other indication that it is carrying cannabis or a cannabis-infused product.
- G. All test samples shall be transported by a qualified employee of a licensed testing facility and shall not be transported in the same vehicle as other products.
- H. An employee of the medical cannabis establishment from which a test sample is being collected shall be physically present to observe the testing facility employee collect the test sample and ensure that the sample increments are taken from throughout the batch.
- I. No employee of the medical cannabis establishment from which a test sample is being collected shall assist the testing facility employee nor touch the harvest and/or production batch package or sampling equipment while the testing facility employee is obtaining the test sample.
- J. After test samples have been selected, both the employee of the medical cannabis establishment having the test samples collected and the employee of the testing facility shall sign and date the chain of custody form, attesting to the following sample information:
 - 1. Product name;
 - 2. Weight of product;
 - 3. All products and test samples are correctly identified in the statewide seed-to-sale system; and,
 - 4. <u>If the test sample is obtained for a retest, the testing facility confirms that it is</u> not accepting a test sample that is prohibited from being retested.
- K. The medical cannabis establishment from which the test sample is collected shall enter in the statewide seed-to-sale system the test sample that is collected by a licensed testing facility, including the date and time the test sample is collected and transferred.
- L. When a test sample is collected from a medical cannabis establishment for testing, that licensee shall quarantine the product that is undergoing the testing from any other product at the facility. The quarantined product may not be packaged, transferred, or sold until passing test results are entered into the statewide monitoring system.
- M. Any cannabis or cannabis product collected for testing shall not be transferred or sold to any person or entity other than the licensee from whom the sample was collected. This provision does not apply to a testing facility that engages another

- testing facility to perform certain safety tests on a subcontracted basis.
- N. A testing facility may collect additional sample material from the same licensee from which the original sample was collected for the purposes of completing the required safety tests as long as the requirements of this Rule are met.
- 5.3.11 An approved laboratory testing entity shall store each test sample under the appropriate conditions to protect the physical and chemical integrity of the sample.
 - A. Analyzed test samples consisting of cannabis or cannabis-derived product shall be appropriately segregated, controlled, and held in a controlled access area pending destruction or other disposal.
 - B. Any portion of a cannabis or cannabis-derived test sample that is not destroyed during analysis shall be:
 - 1. Returned to the licensed producer who provided the sample under chain of custody; or
 - 2. Destroyed in accordance with the wastage disposal requirements of this Rule Part.
- 5.3.12 Sampling must shall be conducted at a cannabis cultivation facility or dispensary processing-entity's premises.
 - A. The testing facility entity personnel shall have access to the entire batch for the purposes of sampling.
 - B. All final-form cannabis products shall be in the retail-ready packaging (i.e., sealed vaporization cartridge/pen, gummies in a carton or mylar bag, whole flower in jars, pre-rolls in tubes, bottles of tincture, etc).
- 5.3.13 A <u>laboratory testing entity</u> <u>must shall</u> maintain the documentation required in these rules for at least five years and <u>must shall</u> provide that information to the Department upon request.
- 5.3.14 <u>A testing entity shall not do any of the following:</u>
 - A. <u>Desiccate samples.</u>
 - B. Pre-test samples.
 - C. Select the best or most desirable material from a batch for testing. All sample increments shall have the same chances of being selected.

D. <u>Manipulate samples in any way that would alter the sample integrity or homogeneity of the sample.</u> All sample increments must have the same chances of being selected; sampling must be random.

5.4 Testing Requirements and Standards.

- 5.4.1 Testing Requirements for Usable Medical Cannabis and Cannabis Products.
 - A. A cultivation facility or processing facility shall test eEvery harvest batch of usable medical cannabis (raw plant material) and production batch of raw pre-rolls shall be tested in it's the final form intended for sale or distribution to a qualified patient or caregiver, for the following prior to selling sale or transferring the usable medical cannabis for the following:
 - 1. Pesticides in accordance with Rule 1.7.4-5.4.4 of this Chapter Part;
 - 2. Water activity and moisture content in accordance with Rule 1.7.6-5.4.6 of this Chapter Part;
 - 3. THC and CBD concentration in accordance with Rule 1.7.7 5.4.7 of this Chapter Part;
 - 4. Heavy Metals in accordance with Rule 1.7.8 5.4.8 of this Chapter Part;
 - 5. Mycotoxins in accordance with Rule 1.7.9 5.4.9 of this Chapter Part;
 - 6. Microbiological contaminants in accordance with Rule 1.7.3 <u>5.4.3</u> of this Chapter Part;
 - 7. Terpenes, if performed, in accordance with Rule 1.7.10 5.4.10 of this Chapter Part;
 - 8. Foreign material in accordance with Rule 1.7.11 of this Chapter Part.

Testing Requirements for Concentrates, Extracts, and Edibles.

- B. A cultivation facility or processing facility shall test e Every process lot production batch of cannabinoid concentrate, and extract or edible for sale or distribution to a qualified patient prior to selling or transferring the cannabinoid concentrate, extract or edible shall be tested for the following prior to sale or transfer:
 - 1. Pesticides in accordance with Rule 1.7.4-5.4.4 of this Chapter Part;
 - 2. Water activity and moisture content in accordance with Rule 1.7.6.5.4.6 of this Chapter Part;
 - 3. THC and CBD concentration in accordance with Rule 1.7.7 5.4.7 of this Chapter Part;

- 4. Heavy Metals in accordance with Rule 1.7.8 5.4.8 of this Chapter Part;
- 5. Mycotoxins in accordance with Rule 1.7.9 5.4.9 of this Chapter Part;
- 6. Microbiological contaminants in accordance with Rule 1.7.3 5.4.3 of this Chapter Part;
- 7. Terpenes, if performed, in accordance with Rule 1.7.10 5.4.10 of this Chapter Part;
- 8. Foreign material in accordance with Rule 1.7.11 5.4.11 of this Chapter Part.
- 9. A cultivation facility or processing facility entity is exempt from testing concentrates for solvents under this Rule if the cultivation facility or processing facility entity:
 - a. Did not use any solvent listed in Appendix A, Table 2 1; and,
 - b. Solvents in Used a mechanical extraction process to separate cannabinoids from the cannabis; or
 - c. Used only water, animal fat or vegetable oil as a solvent to separate the cannabinoids from the cannabis.
- C. Every production batch of infused cannabis products shall be tested for the following prior to sale or transfer:
 - 1. Pesticides in accordance with Rule 5.4.4 of this Part;
 - 2. Water activity and moisture content in accordance with Rule 5.4.6 of this Part;
 - 3. THC and CBD concentration in accordance with Rule 5.4.7 of this Part;
 - 4. Heavy Metals in accordance with Rule 5.4.8 of this Part;
 - 5. Mycotoxins in accordance with Rule 5.4.9 of this Part;
 - 6. Microbiological contaminants in accordance with Rule 5.4.3 of this Part;
 - 7. Terpenes, if performed, in accordance with Rule 5.4.10 of this Part;
 - 8. Foreign material in accordance with Rule 5.4.11 of this Part; and
 - 9. Homogeneity.
- D. <u>Final form edible cannabis products shall meet the following additional requirements:</u>
 - 1. Produced and sold with a standardized concentration of cannabinoids not to exceed ten milligrams (10 mg) of total tetrahydrocannabinol (THC) per serving with an allowable variance of $\pm 10\%$ when testing.
 - 2. Must demonstrate uniform disbursement of cannabinoids throughout the

- product when sampled and tested.
- E. Non-edible or beverage are exempt from water activity and moisture content testing.
- F. Every production batch of Keif shall be tested in the final form intended for sale or distribution to a qualified patient or caregiver for the following prior to sale or transfer:
 - 1. Pesticides in accordance with Rule 5.4.4 of this Part;
 - 2. Water activity and moisture content in accordance with Rule 5.4.6 of this Part;
 - 3. THC and CBD concentration in accordance with Rule 5.4.7 of this Part;
 - 4. Heavy Metals in accordance with Rule 5.4.8 of this Part;
 - 5. Mycotoxins in accordance with Rule 5.4.9 of this Part;
 - 6. <u>Microbiological contaminants in accordance with Rule 5.4.3 of this Part;</u>
 - 7. Terpenes, if performed, in accordance with Rule 5.4.10 of this Part; and
 - 8. Foreign material in accordance with Rule 5.4.11 of this Part; and
- G. Every production batch of infused pre-rolls and inhalable compound concentrate products shall be tested in the final form intended for sale or distribution to a qualified patient or caregiver for the following prior to sale or transfer:
 - 1. Pesticides in accordance with Rule 5.4.4 of this Part;
 - 2. Water activity and moisture content in accordance with Rule 5.4.6 of this Part;
 - 3. THC and CBD concentration in accordance with Rule 5.4.7 of this Part;
 - 4. Heavy Metals in accordance with Rule 5.4.8 of this Part;
 - 5. Mycotoxins in accordance with Rule 5.4.9 of this Part;
 - 6. Microbiological contaminants in accordance with Rule 5.4.3 of this Part;
 - 7. Terpenes, if performed, in accordance with Rule 5.4.10 of this Part; and
 - 8. Foreign material in accordance with Rule 5.4.11 of this Part.
- 5.4.2 <u>Testing Standards: All compliance testing requirements by product type are summarized in Appendix D and all compliance testing requirements by final packaging are summarized in Appendix E.</u>
- 5.4.3 Standards for Testing Microbiological Contaminants.

- A. <u>Usable Medical cannabis and medical cannabis products</u> required to be tested for microbiological contaminants shall be sampled using appropriate aseptic technique and tested by a Mississippi licensed and registered cannabis testing facility entity for microbial impurities.
- B. The cannabis testing <u>facility entity</u> shall report the result of the microbial impurities testing by indicating "pass" or "fail" on the Certificate of Analysis.
- C. All cannabis products shall be deemed to have passed the microbial impurities testing if all of the following conditions are met:
 - 1. Total *Escherichia coli* coliform is not detected above 100 colony forming units/gram.
 - 2. Shiga toxin–producing Escherichia coli is not detected in 1 gram;
 - 3. Salmonella spp. is not detected in 1 gram; and
 - 4. Pathogenic Aspergillus species *A. fumigatus*, *A. flavus*, *A. niger*, and *A. terreus* are not detected in 1 gram.
 - 5. Total Yeast and Mold is not detected above 1,000 colony forming units/gram.
- D. <u>Microbial impurities testing shall include an optimized incubation period for all plating-based methods used to report total coliform and total yeast and mold results.</u>

The sample of non-inhalable cannabis and cannabis products shall be deemed to have passed the microbial impurities testing if both the following conditions are met:

- a. Total Escherichia coli is not detected above 100 colony forming units/gram.
- b. Shiga toxin producing Escherichia coli is not detected in 1 gram, and
- c. Salmonella spp. is not detected in 1 gram.
- E. If the 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. The testing entity shall follow the protocol or product instructions provided by the equipment manufacturer, including any enrichment steps. If enrichment is recommended but not required, the enrichment shall be performed.
- G. The testing entity shall enter all test results into the seed-to-sale system within three (3) business days of test completion.

5.4.4 Standards for Testing Pesticides

- A. <u>Usable Medical cannabis and medical cannabis products</u> required to be tested for pesticides shall be tested by a Mississippi licensed, and registered cannabis testing <u>facility entity</u> approved for the analytes listed in Appendix A, Table 1.
- B. The cannabis testing <u>facility entity</u> shall report whether any Residual Pesticides are detected above the limit of detection (LOD) and shall report the result of the testing in ppms on the Certificate of Analysis. The cannabis testing facility shall indicate "pass" or "fail" on the Certificate of Analysis.
- C. A batch fails pesticide testing if a cannabis testing <u>facility entity</u> detects the presence of a pesticide above the action levels listed in Appendix A, Table 1 in a sample:
 - 1. During an initial test where no reanalysis is requested; or
 - 2. Upon reanalysis as described in Rule 1.6.7-5.5.1 of this Chapter Part.

5.4.5 Standards for Testing Solvents.

- A. <u>Usable Mmedical cannabis products</u> required to be tested for solvents shall be tested by a Mississippi licensed, and registered cannabis testing <u>facility entity</u> approved for the analytes listed in Appendix A, Table 2-1.
- B. The cannabis testing facility entity shall report the result of the residual solvents testing in ppm on the Certificate of Analysis and indicate "pass" or "fail" on the Certificate of Analysis.
- C. A batch fails solvent testing if a cannabis testing <u>facility entity</u>, during an initial test where no reanalysis is requested or upon reanalysis as described in <u>subchapter 6</u> section 5.5 of this <u>Chapter Part</u>:
 - 1. Detects the presence of a solvent above the action level listed in Appendix A, Table 2-1; or
 - 2. Calculates a RPD of more than 20 percent between the field primary result of the sample and the field duplicate result.

5.4.6 Standards for Testing Water Activity and Moisture Content.

- A. Usable Medical cannabis and medical cannabis products required to be tested for water activity and moisture content shall be tested by a currently Mississippi licensed and registered cannabis testing facility entity. for:
 - 1. Water activity; and
 - 2. Moisture content.

- B. If a sample has a water activity rate of more than 0.65 a_w the sample fails <u>except</u> for an edible infused cannabis product.
- C. An edible marijuana-infused product fails water activity testing if the water activity rate of more than $0.85 a_{w}$.
- D. Non-edible infused products are not subject to water activity testing.
- E. The cannabis testing facility entity shall report the result of the water activity test on the COA and indicate "pass" or "fail" on the COA.
- F. If a sample has a moisture content of more than fifteen percent (15%), the sample fails. The cannabis testing facility entity shall report the result of the moisture content on the COA and indicate "pass" or "fail" on the COA.
- G. The testing entity shall enter all test results into the seed-to-sale system within three (3) business days of test completion.
- 5.4.7 Standards for Potency (THC and CBD) Testing.
 - A. In the preparation of samples intended for potency analysis, the testing entity may not adulterate or attempt to manipulate the total potency of the sample by any means, including by the addition of trichomes that were removed during the grinding and homogenization process.
 - B. All flower material used for potency testing shall be representative of the product used by the end consumer and homogenized in such a way that it is representative of the way a consumer would be using the product. Kief shall not be reintroduced to the flower sample during the homogenization process.
 - C. A Mississippi-licensed and registered cannabis testing facility entity shall test for the following at a minimum when testing usable-medical cannabis and medical cannabis products for potency without any corrective factor taken for moisture content:
 - 1. Delta-8- tetrahydrocannabinol;
 - 2. Delta-8- tetrahydrocannabinolic acid;
 - 3. Delta-9-tetrahydrocannabinol;
 - 4. Delta-9-tetrahydrocannabinolic acid;
 - 5. Cannabidiol (CBD);
 - 6. Cannabidiolic acid (CBDA);
 - 7. THC content;

- 8. Cannabinol (CBN); and
- 9. Any other cannabinoid determined by the department.
- D. A cannabis testing facility entity shall establish a limit of quantitation of 1.0 mg/g or lower for all cannabinoids analyzed and reported.
- E. A cannabis testing facility entity shall report the result of the cannabinoid testing on the Certificate of Analysis, including, at minimum:
 - 1. A percentage for THC, THCA, CBD, and CBDA. The dry-weight percent shall be calculated using the below equation: Dry-weight percent cannabinoid = wet-weight percent cannabinoid/(1 percent moisture/100);
 - 2. A percentage for Total THC and Total CBD, if applicable;
 - 3. Milligrams per gram (mg/g) if by dry-weight or milligrams per milliliter (mg/mL) if by volume for THC, THCA, CBD, and CBDA;
 - 4. Milligrams per gram (mg/g) if by dry-weight or milligrams per milliliter (mg/mL) if by volume for Total THC and Total CBD, if applicable;
 - 5. Total cannabinoid concentration shall be calculated for concentration expressed in weight: Total cannabinoid concentration (mg/g) = (cannabinoid acid form concentration (mg/g) x 0.877) + cannabinoid concentration (mg/g);
 - 6. Milligrams per package for THC and CBD;
 - 7. Milligrams per package for Total THC and Total CBD, if applicable;
 - 8. Milligrams per serving for THC and CBD, if any;
 - 9. Milligrams per serving for Total THC and Total CBD, if any and if applicable;
 - 10. For edible cannabis products, the cannabis testing entity shall also report, the concentration in milligrams per serving (mg/serving) and milligrams per package (mg/package).
 - 11. The results of all other cannabinoids analyzed on the COA both as a percentage and in either milligrams per gram (mg/g) if by weight or milligrams per milliliter (mg/mL) if by volume.
 - 12. The sample shall be deemed to have passed the cannabinoid testing if the amount of THC does not exceed the limits below:
 - a. Cannabis flower or trim potency $\leq 30\%$ total THC;
 - b. Cannabis tinctures, oils or concentrates $\leq 60\%$ total THC.
- F. A cannabis testing facility entity shall report the test results and indicate an overall "pass" or "fail" for the cannabinoid testing on the Certificate of Analysis.

- G. Total THC, and/or Total CBD claimed to be present on a label shall not be considered inaccurate if the difference in percentage on the certificate of analysis is plus or minus 10.0%.
- H. A process lot-production batch of cannabinoid concentrate or extract fails potency testing if, based on an initial test where no reanalysis is requested or upon reanalysis, the amount of THC, as calculated pursuant to Rule 1.7.7-5.4.7 of this chapter Part, between samples taken from the batch exceeds thirty twenty percent (320%) RSD.
- I. The testing facility shall enter all test results into the seed-to-sale system within three (3) business days of test completion.

5.4.8 Standards for Testing for Heavy Metals.

- A. <u>Usable Medical cannabis and medical cannabis products</u> shall be tested by a current Mississippi licensed and registered cannabis testing <u>facility entity</u> for the metals listed in Appendix A.
- B. A cannabis testing facility entity shall report the result of the heavy metals test on the Certificate of Analysis and indicate "pass" or "fail" on the COA.
- C. A batch fails metals testing if a cannabis testing facility entity, during an initial test where no reanalysis is requested or upon reanalysis as described in subchapter 6 section 5.5 of this Chapter Part detects the presence of metals above the action level listed in Appendix A, Table 3-1.
- D. The testing entity shall enter all test results into the seed-to-sale system within three (3) business days of test completion.

5.4.9 Standards for Mycotoxin Testing.

- A. <u>Usable Medical cannabis and medical cannabis products</u> shall be tested by a Mississippi licensed and registered cannabis testing <u>facility entity</u> for the following mycotoxins: Aflatoxin B1, B2, G1, and G2 Ochratoxin A <u>listed</u>.
- B. A batch shall be deemed to have passed mycotoxin testing if both the following conditions are met:
 - 1. Total of aflatoxin B1, B2, G1, and G2 does not exceed 20 $\mu g/kg$ of substance, and
 - 2. Ochratoxin A does not exceed 20 µg/kg of substance.
- C. A cannabis testing facility entity shall report the result of the mycotoxin testing on

- the Certificate of Analysis and indicate "pass" or "fail" on the COA.
- D. A batch fails mycotoxin testing if a cannabis testing facility entity, during an initial test where no reanalysis is requested or upon reanalysis as described in subchapter 6-section 5.5 of this Chapter Part detects the presence of mycotoxins above the action level listed in Appendix A, Table 1.
- E. The testing facility shall enter all test results into the seed-to-sale system within three (3) business days of test completion.

5.4.10 Standards for Terpenoid Testing.

- A. Terpene analysis is not required. However, if terpene content is listed on product packaging or label, a terpene analysis from a Mississippi licensed and registered cannabis testing <u>facility entity</u> <u>must-shall</u> be performed to confirm the product label.
- B. A cannabis testing facility shall report the result of the terpenoid testing on the COA both as a percentage and in either milligrams per gram (mg/g) if by weight or milligrams per milliliter (mg/mL) if by volume.
- C. The terpenoid testing results on the label of any one terpenoid claimed to be present shall not be considered inaccurate if the difference in percentage on the COA is plus or minus 10.0%.
- D. The testing entity shall enter all test results into the seed-to-sale system within three (3) business days of test completion.

5.4.11 Standards for Foreign Material Testing.

- A. <u>Usable Medical cannabis and medical cannabis products</u> shall be tested by a Mississippi licensed and registered cannabis testing facility entity to determine whether foreign material is present.
- B. A cannabis testing facility entity shall report the result of the foreign material test by indicating "pass" or "fail" on the COA.
- C. A cannabis testing facility entity shall perform foreign material testing on the total representative sample prior to sample homogenization.
- D. When the licensed laboratory testing entity performs foreign material testing, at minimum, the laboratory it shall do all of the following:
 - 1. Examine both the exterior and interior of the dried flower sample, and;
 - 2. Examine the exterior of the cannabis product sample.
- E. The sample shall be deemed to have passed the foreign material testing if the

presence of foreign material does not exceed:

- 1. One-fourth (1/4) of the total sample area covered by sand, soil, cinders, or dirt;
- 2. One-fourth (1/4) of the total sample area covered by mold;
- 3. One (1) insect fragment, 1 hair, or 1 count mammalian excreta per 3.0 grams; or
- 4. One-fourth (1/4) of the total sample area covered by an imbedded foreign material.
- F. If the sample fails foreign material testing, the batch from which the sample was collected fails foreign material testing and shall not be released for retail sale.
- G. The testing entity shall enter all test results into the seed-to-sale system within three (3) business days of test completion.

5.4.12 <u>Standards for Homogeneity Testing.</u>

- A. Except for cannabis flower products, a final cannabis product must be homogenous, with phytocannabinoid content evenly distributed throughout the cannabis product.
- B. <u>Unless otherwise approved by the department, cannabis product shall not be considered homogenous if the concentration of total THC and CBD in milligrams per single serving for five (5) samples of a cannabis product lot/batch submitted for testing is greater than +/- one (1) standard deviation of the mean concentration for total THC and CBD in milligrams per serving for that submitted lot/batch.</u>
- C. <u>Laboratories must test five (5) samples of initial cannabis product for homogeneity when products submitted for testing are new offerings from a processing facility.</u>
- D. <u>Homogeneity testing is required on the initial batch and every six months</u> thereafter, as verification, if the manufacturing process does not change.
- E. A cannabis product that fail homogeneity testing shall not be released for retail sale.
- F. All subsequent products released by the processor will be required to undergo homogeneity testing until three lots pass.
- G. The testing entity shall enter all test results into the seed-to-sale system within three (3) business days of test completion.

- 5.4.13 If a testing <u>facility entity</u> is not accredited for the full scope of state-required tests, the testing facility will need to subcontract with another Department-licensed testing facility for the relevant tests needed. All subcontracted testing <u>must shall</u> be documented in the seed-to-sale system and be transferred using appropriate transport processes and chain of custody.
- 5.4.14 <u>If a testing entity performs research and development testing, the laboratory shall comply with these rules.</u>
 - A. <u>Punitive action shall not be taken against a licensed medical cannabis establishment for conducting research and development testing when permitted.</u>
 - B. The Department may publish guidance for research and development testing that shall be followed by all licensed medical cannabis establishments.
 - C. Research and development testing is only permitted BEFORE compliance testing for all analytes except Terpenes, which shall always be ordered as an R&D test.
 - D. All research and development testing shall be fully completed and reported into the seed-to-sale system by the testing entity BEFORE the final compliance testing can be ordered by the licensee.
 - E. Research and development testing shall not replace the Department's required safety compliance testing.
- 5.4.15 The agency Department shall take immediate disciplinary action, including sanctions, fines, or both, against any laboratory testing entity that falsifies records or does not fails to comply with the provisions of this rule Part.
- 5.4.16 A laboratory testing entity shall comply with random compliance checks at the request of the agency Department. The agency Department or its authorized agents may collect a random sample of a medical cannabis product from a testing facility entity or designate another testing facility entity to collect a random sample of a medical cannabis product in a secure manner to test that sample for compliance pursuant to these Rules.

5.5 Failed Test Samples.

5.5.1 If a sample fails any initial test, the cannabis testing facility entity that did the testing may reanalyze the sample. If the sample passes, another cannabis testing facility entity

must shall resample the batch and confirm that result in order for the batch to pass testing.

- 5.5.2 If a sample fails a test or a reanalysis under Rule 1.6.1-5.5.1 of this Chapter, the batch:
 - A. May be remediated or sterilized in accordance with this subchapter; or
 - B. If it is not or cannot be remediated or sterilized under this rule, it must shall be destroyed in a manner specified by the Department.
- 5.5.3 If a <u>Ccultivation</u> facility or dispensary is permitted under this <u>subchapter Part</u> to sell or transfer a <u>harvest</u> batch that has failed a test, the <u>Ccultivation</u> facility or dispensary must shall notify the <u>Ccultivation</u> facility or dispensary to whom the <u>harvest</u> batch is sold or transferred of the failed test within twenty-four (24) hours of receipt of the COA.
- 5.5.4 Failed Microbiological Contaminant Testing.
 - A. If a sample from a batch of usable medical cannabis 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 CO2 closed loop system.
 - B. 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 CO2 closed loop system.
 - C. A batch that is sterilized in accordance with subsection (A) or (B) of this rule must shall be sampled and tested in accordance with this Chapter and must be tested, if not otherwise required for that product, for microbiological contaminants, solvents and pesticides.
 - D. A batch that fails microbiological contaminant testing after undergoing a sterilization process in accordance with subsection (A) or (B) of this rule must-shall be destroyed in a manner specified by the Department.
- 5.5.5 Failed Solvent Testing.
 - A. If a sample from a batch fails solvent testing, the batch may be remediated using procedures that would reduce the concentration of solvents to less than the action

level.

- B. A batch that is remediated in accordance with subsection (A) of this rule <u>must-shall</u> be sampled and tested in accordance with this Chapter and <u>must-shall</u> be tested if not otherwise required for that product under this Chapter, for solvents and pesticides.
- C. A batch that fails solvent testing that is not remediated or that if remediated fails testing must-shall be destroyed in a manner specified by the Department.
- 5.5.6 Failed Water Activity Testing and Moisture Testing.
 - A. If a sample from a batch of usable medical cannabis fails for water activity or moisture activity, the batch from which the sample was taken may:
 - 1. Be used to make a cannabinoid concentrate or extract; or
 - 2. Continue to dry or cure.
 - B. A batch that undergoes additional drying or curing as described in subsection (A) of this rule <u>must-shall</u> be sampled and tested in accordance with this <u>Chapter Part</u>.
- 5.5.7 Failed pesticide testing. If a sample from a batch fails pesticide testing, the batch may not be remediated and must shall be destroyed in a manner permitted under this Part and/or approved by the Department and identified on the Department's website.
- 5.5.8 Failed Potency Testing.
 - A. Usable medical cannabis that fails potency testing under Rule 1.5.7-5.4.7 of this Chapter Part may be repackaged in a manner that enables the item to meet the standard in Rule 1.5.7-5.4.7 of this Chapter Part.
 - B. Usable medical cannabis that is repackaged in accordance with this section must shall be sampled and tested in accordance with these Rules.
- 5.5.9 Failed Remediation.
 - A. If a sample fails a test after undergoing remediation or sterilization as permitted under this rule, the batch <u>must_shall</u> be destroyed in a manner approved by the Department.
 - B. A cultivation facility or processing facility entity must shall inform a cannabis testing facility prior to samples being taken that the batch has failed a test and is

being retested after undergoing remediation or sterilization.

- C. A cultivation facility or processing facility entity must-shall, as applicable:
 - 1. Have detailed procedures for sterilization processes to remove microbiological contaminants and for reducing the concentration of solvents.
 - 2. Document all sampling, testing, sterilization, remediation and destruction that are a result of failing a test under these rules.
- D. A cannabis or cannabis product batch may only be remediated twice. If the batch fails after a second remediation attempt and the second retesting, the entire batch shall be destroyed in a manner approved by the Department.
- E. Within one (1) business day of completing the required analyses of a representative sample obtained from a remediated cannabis or cannabis product batch, the cannabis testing facility entity shall upload the COA information into the seed-to-sale system.

5.6 Tentative Identification of Compounds.

- 5.6.1 Tentatively Identified Compounds (TICs) are compounds detected in a sample using gas chromatography mass spectrometry that are not among the target analytes for the residual solvent analysis.
- 5.6.2 The Department may initiate an investigation of a cultivation facility or processing facility entity upon receipt of a TICs report from a cannabis testing facility entity and may require a cultivation facility or processing facility entity to submit samples for additional testing, including testing for analytes that are not required by these rules, at the cultivation facility or processing facility entity's expense.

5.7 Certificate of Analysis (COA).

- 5.7.1 The cannabis testing <u>facility entity</u> shall generate a Certificate of Analysis for each representative sample that the cannabis testing <u>facility entity</u> analyzes.
- 5.7.2 The cannabis testing <u>facility entity</u> shall ensure that the COA contains the results of all required analyses performed for the representative sample.
- 5.7.3 The cannabis testing facility entity shall, within three (3) business day of completing all analyses of a sample, upload the COA into the seed-to-sale system. Passed test

results must shall be in the Department's seed-to-sale system for a batch to be released for immediate processing, packaging, and labeling for transfer or sale in accordance with these Rules.

- 5.7.4 The cannabis testing facility entity shall not release to any person any cumulative or individual test results prior to completing all analyses and providing the COA to the Department.
- 5.7.5 The COA shall contain, at minimum, the following information:
 - A. The term "Regulatory Compliance Testing" in font no smaller than 14-point, which shall appear in the upper-right corner of each page of the COA. No text or images shall appear above the term "Regulatory Compliance Testing" on any page of the COA.
 - B. The cannabis testing facility entity's name, premises address, and license number; dispensary's authorized to engage in distribution's name, premises address, and license number; cultivator's, or processor's name, premises address, and license number;
 - C. Batch number of the batch from which the sample was obtained. For cannabis and cannabis products that are already packaged at the time of sampling, the labeled batch number on the packaged cannabis and cannabis products shall match the batch number on the COA;
 - D. Sample identifying information, including matrix type and unique sample identifiers;
 - E. Sample history, including the date collected, the date received by the cannabis testing facility entity, and the date(s) of sample analyses and corresponding testing results;
 - F. A picture of the sample of cannabis and cannabis products. If the sample is prepackaged, the picture <u>must_shall</u> include an unobstructed image of the packaging;
 - G. For dried flower samples, the total weight of the batch in grams and the total weight of the representative sample in grams;
 - H. For cannabis product or pre-rolls samples, the total unit count of both the representative sample and the total batch size;
 - 1. Measured density of the cannabis and cannabis products;

- I. The analytical methods, analytical instrumentation used, and corresponding Limits of Detection ("LOD)" and Limits of Quantitation ("LOQ");
- J. An attestation on the COA from the cannabis testing facility entity supervisory or management employee that all LQC samples required by this Chapter Part were performed and met the acceptance criteria; and
- K. Analytes detected during the analyses of the sample that are unknown, unidentified, or injurious to human health if consumed, if any.
- 5.7.6 The cannabis testing <u>facility entity</u> shall report test results for each representative sample on the COA as follows: Indicate an overall "pass" or "fail" for the entire batch;
 - A. When reporting qualitative results for each analyte, the cannabis testing facility entity shall indicate "pass" or "fail";
 - B. When reporting quantitative results for each analyte, the cannabis testing facility entity shall use the appropriate units of measurement as required under this chapter Part;
 - C. When reporting results for each test method, the cannabis testing facility entity shall indicate "pass" or "fail";
 - D. When reporting results for any analytes that were detected below the analytical method LOQ, indicate "<LOQ", notwithstanding cannabinoid results;
 - E. When reporting results for any analytes that were not detected or detected below the LOD, indicate "ND"; and
 - F. Indicate "NT" for any test that the cannabis testing facility entity did not perform.
- 5.7.7 The cannabis testing <u>facility entity</u> supervisory or management employee shall validate the accuracy of the information contained on the COA and sign and date the COA.
- 5.7.8 The cannabis testing facility entity supervisory or management employee may request to amend a COA to correct minor errors and upload into the seed-to-sale system.

5.8 Post-Testing Sample Requirements.

5.8.1 The cannabis testing <u>facility entity</u> 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, after which time it may be

destroyed and denatured to the point the material is rendered unrecognizable and unusable.

- 5.8.2 The cannabis testing facility entity shall securely store the reserve sample in a manner that prohibits sample degradation, contamination, and tampering.
- 5.8.3 The cannabis testing facility entity shall provide the reserve sample to the Department upon request.

5.9 Transportation of Samples.

5.9.1 Qualified Eemployees/ agents of a licensed cannabis testing facility entity are responsible for the collection and transportation of testing samples. Only qualified employees of a licensed cannabis testing entity shall collect and transport medical cannabis test samples.

Medical cannabis test samples shall not be transported in the same vehicle with any other usable cannabis or cannabis products.

- 5.9.2 <u>Licensed cannabis testing entities that transport medical cannabis test samples shall</u> also comply with all applicable rules and regulations set forth in subpart 7 of this Part.
- 5.9.3 Qualified Eemployees/agents representatives of a licensed cannabis testing facility entity must shall utilize an electronic inventory management system to create and maintain transportation manifests documenting all transport of medical marijuana cannabis and medical marijuana cannabis products throughout the State of Mississippi.
 - 5.9.4 When transporting medical cannabis or medical cannabis products test samples, all cannabis testing facilities entities and their employees/agents representatives shall provide copies of the inventory manifests to each originating and receiving medical cannabis establishment at the time the product changes possession.
 - 5.9.5 The copy of the inventory manifest to be left with the originating medical cannabis establishment shall include, at a minimum:
 - A. The license number, business name, address, and contact information of the

- originating medical cannabis establishment;
- B. A complete inventory of the medical cannabis and medical cannabis products test samples to be transported, including the quantities by weight or unit of each type of medical cannabis and medical cannabis products and the batch number(s);
- C. The date of transportation and the approximate time of departure;
- D. Printed names, signatures, and identification card numbers of <u>testing entity</u> personnel accompanying the transport;
- E. The license number(s), business name(s), address(es), and contact information for all end point recipients.
- 5.9.6 The copy of the inventory manifest to be left with the receiving medical cannabis establishment shall include, at a minimum:
 - A. The license number, business name, address, and contact information for the receiving medical cannabis establishment;
 - B. The license number, business name, address, and contact information of the originating medical cannabis establishment;
 - C. A complete inventory of the medical cannabis and medical cannabis products test samples delivered to the receiving medical cannabis establishment, including the quantities by weight or unit of each type of medical cannabis and medical cannabis products test sample and the batch number(s);
 - D. The date and estimated time of arrival;
 - E. The printed names, signatures, and identification card numbers of the personnel accompanying the transport; and
 - F. The printed names, titles, and signatures of any personnel accepting delivery on behalf of the receiving medical cannabis establishment.
- 5.9.7 Transportation manifests should reflect a complete chain of custody of all medical cannabis and medical cannabis products test samples being transported, including all instances in which the medical cannabis and medical cannabis products test samples are stored.
- 5.9.8 Originating and receiving licensed entities shall maintain copies of transportation manifests and inventory records logging the quantity of medical cannabis or medical

cannabis products test samples received for at least three (3) years from the date of receipt.

5.9.9 A transportation manifest must shall not be altered after departing from the originating medical cannabis establishment's premises, except for the addition of the printed names, titles, and signatures of any personnel accepting delivery on behalf of the receiving cannabis testing facility entity.

5.10 Quality Assurance Measures for Cannabis Testing Facility Entities.

- 5.10.1 The cannabis testing <u>facility entity</u> shall develop and implement a Quality Assurance (QA) program to assure the reliability and validity of the analytical data produced by the cannabis testing <u>facility entity</u>. The QA program shall, at minimum, include a written QA manual that addresses the following:
 - A. Quality control procedures;
 - B. Cannabis testing <u>facility entity</u> organization and employee training and responsibilities, including good laboratory practice (GLP);
 - C. QA objectives for measurement data;
 - D. Traceability of data and analytical results;
 - E. Instrument maintenance, calibration procedures, and frequency;
 - F. Performance and system audits,
 - G. Corrective action procedures;
 - H. Steps to change processes when necessary;
 - I. Record retention and document control;
 - J. Test procedure standardization; and
 - K. Method validation;
 - L. Chain of custody protocols;
 - M. Premise and sample security;
 - N. Sample handling, including sample receipt, identification, rejection, storage and destruction:
 - O. Contingency plans for data that is not within control limits, or is otherwise unacceptable for analysis; and
 - P. Disposal of marijuana cannabis and laboratory waste.

- 5.10.2 The supervisory or management cannabis testing <u>facility entity</u> employee shall annually review, amend if necessary, and approve the QA program and manual both when they are created and when there is a change in methods, testing <u>facility entity</u> equipment, or the supervisory or management testing <u>facility entity</u> employee.
- 5.10.3 The cannabis testing <u>facilities entity's</u> standard operating procedures for testing methods shall include the following:
 - A. The name of the testing method;
 - B. A list of all analytes used in the testing method;
 - C. The applicable matrix or matrices;
 - D. Sample receipt and acceptance;
 - E. Method sensitivity;
 - F. Potential interferences;
 - G. Analytical instrument and equipment used;
 - H. Consumable supplies, reagents, and standards;
 - I. Sample preservation and hold time;
 - J. Type, frequency, and acceptable criteria for quality control samples;
 - K. Type, frequency, and acceptable criteria for calibration standards;
 - L. Procedures for analyzing batch samples;
 - M. Data quality assessment and acceptance criteria;
 - N. Calibration of results: and
 - O. Reagent solution and reference material preparation.
 - P. Current step-by-step instructions with sufficient detail to perform the assay to include equipment operation and any abbreviated versions used by a testing analyst.
- 5.10.4 Each cannabis testing entity shall maintain a consumables log or inventory for all reagents, reference standards and media purchased and received. All reagents and reference standards, including any working standards, must be:
 - A. <u>Labeled to indicate identity</u>, <u>batch number</u>, <u>date received or prepared</u>, <u>expiration date</u>, <u>and where applicable</u>, <u>concentration or purity</u>, <u>and date opened</u>;

- B. Stored under appropriate conditions to minimize degradation or deterioration of the material;
- C. Within their expiration or re-qualification dates at the time of use; and
- D. <u>Documented on records for each analysis.</u>
- 5.10.5 Each cannabis testing entity shall calibrate and maintain its equipment as specified below, and the calibration, verification and/or check and maintenance must be documented.
 - A. <u>Trend testing space temperatures and humidity daily using NIST-certified temperature devices</u>. Record corrective action if temperatures are out-of-range.
 - B. Check autoclaves performance with bioindicator monthly and use heat-indicating tape with each cycle.
 - C. Check automatic Pipettes or Micropipettors and Pipette Tips dispensing accuracy and precision quarterly and calibrate annually.
 - D. Check balances daily with a documented zero before use and service and recalibrate annually.
 - E. <u>Inspect Biosafety cabinet airflow with each use and have certified annually.</u>
 - F. <u>Clean blenders as required by manufacturer after each homogenization of submitted cannabis or cannabis products.</u>
 - G. Verify centrifuge speeds and temperatures daily and have certified annually.
 - H. Calibrate conductivity monthly.
 - I. <u>Trend freezer and refrigerator temperatures daily using NIST-certified temperature devices</u>. Record corrective action if temperatures are out-of-range.
 - J. <u>Inspect glassware for chemistry cannabis testing entity with each use for cleanliness, chips, and etching with each use. Use class A when specified by the approved method, and keep certificate of conformance per each piece of class A glassware. If class B or class A without a certificate of conformance, perform verification check upon purchase or prior to first use.</u>
 - K. <u>Inspect glassware for microbiological cannabis testing entity with each use for cleanliness, chips, and etching.</u>
 - L. <u>Trend incubator temperatures daily using NIST-certified temperature devices.</u> <u>Record corrective action if temperatures are out-of-range.</u>

- M. Trend water bath temperatures daily using NIST-certified temperature devices. Record corrective action if temperatures are out-of-range.
- N. <u>Trend Laminar Flow Hoods daily and service annually.</u>
- O. <u>Clean Microscope optics and stage daily and check alignment with each use.</u> <u>Service annually.</u>
- P. Follow Microwave digestors manufacturer's instructions.
- Q. Check Muffle furnaces temperature accuracy at least annually.
- R. Standardize pH meters with at least 2 buffer solutions daily before use.
- S. Check Spectrophotometers wavelength.
- T. Check Timers and stop watches at least annually.
- U. Certify reference weights annually.
- V. <u>Follow Analytical Instrumentation manufacturer's instructions for cleaning and maintenance and document all cleaning, calibrations, maintenance, and repairs.</u>
- W. Maintain all service records for the life of equipment.
- 5.10.6 The cannabis testing facilities entities shall develop, implement, and validate test methods for the analyses of samples as follows:
 - A. To the extent practicable, methods shall compart with the following guidelines:
 - B. The Bacteriological Analytical Manual (BAM), 2019, which is incorporated by reference, includes no future editions or amendments, and is available at https://www.fda.gov/food/laboratory-methods-food/bacteriological-analytical-manualbam;
 - C. AOAC Official Methods of Analysis, 21st Edition, 2019, which is incorporated by reference, includes no future editions or amendments, and is available at https://www.aoac.org/official-methods-of-analysis-21st-edition-2019; and
 - D. To the extent practicable, methods shall be validated in accordance with the following guidelines:
 - AOAC Appendix J: Guidelines for Validation of Microbiological Methods for Food and Environmental Surfaces, 2012, which is incorporated by reference, includes no future editions or amendments, and is available at http://www.eoma.aoac.org/app_j.pdf;
 - 2. AOAC Appendix K: Guidelines for Dietary Supplements and Botanicals, 2013, which is incorporated by reference, includes no future editions or

- amendments, and is available at http://www.eoma.aoac.org/app_k.pdf;
- 3. ICH Validation of Analytical Procedures: Text and Methodology Q2(R1) 2005, which is incorporated by reference, includes no future editions or amendments, and is available at https://database.ich.org/sites/default/files/Q2_R1_Guideline.pdf or Unofficial version of the Rules in 9 A.A.C. 17, effective September 8, 2022 Page 115 https://www.fda.gov/regulatory-information/search-fda-guidance-documents/q2-r1- validation-analytical-procedures-text-and-methodology.
- E. Method validation should, at a minimum, verify accuracy, precision, analytical sensitivity, analytical specificity, limit of detection, limit of quantification, reportable range and the identification of interfering substances.
- F. Methods adopted from a matrix specific standard method, inclusivity and exclusivity do not require a comprehensive reassessment, provided that there were no modifications to the methods, including, but not limited to, all of the following:
 - 1. Referenced media.
 - 2. Primers.
 - 3. Probes.
 - 4. Antibodies.
 - 5. Critical chemistries that were not modified.
 - 6. Microbial methods <u>must-shall</u> include environmental monitoring and quality control of all buffers, media, primers, and incubators.
- G. The licensed laboratory shall generate a validation report for each test method. Each validation report shall include the following information:
 - 1. Instrument calibration data, if any;
 - 2. Raw data, including instrument raw data scanned as a PDF, for each test method, if any;
 - 3. Cannabis reference materials or certified reference material results;
 - 4. Data and calculations pertaining to LOD and LOQ determinations, if any;
 - 5. Quality Control Sample report;
 - 6. Worksheets, forms, pictures, or copies of laboratory notebook pages
- H. The laboratory director shall review, approve, sign, and date the validation report for each test method.

- I. Validations <u>must-shall</u> be submitted to the agency for approval with an acceptable and graded external proficiency test by a third party, where all required analytes are shown to have passed.
- J. Upon new test methods or altered test methods being used in the laboratory, the new validation report shall be submitted to the Department within 5 business days.

5.11 <u>Cannabis Testing Facility Entity Quality Control Samples.</u>

- 5.11.1 The cannabis testing <u>facility entity</u> shall use Quality Control samples (QC) and adhere to good, approved laboratory practice ("GLP") in the performance of each analysis according to the specifications of this <u>Chapter Part</u>.
- 5.11.2 The cannabis testing facility entity shall analyze QC samples in the same manner as the cannabis testing facility entity analyzes cannabis and cannabis products samples.
- 5.11.3 The cannabis testing <u>facility entity</u> shall use at least one negative control, one positive control, and one cannabis testing <u>facility entity</u> replicate sample in each analytical batch for each target organism during microbial testing. If one of the controls produces unexpected results, the samples shall be re- prepped and reanalyzed with a new set of controls.
- 5.11.4 If the result of the microbial analyses is outside the specified acceptance criteria in the following Appendix A. Table 2, the cannabis testing facility entity shall determine the cause and take steps to remedy the problem until the result is within the specified acceptance criteria.

Microbiology

Culture Methods – Qualitative and Quantitative

The quality control (QC) samples that are required for culturing of cannabis and cannabis products using qualitative and quantitative methods are included in Appendix A, Table 2.

Molecular Assays/Methods

The QC samples that are required for molecular (i.e., polymerase chain reaction (PCR), gel electrophoresis and probe-based qPCR with or without melting curve analyses) analysis of cannabis and cannabis products are listed in Appendix A, Table 3.

PCR positive DNA controls are used to verify that the PCR master mix and reagents were prepared correctly to produce amplification of the target nucleic acid. This type of positive control is analyzed with each PCR run.

A PCR run is defined as a group of samples that are analyzed at the same time under the same amplification conditions, using the same PCR master mix, and in the same thermocycler. A PCR run may contain more than one extracted sample batches.

A PCR run with multiple assays must have a DNA positive control for each assay.

Inhibition controls are used to verify that interfering constituents from a cannabis form, which may be carried over during isolation of nucleic acids or organisms during sample processing, do not inhibit the PCR. Because cannabis forms are constantly changing, inhibition positive controls must be performed in every extracted sample.

PCR DNA negative controls are used to verify that the PCR master mix and reagents were prepared correctly to produce amplification of the target nucleic acid. This type of negative control is analyzed with each PCR run. A PCR run is defined as a group of samples that are analyzed at the same time under the same amplification conditions, using the same PCR master mix, and in the same thermocycler. A PCR run may contain more than one extracted sample batches. A PCR run with multiple assays must have a DNA negative control for each assay to verify that the amplification conditions are working properly.

No template controls are used to verify no contaminating nucleic acid has been introduced into the master mix. These controls are prepared when template is added to the master mix. They are prepared as separate PCR reactions to which aliquots of molecular-grade water or buffer are added to the master mix in place of target nucleic acid or sample. A negative result with this control indicates that the master mix and final processing reagents are not contaminated. This type of negative control is analyzed with each PCR run. A PCR run is defined as a group of samples that are analyzed at the same time under the same amplification conditions, using the same PCR master mix, and in the same thermocycler. A PCR run may contain more than one extracted sample batch. A PCR run with multiple assays must have not template controls for each assay to verify that the sterility of the assays.

One duplicate sample is required per run. A duplicate sample is subjected to all of the same steps as the original sample. For qualitative analyses, if the duplicate sample does not equal the sample result, the sample and its duplicate must be reanalyzed. Consideration should also be given to possibility of re-preparing and reanalyzing all associated samples. For quantitative analyses, if the RPD of the sample and duplicate is greater than 100, the parent sample and duplicate sample must be reanalyzed. Consideration should also be given to possibility of re-preparing and reanalyzing all

associated samples. When data are accepted, the result for the sample portion designated as the "original sample" is reported.

5.11.5 <u>Chemistry – Analytical, Organic and Inorganic (Metals).</u>

Quality control must be performed for each analytical, organic and metal chemistry method.

Each cannabis testing entity shall maintain sufficient raw data records to ensure the QC was performed at the frequency specified.

'Bracketing' of QC samples, rotating from across the calibration curve range, is required.

QC samples must follow the first twenty (20) samples after an initial calibration, every 20 samples thereafter, and at the end of testing samples. This would also apply to a continuing calibration.

Initial Calibration

- A. <u>Samples results must be associated with an acceptable initial calibration.</u> If the <u>initial calibration is not acceptable, corrective actions must be performed and all associated samples re-analyzed.</u>
- B. No sample results are to be reported nor data qualified for a failed initial calibration.
- C. <u>Samples must be analyzed under an initial calibration that was performed no more than one month prior.</u>
- D. The following items are required elements of an initial calibration:
 - 1. The details of the initial calibration procedures including calculations, integrations, acceptance criteria, and associated statistics must be included or referenced in the method SOP. When initial calibration procedures are referenced in the method SOP, then the referenced material must be retained by the cannabis testing entity and be available for review;
 - 2. Sufficient raw data records must be retained to permit reconstruction of the initial calibration (e.g., calibration date, method, instrument, analysis date, each analyte name, and analyst or technician's initials or signature; concentration and response, calibration curve or response factor; or unique equation or coefficient used to reduce instrument responses to concentration);
 - 3. The cannabis testing entity must use the most recent initial calibration analyzed prior to the analytical batch;

- 4. <u>Standards used for calibration must be traceable to an international or national standard, when commercially available; and</u>
- 5. The cannabis testing entity must have a written procedure addressing removal and replacement of calibration standards.
- E. The lowest calibration standard must be at or below the lowest concentration for which quantitative data are to be reported without qualification.
- F. The highest calibration standard shall be at or above the highest concentration for quantitative data are to be reported without qualification.
- G. <u>Sample results must be quantitated from the initial calibration and may not be quantitated from any continuing calibration verification.</u>
- H. Criteria for the acceptance of an initial calibration must be established including any calculations (e.g., relative error, relative standard deviation).
 - 1. $R2 \ge 0.990$, and
 - 2. Curve recovery of $\pm 20\%$ (and $\pm 30\%$ for the lowest point) for all points must be maintained.
- I. The cannabis testing entity must use and document a measure of relative error in the calibration as specified in the method SOP.

Initial Calibration Verification

- A. All initial calibrations must be verified with a standard obtained from a second manufacturer or a separate lot prepared independently by the same manufacturer.
- B. <u>Initial calibration verification is performed by analyzing a test solution of known analyte concentration(s) after initial calibration and prior to sample analysis.</u>
- C. In general, the check must be ± 20% (± 30% for the lowest point) of the known value. Some individual methods may require tighter tolerances (± 10% of the known value).

Continuing Calibration Verification

- A. The validity of the initial calibration must be verified prior to sample analyses by a continuing calibration verification with each analytical batch.
- B. A CCV is performed by analyzing a test solution of known analyte concentration(s) prior to sample testing on each testing day and continued periodically during the analytical batch run, no less frequently than once after each set of 20 samples, and at the end of each run.
- C. The CCV must be a standard that is from the same vendor/lot that is used for the calibration curve.

- D. In general, the check must be \pm 20% (and \pm 30% for the lowest point) of the known value.
- E. Calibration must be verified for each compound, element, or other discrete chemical analyte, except for multi-component analytes where a representative chemical, related substance or mixture can be used.
- F. <u>Instrument continuing calibration verification must be performed at the beginning and end of each analytical batch, and at the frequency defined in the method.</u>
- G. Sufficient raw data records must be retained to permit reconstruction of the continuing instrument calibration verification (e.g., method, instrument, analysis date, each analyte name, concentration and response, calibration curve or response factor, or unique equations or coefficients used to convert instrument responses into concentrations).
- H. <u>Continuing calibration verification records must explicitly connect the continuing</u> calibration verification data to the initial calibration.
- I. <u>If the continuing instrument calibration verification results obtained are outside the established acceptance criteria, the following steps must be taken:</u>
 - 1. If a cause for the calibration verification failure is identified that impacts only the calibration verification sample (e.g., a missed autosampler injection), then analysis may proceed if a second calibration verification sample is analyzed immediately and the result is within acceptance criteria. Samples analyzed previously must be considered valid if bracketed by a passing calibration verification sample. The cause for the failure of the first calibration verification result must be documented; and
 - 2. If the cause for the calibration verification failure is not identifiable or has impacted other samples, then corrective action must be performed and documented. Prior to analyzing samples, the cannabis testing entity must demonstrate acceptable performance after corrective action with calibration verification or a new initial calibration must be performed. Samples analyzed prior to the calibration verification failure must be reanalyzed.
- J. <u>Data associated with an unacceptable calibration verification must not be reported with a qualifier. Qualifying the data is not an acceptable approach.</u>

Low Level Continuing Calibration Verification

- A. A LLCCV will be run at the end of each analytical batch.
- B. The measured value must be within ± 30 % of the prepared value.

The cannabis testing facility entity shall prepare and analyze at least one of each of the following QC samples for each analytical batch:

- A. Negative Control, Method Blank; and
- B. Positive Control, Cannabis testing entity Control Sample (LCS);
- C. Matrix spike sample;
- D. <u>Duplicate matrix spike sample</u>; and
- E. <u>Duplicate sample.</u>

The required QC is summarized in Appendix 2, Table 4.

Negative Control – Method Blank (MB)

- A. A method blank must be analyzed at a minimum of one (1) per preparation batch.
- B. The MB must be processed along with and under the same conditions as the associated samples to include all steps of the preparation and analytical procedure.
- C. The MB is used to assess the samples in the preparation batch for possible contamination during the preparation and processing steps.
- D. The measured concentration of each analyte in the MB or LRB must be < LOQ or MRL.
- E. Procedures must be in place to determine if a MB or LRB is contaminated. While the goal is to have no detectable contaminants, each method blank must be critically evaluated as to the nature of the interference and the effect on the analysis of each sample within the batch.
- F. The source of contamination must be investigated and measures taken to minimize or eliminate the problem and affected samples reprocessed if the concentration of a targeted analyte in the blank is at or above the LOQ, if the blank contamination otherwise affects the sample results as per the method requirements or the individual project data quality objectives, and a blank is determined to be contaminated. Samples associated with a contaminated blank must be evaluated as to the best corrective action for the samples (e.g., reprocessing or data qualifying codes). In all cases, the corrective action must be documented.
- G. Any affected samples associated with a contaminated MB or LRB must be reprocessed for analysis.

Positive Control – Laboratory Control Sample (LCS)

A. The LCS is used to evaluate the performance of the total analytical system, including all preparation and analysis steps.

- B. The LCS must be carried through the entire sample preparation process and analyzed.
- C. The LCS must be spiked with all target analytes at a mid-level concentration in the curve.
- D. The LCS must be analyzed at a minimum of one (1) per preparation batch.
- E. The LCS is a quality system matrix, known to be free of analytes of interest, spiked with known concentrations of analytes that are within the calibration range.
 - 1. A laboratory control sample (LCS) may be used in place of a continuing calibration verification (CCV) (but not as a replacement for a failing CCV) for methods where the calibration goes through the same process as the LCS. Note that the more stringent acceptance criteria must be met.
 - 2. The matrix spike may be used in place of this control as long as the acceptance criteria are as stringent as for the LCS.
 - 3. The lab may use commercially available or pre-prepared standards (separate from calibrators) for QC.
- F. All analyte concentrations must be within the calibration range of the methods.
- G. The individual LCS must be compared to the acceptance criteria stated in the standard operating procedure. The results of the individual batch LCS are calculated in percent recovery or other appropriate statistical technique that allows comparison to established acceptance criteria. The cannabis testing entity must document the calculation.
- H. When the acceptance criteria for the positive control are exceeded, those sample results must be investigated, and a corrective action implemented.

Matrix Spikes and Matrix Spike Duplicates

- A. Analyze an actual sample with a known amount of standard added (matrix spike. MS). A second portion of the actual sample used to prepare the MS that is spiked and processed in the same manner as the MS (matrix spike duplicate, MSD).
 - 1. For potency testing, a "representative matrix" may be used to prepare the MS/MSD.
 - 2. MS/ MSD shall be spiked at a midlevel concentration with the target analytes.
- B. <u>Calculate the relative percent difference (RPD) between first sample and replicate.</u>

 The calculations must be documented, and the target value must be close to the first value and have a RPD of less than 20%.

- C. Matrix-specific QC samples indicate the effect of the sample matrix on the precision and accuracy of the results generated using the selected method. The information from these controls is sample/matrix specific and would not normally be used to determine the validity of the entire batch.
- D. For methods that include one (1) to twenty (20) targets, spike all components.
- E. For methods with more than twenty (20) targets, randomly spike at least sixteen (16) components.

Sample Duplicate

- A. <u>Analyze the same sample twice, using two separate preparations. The sample should be chosen at random and run together on the same analytical run.</u>
- B. Calculate the relative percent difference (RPD) between first sample and replicate. Calculations must be documented, and the target value must be close to the first value and have a RPD of less than 20%.
- C. Variability may be introduced during sample preparation. To account for this, if more than one staff member is prepping samples, each staff must also prepare and analyze a sample matrix duplicate for each set of prepared samples.

5.11.6 Physical Chemistry.

Water Activity:

- A. Sample Duplicates. Analyze the same sample twice, using two separate preparations. The sample should be chosen at random and run together on the same analytical run. Calculate the relative percent difference (RPD) between first sample and replicate. Calculations must be documented, and the target value must be close to the first value and have a RPD of less than 20%. Variability may be introduced during sample preparation. To account for this, if more than one staff member is prepping samples, each staff must also prepare and analyze a sample matrix duplicate for each set of prepared samples.
- B. Calibration. If the aw instrument is being used in a single location at the same temperature (61°C) and humidity (65% relative humidity), calibrate if it has been more than seven consecutive days since the last calibration. If the aw instrument is physically moved from one location to another, calibrate immediately following the move and prior to analyzing samples. If the aw instrument has been cleaned, then calibrate immediately following the cleaning. Follow any other calibration procedures listed in a consensus method and manufacturer's instructional manual. c. Monitor temperature and humidity daily or on day of use, and keep a record of the check

5.12 Required Formulas.

- 5.12.1 The cannabis testing facility entity shall prepare and analyze at least one of each of the following QC samples for each analytical batch:
 - A. Method Blank; and
 - B. Laboratory control sample (LCS); and
 - C. Matrix spike sample; and
 - D. Duplicate matrix spike sample.
- 5.12.2 The cannabis testing facility entity shall analyze, at minimum, a continuing calibration verification ("CCV") sample prior to sample testing on each testing day and continued periodically during the analytical batch run no less frequently than once after each set of twenty (20) samples and at the end of each run. The CCV must shall be a standard that is not from the same vendor/lot that is used for the calibration curve.
- 5.12.3 If the result of the chemical analyses is outside the specified minimum acceptance criteria in the following Appendix A. Table 3, the cannabis testing facility entity shall determine the cause and take steps to remedy the problem until the result is within the specified acceptance criteria.
- 5.12.4 A cannabis testing facility entity shall use the following calculation for determining Relative Percentage Difference (RPD):

$$RPD = (|Num1-Num2|/((Num1+Num2)/2)) \times 100$$

Where:

Num1= Original Number

Num2= Second Number

5.12.5 A cannabis testing facility entity shall use the following calculation for determining Relative Standard Deviation (RSD):

$$SD = \sqrt{\frac{(sample1 - mean)^2 + (sample2 - mean)^2, ..., (sample10 - mean)^2}{total\; number\; of\; samples - 1}}$$

$$RSD = \frac{SD}{mean} x \ 100$$

- 5.12.6 For calculating both RPD and RSD if any results are less than the LOQ, the absolute value of the LOQ is used in the equation.
- 5.12.7 If any analyte is detected above any action level, as described in this chapter Part, the sample shall be re-prepped and reanalyzed in replicate within another analytical batch.
- 5..12.8 For quantitative analyses, the re-prepped sample and its associated replicate shall meet the acceptance criteria of RPD $\leq 320\%$.
- 5.12.9 For qualitative analyses, the re-prepped sample and its associated replicate results must shall concur.
- 5.12.10 If any quality control sample produces a result outside of the acceptance criteria, the cannabis testing <u>facility_entity</u> cannot report the result and the entire batch cannot be released for retail sale. The cannabis testing_<u>facility_entity</u> shall determine the cause and take steps to remedy the problem until the result is within the specified acceptance criteria.
- 5.12.11 If the cannabis testing <u>facility entity</u> determines that the result is a false-positive or a false-negative, the Department may ask for the cannabis testing <u>facility entity</u> to resample or re-test.

5.12.12 The cannabis testing facility entity shall compile and generate one LQC sample report for each analytical batch that includes LQC acceptance criteria, measurements, analysis date, and matrix.

5.13 Limits of Detection (LOD) and Limits of Quantitation (LOQ) for Quantitative Analyses.

- 5.13.1 The cannabis testing facility entity shall calculate the LOD for chemical method analyses according to any of the following methods:
 - A. Signal-to-noise ratio of between 3:1 and 2:1;
 - B. Standard deviation of the response and the slope of calibration curve using a minimum of seven (7) spiked blank samples calculated as follows:

 $LOD = (3.3 \text{ x standard deviation of the response})/slope of the calibration curve};$ or

- C. A method published by the United States Food and Drug Administration (USFDA) or the United States Environmental Protection Agency (USEPA).
- 5.13.2 The cannabis testing facility entity shall calculate the LOQ for chemical method analyses according to any of the following methods:
 - A. Signal-to-noise ratio of 10:1, at minimum;
 - B. Standard deviation of the response and the slope using a minimum of seven (7) spiked Blank samples calculated as follows:

 $LOQ = (10 \times standard\ deviation\ of\ the\ response)/slope\ of\ the\ calibration\ curve;$ or

C. A method published by the USFDA or the USEPA.

5.14 Cannabis Testing Facility Entity Data Package.

- 5.14.1 The cannabis testing facility entity shall compile and generate one data package for each representative sample that the cannabis testing facility analyzes.
 - A. 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.

- B. In automated data collection systems, the individual responsible for direct data input shall be identified at the time of data input. Any change in an entry 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. A corrective action report shall accompany such change and shall be made available to the department, a non-profit producer, and a manufacturer upon their request for up to two years after the analysis is completed.
- C. For each final result reported, an approved laboratory testing entity shall verify that:
 - 1. Any calculations or other data processing steps were performed correctly;
 - 2. The data meet any data quality requirements such as for accuracy, precision, linearity, etc.;
 - 3. Any reference standards used were of the appropriate purity and within their expiration or requalification dates;
 - 4. Any volumetric solutions were properly standardized before use; and,
 - 5. Any test or measuring equipment used has been properly tested, verified, and calibrated, and is within its verification or calibration period.
- 5.14.2 The cannabis testing <u>facility entity</u> shall provide requested data packages to the Department immediately upon request.

5.15 Required Proficiency Testing.

- 5.15.1 The A cannabis testing facility entity shall participate in a proficiency testing program for all methods available from an organization that operates in conformance with the requirements of ISO/IEC 17043 at least once every six (6) months tests if offered by an ISO/IEC 17043 approved proficiency test provider, at a frequency specified under this Part and have successfully passed two (2) out of the most recent three (3) proficiency tests as part of the permit requirements.
- 5.15.2 The cannabis testing <u>facility entity</u> shall annually, successfully participate in a proficiency testing program for each test method performed for the below:
 - A. Cannabinoids;
 - B. Heavy metals;
 - C. Microbial impurities;

- D. Mycotoxins;
- E. Residual pesticides;
- F. Residual solvents and processing chemicals;
- G. Foreign Material; and
- H. Terpenoids, if performed.
- 5.15.3 The cannabis testing facility entity shall report all analytes available by the proficiency testing program provider and for which the licensee is required to test as required under the rules in this chapter Part.
- 5.15.4 The cannabis testing <u>facility entity</u> shall participate in the proficiency testing program by following the cannabis testing <u>facility entity</u>'s existing SOPs for testing cannabis and cannabis products.
- 5.15.5 The cannabis testing facility entity shall rotate the proficiency testing program among the cannabis testing facility entity employees who perform the test methods.
- 5.15.6 Cannabis testing <u>facility_entity</u> employees who participate in a proficiency testing program shall sign the corresponding analytical reports or attestation statements to certify that the proficiency testing program was conducted in the same manner as the cannabis testing <u>facility_entity</u> tests of cannabis and cannabis products.
- 5.15.7 A supervisory or management cannabis testing <u>facility entity</u> employee shall review and verify the accuracy of results reported for all proficiency testing program samples analyzed.
- 5.15.8 The cannabis testing <u>facility entity</u> shall request the proficiency testing program provider to send results concurrently to the Department, if available, or the cannabis testing <u>facility entity</u> shall provide the proficiency testing program results to the Department within three (3) business days after the cannabis testing <u>facility entity</u> receives notification of their test results from the proficiency testing program provider.

5.16 Proficiency Testing Performance.

- 5.16.1 The cannabis testing <u>facility entity</u> shall be deemed to have successfully participated in a proficiency testing program for an analyte tested in a specific method if the test results demonstrate a "satisfactory" or otherwise proficient performance determination by the proficiency testing program provider.
- 5.16.2 The cannabis testing facility entity may not report test results for analytes that are deemed by the proficiency testing program provider as "unacceptable," "questionable," "unsatisfactory", or otherwise deficient. Testing with the deficient method must shall stop immediately upon receiving deficient proficiency testing results.
- 5.16.3 The cannabis testing facility entity may resume reporting test results for analytes that were deemed "unacceptable," "questionable," "unsatisfactory", or otherwise deficient, only if both of the following conditions are met:
 - A. The cannabis testing facility entity satisfactorily remedies the cause of the failure for each analyte; and
 - B. The cannabis testing <u>facility entity</u> submits to the Department a written corrective action report demonstrating how the cannabis testing <u>facility entity</u> has fixed the cause of the failure.
- 5.16.4 The cannabis testing entity shall immediately perform a follow-up proficiency test on any method associated with a deficient report until the testing entity obtains an acceptable result for all analytes.
- 5.16.5 The Department shall take immediate disciplinary action against any cannabis testing entity that is unable to successfully participate in a proficiency program for any available method/analyte every six (6) months.

5.17 Cannabis Testing Facility Entity Audits.

- 5.17.1 The cannabis testing <u>facility entity</u> shall conduct an internal audit at least once per year or in accordance with the ISO/IEC 17025 accrediting body's requirement, whichever is more frequent.
- 5.17.2 The internal audit shall include all the components required by the ISO/IEC 17025 internal-audit standards.

- 5.17.3 Within three (3) business days of completing the internal audit, the cannabis testing facility entity shall submit the results of the internal audit to the Department.
- 5.17.4 A cannabis testing <u>facility entity</u> shall contract with an independent, third-party auditor certified to conduct on-site audits at least annually or in accordance with ISO/IEC 17025 accrediting body's requirements standards.
- 5.17.5 Within three (3) business days of receiving the accrediting body on-site audit findings, the cannabis testing facility shall submit the report to the Department.
- 5.17.6 The Department reserves the rights to perform additional audits as needed and without advance notice.
- 5.18 Product Safety Measures: Quality Assurance and Controls for Licensed Medical Cannabis Establishments Other Than Licensed Testing Entities.
- 5.18.1 <u>Licensed cultivation and processing entities shall establish written production and control standard operating procedures for the cultivation of cannabis and manufacture of cannabis products (e.g., formulations, processing procedures, in-process control methods, packaging procedures, procedures for operating equipment) which shall include provisions to ensure that:</u>
 - A. The selection, weighing, and measuring of ingredients and the determination of finished yield are reviewed by a second individual;
 - B. <u>Major equipment, transfer lines, containers and tanks used for processing, holding, or filling are identified to indicate contents, batch identification, stage of processing, and control status;</u>
 - C. There are appropriate measures to prevent contamination with microorganisms, chemicals, filth, or other extraneous material;
 - D. There are in-process controls to ensure product uniformity, integrity (for example, in-process batch weights), accurate fill of mixing containers, and adequacy of mixing;
 - E. The theoretical yield for a production batch is compared with the actual yield;
 - F. The storage and handling of packaging materials that are intended to come into direct contact with the product prevent mix-ups and microbiological or chemical

contamination; and

G. Finished product packages bear permanent, meaningful, unique batch numbers.

Documentation of standard operating procedures shall be sufficient to prevent errors of interpretation and loss of information. Such documentation shall be maintained for a minimum of five (5) years.

- 5.18.2 Quality Control: Review and Disposition. Licensees shall establish and follow written standard operating procedures and assign specific staff persons as quality control personnel to fulfill the following requirements for quality assurance and control:
 - A. Quality control personnel shall conduct a review and make a disposition decision if:
 - 1. A contaminant limit or water activity limit set forth in this Part is exceeded;
 - 2. <u>Production of a batch deviates from established standard operating procedures, including when any step is not completed;</u>
 - 3. There is any unanticipated occurrence during production operations that contaminates or may lead to contamination of cannabis, a manufactured cannabis product, component, or packaging, or could lead to the use of an incorrect label;
 - 4. Calibration of an instrument or control suggests a problem that may have resulted in a failure to ensure the quality of a batch of cannabis or cannabis product; or
 - 5. Cannabis or a cannabis product is returned.
 - B. The quality control review shall include examination of the following, as applicable:
 - 1. Batch production records;
 - 2. Certificates of analysis or other testing records for ingredients;
 - 3. Laboratory analysis records for finished product;
 - 4. <u>Label and packaging integrity</u>;
 - 5. Use by date; and
 - 6. Any other examinations necessary to determine whether quality standards are met.
 - C. When there is a deviation or unanticipated occurrence during the production and in-process control system that results in or could lead to contamination of cannabis,

a cannabis product, a component, or packaging, or could lead to the use of an incorrect label, quality control personnel shall reject the cannabis, cannabis product, component, packaging, or label unless quality control personnel approve a treatment, an in-process adjustment, or reprocessing to correct the applicable deviation or occurrence.

D. The person who conducts the review and makes the disposition decision shall, at the time of performance, document that review and disposition decision.

5.18.3 Quality Control Review and Disposition Decisions.

- A. <u>Licensed medical cannabis establishments shall establish and follow written standard operating procedures and assign specific staff persons as quality control personnel to fulfill the requirements of this Rule.</u>
- B. Quality control personnel shall conduct a review and make a disposition decision if:
 - 1. A contaminant limit or water activity limit established in this Part is exceeded;
 - 2. <u>Production of a batch deviates from established standard operating procedures, including when any step is not completed;</u>
 - 3. There is any unanticipated occurrence during production operations that contaminates or may lead to contamination of cannabis, a cannabis product, component, or packaging, or could lead to the use of an incorrect label;
 - 4. Calibration of an instrument or control suggests a problem that may have resulted in a failure to ensure the quality of a batch of cannabis or cannabis product; or
 - 5. Cannabis or a cannabis product is returned.
- C. The quality control review shall include examination of the following, as applicable:
 - 1. Batch production records;
 - 2. Certificates of analysis or other testing records for ingredients;
 - 3. <u>Laboratory analysis records for finished product;</u>
 - 4. Label and packaging integrity;
 - 5. Use by date; and
 - 6. Any other examinations necessary to determine whether quality standards are met.

- D. When there is a deviation or unanticipated occurrence during the production and in-process control system that results in or could lead to contamination of cannabis, a cannabis product, a component, or packaging, or could lead to the use of an incorrect label, quality control personnel shall reject the cannabis, cannabis product, component, packaging, or label unless quality control personnel approve a treatment, an in-process adjustment, or reprocessing to correct the applicable deviation or occurrence.
- E. The person who conducts the review and makes the disposition decision shall, at the time of performance, document that review and disposition decision.

5.18.4 Returned Cannabis or Cannabis Products.

- A. <u>Licensees shall establish and follow written standard operating procedures to fulfill</u> the requirements of this Rule.
- B. Quarantine and investigation of production processes. Returned cannabis or cannabis products shall be identified and quarantined until quality control personnel conduct a review and document a corrective action plan consistent with this Part.
- C. <u>Investigation of other batches</u>. <u>If the reason for cannabis or a cannabis product being returned implicates other batches</u>, <u>licensees shall conduct an investigation of each of those other batches in accordance with this Part to determine compliance</u>.
- D. <u>Destruction</u>. Any returned cannabis or cannabis product(s) shall be destroyed in accordance with the disposal requirements set forth in this Part., including, as applicable, use of a licensed disposal entity.

5.18.5 Product Complaints.

- A. <u>Licensees shall establish and follow written procedures to fulfill the requirements of this Rule.</u>
- B. Review and investigation of product complaints. A qualified person shall:
 - 1. Review all product complaints to determine whether the product complaint involves a possible failure of cannabis or a cannabis product to meet any of the contaminant limits or other requirements specified in this Part, including those requirements that, if not met, may result in a risk of illness or injury; and,
 - 2. Investigate any product complaint that involves a possible failure of cannabis or cannabis product(s) to meet any of the contaminant limits or other requirements of this Part, including those requirements that, if not met, may result in a risk of illness or injury.

- C. Quality control personnel shall review and approve decisions about whether to investigate a product complaint and review and approve the findings and follow-up action of any investigation performed.
- D. The review and investigation of the product complaint by a qualified person, and the review by quality control personnel about whether to investigate a product complaint, and the findings and follow-up action of any investigation performed, shall extend to all relevant batches and records.

5.18.6 Adverse events.

- A. <u>Licensees shall establish and follow written procedures to fulfill the requirements</u> of this section.
- B. A licensee shall notify the department within forty-eight hours after learning of an adverse event associated with cannabis or a cannabis product sold at a retail dispensing location operated by a dispensary licensee. For the purposes of this section, "adverse event" means any untoward (i.e., any unexpected and inappropriate) medical occurrence associated with the use of cannabis or a cannabis product, which may include any unfavorable or unintended sign, symptom, or disease.
- 5.18.7 The Department may issue public notice of a medical cannabis recall if, in its judgment, any particular cannabis and/or cannabis product presents a threat to the health and safety of qualifying patients. All medical cannabis establishments are responsible for complying with recall notices. Recalled items must-shall be immediately pulled from production or inventory and held until such time as the Department determines the item is safe, may be remediated, or must-shall be destroyed.

5.18.8 Recalls.

- A. <u>Licensees shall establish a written recall plan for cannabis and for each cannabis product.</u>
- B. The written recall plan shall include procedures that describe the steps to be taken, and assign responsibility for taking those steps, to perform the following actions as appropriate to the licensed establishment category:
 - 1. Notify the retail dispensing locations of the product being recalled, including how to return or dispose of the affected product;
 - 2. Notify qualifying patients, qualifying out-of-state patients, and the public about

- any hazard presented by the product when appropriate to protect public health;
- 3. Conduct effectiveness checks to verify that the recall is carried out; and
- 4. Appropriately dispose of recalled product (e.g., through reprocessing or destroying the product).
- C. <u>Licensees shall notify the department in writing within twenty-four hours of initiating a recall.</u>

5.18.9 Recordkeeping for Quality Control.

- A. <u>Licensees shall establish and maintain the following records documenting compliance with this Part</u>
 - 1. Written procedures for quality control operations, including:
 - a. Conducting a review and making a disposition decision;
 - b. Approving or rejecting any reprocessing;
 - c. Identifying and investigating additional potentially implicated batches;
 - d. <u>Handling of returned cannabis or cannabis products, including procedures</u> for quarantine, destruction, and salvaging and reprocessing; and
 - e. Reviewing and investigating product complaints;
 - 2. Written documentation, at the time of performance, that quality control personnel performed the review, approval, or rejection requirements by recording the following:
 - a. Date that the review, approval, or rejection was performed; and
 - b. Signature of the person performing the review, approval, or rejection;
 - 3. <u>Documentation of any quality control review and disposition decision and follow-up shall be included in the appropriate batch production record and shall include:</u>
 - a. Identification of the specific deviation or unanticipated occurrence;
 - b. <u>Description of the investigation into the cause of the deviation or unanticipated occurrence;</u>
 - c. Evaluation of whether or not the deviation or unanticipated occurrence has resulted in or could lead to a failure to ensure the quality of the cannabis or cannabis product;
 - d. Identification of the action(s) taken to correct, and prevent a recurrence of,

- the deviation or unanticipated occurrence;
- e. Explanation of what was done with the cannabis, cannabis product, packaging, or label;
- f. A scientifically valid reason for any reprocessing of a cannabis product that is rejected; and
- g. The signature of the individual(s) designated to perform the quality control operation, who conducted the review and made the disposition decision, and of each qualified individual who provides information relevant to the review and disposition decision;
- 4. The results of any laboratory analyses conducted as part of a quality control review or product complaint investigation;
- 5. Documentation of the re-evaluation by quality control personnel of a cannabis product that is reprocessed and the determination by quality control personnel of whether the reprocessed cannabis product meets contaminant limits established in this Part;
- 6. A written record documenting each product complaint detailing the following:
 - i. The name and description of the cannabis or cannabis product;
 - ii. The batch number of the cannabis or cannabis product, if available;
 - iii. The date the complaint was received and the name, address, or telephone number of the complainant, if available;
 - iv. The nature of the complaint including, if known, how the cannabis or cannabis product was used;
 - v. The reply to the complainant, if any; and
 - vi. <u>Findings of the investigation and follow-up action taken when an</u> investigation is performed;
- 7. A written record documented each adverse event known or reported; and,
- 8. A written recall plan.

5.18.10 Remediation and Reanalysis.

- A. As permitted under this Part, a batch of cannabis or cannabis products may be remediated and submitted for reanalysis by a Mississippi licensed cannabis testing enity in accordance with the following procedures:
 - 1. The licensee shall submit the sampling plan, certificate of analysis, and a

remediation plan to the Department within fourteen (14) calendar days of issuance of the certificate of analysis by the certified laboratory. The remediation plan shall include:

- a. A description of how the batch of cannabis or cannabis products will be remediated so that the batch, or any product produced therefrom, will meet all laboratory testing and quality assurance requirements; and,
- b. Evidence of the effectiveness of the proposed remediation strategy;
- 2. The licensee shall begin remediating the cannabis or cannabis products within fourteen (14) calendar days of receiving approval from the Department;
- 3. Any batch of cannabis or cannabis products that has been remediated shall be reanalyzed and the licensee shall submit the post-remediation certificate of analysis to the Department;
- 4. The licensee shall not distribute any cannabis or cannabis products from the remediated batch until receiving approval from the Department; and
- 5. The licensee shall dispose of the batch of cannabis or cannabis products in accordance with the disposal requirements contained in this Part if:
 - a. The licensee does not receive approval of its remediation plan from the Department;
 - b. The licensee is unable to begin remediation within fourteen (14) calendar days of receiving approval; or
 - c. The reanalysis results fail to meet any of the specifications for remediation contained in this Part.
- B. If any non-conforming cannabis or cannabis product is mixed with another batch of cannabis or cannabis product or remediated in violation of this Part, the batch or mixture shall be deemed contaminated, regardless of any analytical results, and shall be disposed of in a manner authorized under this Part.
- C. All remediation activities conducted under this rule shall be documented in batch production records.
- D. Remediated cannabis, cannabis products, and products produced therefrom shall be tested and undergo quality assurance review in accordance with all applicable requirements of this Part prior to distribution for dispensing.

Source: Miss. Code Ann. §§ 41-137-1 – 41-137-67.

Subpart 6 PACKAGING AND LABELING

6.1

- 6.1.1 Cannabis cultivation facilities <u>Licensees</u> shall not sell, or otherwise transfer cannabis and/or cannabis products to other medical cannabis establishments licensed by the Department and/or the MS Department of Revenue <u>MDOR</u> that are not packaged and labeled in accordance with these regulations.
- 6.1.2 Medical cannabis establishments receiving a sale or transfer from another medical cannabis establishment shall refuse to accept or shall return to the medical cannabis establishment transferring cannabis and/or cannabis products, any cannabis and/or cannabis products that are not packaged and labeled in accordance with these regulations. The medical cannabis establishment that sold or otherwise transferred the nonconforming cannabis and/or cannabis products shall accept such return.
- 6.1.3 Medical cannabis establishments shall document any such return, nonacceptance, or disposal, and such documentation shall include at a minimum:
 - 1. The license number, name, contact information, and address of the medical cannabis establishment that sold or otherwise transferred the nonconforming cannabis and/or cannabis products;
 - 2. A complete inventory of the cannabis and/or cannabis products to be returned or disposed, including the batch number;
 - 3. The reason for the nonacceptance, return, or disposal; and,
 - 4. The date of the nonacceptance, return, or disposal.
- 6.1.4 The following packaging requirements apply to all usable medical cannabis (retail-ready) being transferred to or sold to a medical cannabis dispensary for sale to a qualified patient and/or caregiver. Packaging and labelling, meeting the following requirements, shall be in place when transferred or sold to a medical cannabis dispensary:
 - Labels, packages, and containers shall not be attractive to minors and shall
 not contain any content that reasonably appears to target children, including
 toys, cartoon characters, or any color scheme, image, graphic, or feature that
 might reasonably be expected to make the product label, package, or
 container entice or appealing to children.

- 2. Packages should be designed to minimize appeal to children and shall not depict images other than the business name and logo of the medical cannabis establishment.
- 3. Packaging must shall contain a label that reads: "Keep out of reach of children".
- 4. All usable medical cannabis and cannabis products must shall be packaged in child-resistant containers at the point of sale or other transfer to a patient, a patient's parent, or legal guardian if patient is a minor, or a caregiver.
- 5. Packages and labels shall not contain product names related to candy or candies or any spellings thereof (e.g., kandy, kandies, etc.) or feature images that look like candy.
- 6. No cannabis and/or cannabis products shall be intentionally or knowingly packaged or labeled to cause a reasonable patient confusion as to whether the medical cannabis or medical cannabis product is a trademarked product or any commercially available candy, snack, baked good or beverage.
- 7. Packages and labels shall not make any claims or statements that the medical cannabis or medical cannabis products provide health or physical benefits to the patient.
- 8. <u>Must-Shall</u> not contain the logo of the Department or any seal, flag, crest, coat of arms, or other insignia that could reasonably mislead any person to believe the product has been endorsed, manufactured, or used by any state, county, or municipality or any agency thereof.
- 9. Cannabis products that have a potency of over thirty percent (30%) total THC must shall be labeled as "extremely potent".
- 10. Edible cannabis products must shall be labeled with a clear determination of how much total THC is in a single serving size and how much THC is in the entire package in a manner which indicates the number of servings of THC in the product and include a statement that the product's potency was tested with an allowable variance of plus or minus 10%. Potency of all products shall test +/- 10% of label claim or be repackaged to meet actual concentration. The single serving size must shall also be included on the label. An-All edible cannabis product must shall be labeled.
- 11. Usable medical cannabis must shall include the following on the label:
 - a. Name of the cannabis and/or cannabis product;
 - b. Batch number of the cannabis and/or cannabis product;

Unique identifier number created by the seed to sale system;

- c. Net quantity or weight of contents;
- d. The length of time it typically takes for the product to take affect;
- e. Disclosure of ingredients and possible allergens;
- f. A nutritional fact panel (applicable to cannabis products meant to be ingested);
- g. The total amount of THC and CBD in the product as verified by the cannabis testing facility;
- h. Terpenoid profile in the product as verified by the cannabis testing facility (if applicable);
- i. A notice of the potential harm caused by consuming medical cannabis; and,
- j. For edible cannabis products, when practicable, the Mississippi standard symbol indicating the product contains cannabis. This symbol is required on packaging as of July 1, 2023. The required symbol will be available for download from the Department.



- 6.1.5 All usable medical cannabis and/or cannabis products much be in compliant packaging upon entering the medical cannabis dispensary space.
- 6.1.6 All labeling must shall be in plain font that can be easily read.
- 6.1.7 All labeling on topical products must shall also state "For Topical Application Do Not Eat or Smoke".
- 6.1.8 Labels and packaging for food containing cannabis shall comply with all applicable requirements in existing Mississippi law, rules and regulations.

- 6.1.9 In addition to the labeling requirements in this Part, all usable (retail-ready) cannabis and/or cannabis products must-shall be packaged to meet the following:
 - 1. Packaging must shall be opaque and light resistant. The Department does not specify package coloring.
 - 2. Packing must shall fully enclose the product so that it cannot be seen from outside the packaging.
 - 3. Packaging must shall protect the product from contamination;
 - 4. Not impart any toxic or deleterious substance to the medical cannabis product;
 - 5. Must-Shall be in child-resistant packages or containers; and,
 - 6. <u>Must—Shall</u> be in a resealable package or container that meets the effectiveness specifications outlined in 16 CFR 1700.15, to the extent that such laws, rules, regulations do not conflict with the Mississippi Medical Cannabis Act, if the product contains more than one serving.
- 6.1.10 All cannabis and/or cannabis products sold or transferred between cannabis cultivation facilities and/or cannabis processing facilities shall be labeled (in addition to the required seed-to-sale tagging), and the label shall contain, at a minimum, the following information:
 - Name and license number of the cultivator/grower or <u>processor/manufacturer</u> who is selling or otherwise transferring the medical cannabis or medical cannabis product;
 - 2. The batch number of the medical cannabis or medical cannabis product;
 - 3. Date of harvest or production; and,
 - 4. Unique identifier number generated by the seed-to-sale system.

Source: Miss. Code Ann. §§ 41-137-1 – 41-137-67.

Subpart 7 TRANSPORTATION

7.1 General Requirements.

7.1.1 Cannabis transportation entities must shall comply with any and all motor vehicle laws in the State of Mississippi.

- 7.1.2 All employees must-shall possess a valid, unrestricted driver's license issued by the State of Mississippi and a valid work permit issued by the Department. The cannabis transportation entity must shall also issue each employee an identification badge, with picture. All documents referenced in this Rule must shall be in the employee's possession when in a vehicle transporting cannabis and/or cannabis products.
- 7.1.3 A cannabis transportation entity shall be responsible for any and all cannabis and/or cannabis products within its custody, control, or possession.
- 7.1.4 A cannabis transportation entity may transport cannabis and/or cannabis products to medical cannabis establishments during the hours of 5:00 a.m. until 9:00 p.m.
- 7.1.5 Prior to the transport of cannabis and/or cannabis products, the cannabis transportation entity <u>must_shall</u> ensure a trip plan has been created for each transportation event. At a minimum, a trip plan <u>must_shall</u> include the following:
 - 1. Names of employees transporting the cannabis and/or cannabis products;
 - 2. State issued work permits of the employees transporting the cannabis and/or cannabis products;
 - 3. Date and start time of the transport;
 - 4. Physical location of the originating medical cannabis establishment;
 - 5. Physical location of the receiving medical cannabis establishment;
 - 6. A description of the cannabis and cannabis products to be transported to include: quantities by weight or unit of each type of cannabis and/or cannabis products contained in the transport, along with the unique identifying numbers issued by the seed to sale system for each item;
 - 7. Any anticipated stops during the trip, including the locations of the stop and arrival and departure time from the location;
 - 8. The anticipated route of transportation;
 - 9. Any and all instances in which cannabis and/or cannabis products are stored at cannabis transportation entity's facilities; and,
 - 10. Estimated date and time of arrival at the receiving medical cannabis establishment.

- 11. The make, model, color and license plate number of the vehicles transporting cannabis and/or cannabis products.
- 7.1.6 A copy of the trip plan must shall be provided to the originating medical cannabis establishment and maintained by the cannabis transportation entity. A copy of the applicable trip plan must shall be kept in the vehicle during transport.
- 7.1.7 A cannabis transportation entity may make reasonable deviations from the anticipated routes identified on the trip plan when needed (for example, unanticipated mandatory detours for construction, traffic accidents, etc.). All deviations must_shall be reflected in the transportation entity's vehicle GPS system at all times.
- 7.1.8 Should a cannabis transportation entity possess cannabis and/or cannabis products outside of the approved transportation hours, the licensee must-shall immediately go to its nearest facility and store the cannabis and/or cannabis products in accordance with the rules in this Part.
- 7.1.9 To maintain the independence required, eCannabis transportation entities are prohibited from the following activities related to the medical cannabis program shall not:
 - 1. Growing/cultivating cannabis;
 - 2. Manufacturing/processing cannabis and/or cannabis products;
 - 3. Retail sales of cannabis and/or cannabis products;
 - 4. The resale of cannabis and/or cannabis products to other entities and medical cannabis establishments:
 - 5. Transportation, storage, and or delivery of cannabis and/or cannabis products to entities who are not licensed by the Department as medical cannabis establishments or the MS Department of Revenue MDOR as cannabis dispensaries; and,.
 - 6. Provision of cannabis and/or cannabis products directly to qualifying patients and/or caregivers as defined in this Part.

- 7.1.10 A cannabis transportation entity <u>must shall</u> have inventory tracking processes and procedures in place that include, but are not limited to, the following:
 - 1. Prior to the transport of cannabis and/or cannabis products, the originating medical cannabis establishment must_shall provide the transporter with a copy of the inventory/transportation manifest generated from the seed-to-sale system. At a minimum, the manifest must_shall include the following:
 - a. License number of the originating medical cannabis establishment;
 - b. Name and contact information of the originating medical cannabis establishment:
 - c. License number of the receiving medical cannabis establishment;
 - d. Name and contact information of the receiving medical cannabis establishment;
 - e. Physical address of the receiving medical cannabis establishment where cannabis and/or cannabis products are being delivered;
 - f. Quantities by weight or unit of each type of cannabis and/or cannabis products contained in the transport, along with the unique identifying numbers issued by the seed-to-sale system for each item;
 - g. The date of transport to include the time of departure and approximate arrival time;
 - h. Names and work permit numbers issued by the Department of the individuals accompanying the transport;
 - i. The make, model, color, and license plate number of the vehicles providing transport of cannabis and/or cannabis products.
- 7.1.11 An inventory/transportation manifest must shall be included with each transport.
- 7.1.12 An inventory/transportation manifest shall not be altered after departing the originating medical cannabis establishment. Such manifest made be made available to law enforcement, if requested.
- 7.1.13 There <u>must shall</u> not be any passenger or operator in a vehicle transporting cannabis and/or cannabis products that is not employed by the cannabis transportation entity while cannabis and/or cannabis products are present.

- 7.1.14 <u>Transportation of Cannabis or Cannabis Products to Retail Dispensary Locations.</u>
 - A. Cannabis and/or cannabis products that have undergone and passed regulatory compliance testing and have an accompanying COA may be transferred to one or more licensed dispensaries via a licensed cannabis transportation entity.
 - B. Cannabis and/or cannabis products that have not been transported to a licensed dispensary for retail sale within twelve (12) months of the date on the COA shall be destroyed or retested by the licensee in possession thereof. Retesting pursuant to this subsection shall only be conducted if the cannabis and/or cannabis products have not been modified in any way.

7.2 Vehicle Requirements.

- 7.2.1 Prior to use, a licensed cannabis transportation entity shall submit to the Department the license plate numbers, proof of insurance, and vehicle identification numbers for each vehicle being used to transport cannabis or cannabis-infused products.
- 7.2.2 Vehicles used to transport cannabis and/or cannabis products must shall be insured at or above the legal requirements in Mississippi.
- 7.2.3 Vehicles used to transport cannabis and/or cannabis products must shall be equipped with the following:
 - 1. An alarm system;
 - 2. A global positioning system (GPS) to monitor location, routes, etc. at all times with the ability to grant the Department and/or state and local law enforcement access to the system; and,
 - 3. Locked storage container as defined in Rule 7.1.2-1.2.73.
- 7.2.4 All vehicles used to transport cannabis and/or cannabis products must-shall meet one of the following requirements for video surveillance or staffing required during transport of cannabis and/or cannabis products:
 - 1. Staffed with a minimum of two (2) employees when a vehicle contains cannabis and/or cannabis products. At least one (1) employee shall remain

- with the vehicle any time it contains cannabis and/or cannabis products; or
- 2. Utilize video surveillance of the vehicle (meeting video surveillance requirements in Rule 7.11.5-7.3.5 of this Subpart) to include:
 - a. Installation of video cameras in the interior of vehicles transporting cannabis and/or cannabis products; and,
 - b. Video surveillance of the interior of the vehicle, particularly the locked storage areas where cannabis and/or cannabis products are located.
- 7.2.5 All vehicles used for the purpose of transporting cannabis and/or cannabis products shall be maintained in a sanitary condition.
- 7.2.6 A vehicle transporting cannabis and/or cannabis products must shall not bear any markings to indicate the vehicle contains cannabis or bear the name or logo of the medical cannabis establishment.
- 7.3 Storage Requirements During and Outside of Transport.
- 7.3.1 A transporter shall not transport cannabis and/or cannabis-products unless it is first packed in a cannabis container by the originating medical cannabis establishment.
- 7.3.2 A cannabis container for transport must shall be:
 - 1. Sealable and sealed during transport;
 - 2. Locked during transport;
 - 3. Clearly labeled as medical cannabis and/or medical cannabis-product;
 - 4. Maintained in a locked and secure storage compartment that is part of the vehicle or a locked storage container with a separate key or combination lock.
- 7.3.3 A transporter shall not open a cannabis container. Once a cannabis container is packed and sealed for delivery, only the following may open a cannabis container:
 - 1. The originating medical cannabis establishment;
 - 2. The medical cannabis establishment intended for delivery;

- 3. Local, State, or federal law enforcement;
- 4. An employee of the Department or the MS Department of Revenue MDOR.
- 7.3.4 Cannabis and/or cannabis-products shall be transported so it is not visible or recognizable from outside the vehicle.
- 7.3.5 If a cannabis transportation entity is required to store cannabis and/or cannabis products, the storage location must_shall, at a minimum, meet the following requirements:
 - 1. Cannabis and/or cannabis products must be stored at location Approved licensed by the Department during the application process as part of the cannabis transportation entity's license;
 - 2. Be secure, and enclosed with permanent walls, and controls for temperature and relative humidity to ensure storage in a manner that prevents the cannabis and cannabis products from becoming adulterated.;
 - 3. Be locked at all times:
 - 4. Be accessible only to specifically identified employees of the cannabis transportation entity;
 - 5. Have an alarm system that meets the following:
 - a. Upon attempted unauthorized entry, the alarm system shall transmit a signal directly to a central protection company or a law enforcement agency that has a legal authority to respond. A designated employee of the cannabis transportation entity must-shall also be notified.
 - b. Provide continuous, uninterrupted coverage (24 hours/7 days) for all points of ingress and egress to the facility, including without limitation doorways, windows, loading areas;
 - c. Provide continuous, uninterrupted coverage (24 hours/7 days) of any room with an exterior wall, any room containing a safe, and any room used to store cannabis and/or cannabis products;
 - d. Be equipped with failure notification systems to notify the transporter and law enforcement of any failure in the alarm system; and,
 - e. Have the ability to remain operational during a power outage.
 - 6. Have continuous, uninterrupted video surveillance that meets the following:

- a. Provide continuous, uninterrupted coverage (24 hours/7 days) for all points of ingress and egress to the facility, including without limitation doorways, windows, loading areas, and parking areas;
- b. Provide continuous, uninterrupted coverage (24 hours/7 days) of any room with an exterior wall, any room containing a safe, and any room used to store cannabis and/or cannabis products;
- c. Digital archiving capabilities for a minimum of (120) days;
- d. On-site and off-site monitoring capabilities;
- e. Have the date and time embedded on all surveillance recordings without significantly obscuring the picture; and,
- f. Use cameras that are capable of recording in both high and low lighting conditions.
- 7.3.6 Transportation of cannabis, cannabis products, and components shall be under conditions that will protect against allergen cross-contact and against biological, chemical (including radiological), and physical contamination of cannabis, cannabis products, or components as well as against deterioration of the cannabis, cannabis product, or component and the container.
- 7.3.7 Upon request, a medical cannabis establishment must shall make all information related to security alarm systems and video surveillance, monitoring, and recordings available to the Department within the timeframe requested.

Source: Miss. Code Ann. §§ 41-137-1 – 41-137-67.

Subpart 8 WASTE DISPOSAL

- 8.1.1 Cannabis disposal entities must shall also comply with all applicable rules and regulations in this Part to include, but not limited to, licensure and registration as a cannabis transportation entity (see 15 Miss. Admin Code Pt. 22, Subpart 7 for transportation requirements) if the cannabis disposal entity transports cannabis and/or cannabis products.
- 8.1.2 All employees must shall possess a valid, unrestricted driver's license issued by the State of Mississippi and a valid work permit issued by the Department. The

cannabis disposal entity <u>must_shall</u> also issue each employee an identification badge, with picture. All documents referenced in this Rule <u>must_shall</u> be in the employee's possession when in a vehicle transporting cannabis and/or cannabis products.

- 8.1.3 A cannabis disposal entity shall be responsible for any and all cannabis and/or cannabis products within its custody, control, or possession.
- 8.1.4 Unless specifically licensed by the Department to do so, cannabis disposal entities are prohibited from the following activities related to the medical cannabis program:
 - 1. Growing/cultivating cannabis;
 - 2. Manufacturing/processing cannabis and/or cannabis products;
 - 3. Retail sales of cannabis and/or cannabis products;
 - 4. The resale of cannabis and/or cannabis products to other entities and medical cannabis establishments:
 - 5. Transportation, storage, and delivery of cannabis and/or cannabis products (outside of the purposes of disposal and/or destruction of cannabis waste); and,
 - 6. Provision of cannabis and/or cannabis products directly to qualifying patients and/or caregivers as defined in this Part.
- 8.1.5 If a cannabis disposal entity is required to store cannabis and/or cannabis products, the storage location must_shall, at a minimum, meet the following requirements:
 - 1. Cannabis and/or cannabis products must shall be stored at location licensed by the Department as part of the cannabis disposal entity's license;
 - 2. Be secure and enclosed with permanent walls;
 - 3. Be locked at all times:
 - 4. Be accessible only to specifically identified employees of the cannabis transportation entity;
 - 5. Have an alarm system that meets the following:

- a. Upon attempted unauthorized entry, the alarm system shall transmit a signal directly to a central protection company or a law enforcement agency that has a legal authority to respond. A designated employee of the cannabis transportation entity must shall also be notified;
- b. Provide continuous, uninterrupted coverage (24 hours/7 days) for all points of ingress and egress to the facility, including without limitation doorways, windows, loading areas;
- c. Provide continuous, uninterrupted coverage (24 hours/7 days) of any room with an exterior wall, any room containing a safe, and any room used to store cannabis and/or cannabis products;
- d. Be equipped with failure notification systems to notify the transporter and law enforcement of any failure in the alarm system; and,
- e. Have the ability to remain operational during a power outage.
- 6. Have continuous, uninterrupted video surveillance that meets the following:
 - a. Provide continuous, uninterrupted coverage (24 hours/7 days) for all points of ingress and egress to the facility, including without limitation doorways, windows, loading areas, and parking areas;
 - b. Provide continuous, uninterrupted coverage (24 hours/7 days) of any room with an exterior wall, any room containing a safe, and any room used to store cannabis and/or cannabis products;
 - c. Digital archiving capabilities for a minimum of (120) days;
 - d. On-site and off-site monitoring capabilities;
 - e. Have the date and time embedded on all surveillance recordings without significantly obscuring the picture; and,
 - f. Use cameras that are capable of recording in both high and low lighting conditions.
- 8.1.6 All medical cannabis waste set designated for disposal shall be properly weighed and recorded in the state's seed-to-sale system. Waste set for disposal must be weighed and recorded, at the following points at a minimum:
 - 1. On-site at the medical cannabis establishment for which the cannabis disposal entity is providing services; and,
 - 2. At the final destination where disposal/destruction occurs.

- 8.1.7 Cannabis waste shall be disposed through of either via a process which renders the waste unusable and unrecognizable through physical destruction or a recycling process that the waste disposal facility is authorized to conduct pursuant to by Mississippi law to carry out.
- 8.1.8 The disposal/destruction of cannabis waste must shall be done under video surveillance by the cannabis disposal entity's video surveillance system described in Rule 8.9.3 and made available to the Department upon request.
- 8.1.9 Medical cannabis and/or cannabis products shall be rendered unusable by grinding and incorporating the cannabis plant waste with other ground materials, so the resulting mixture is at least fifty percent 50% non-cannabis waste by volume. This includes compostable mixed waste and non-compostable mixed waste meeting the requirements below.
- 8.1.10 Grinding and incorporating the cannabis waste into compostable mixed waste until it is unusable and unrecognizable: Cannabis waste to be disposed of as compost or in another organic waste method may be mixed with the following types of waste materials:
 - 1. Food waste:
 - 2. Yard waste:
 - 3. Vegetable based grease oils;
 - 4. Agricultural Materials;
 - 5. Biodegradable products and paper;
 - 6. Clean wood;
 - 7. Fruits and vegetables; or
 - 8. Plant matter.
 - 9. Bokashi or other compost activators; or,
 - 10. Other materials or methods approved by the Department that will render the cannabis waste unusable and unrecognizable.
- 8.1.11 Grinding and incorporating the cannabis waste into non-compostable mixed waste until it is unusable and unrecognizable: Cannabis waste to be disposed of

in a landfill or another disposal method, such as incineration, may be mixed with the following types of waste materials:

- 1. Paper waste;
- 2. Cardboard waste;
- 3. Plastic waste;
- 4. Soil;
- 5. Nonrecyclable plastic;
- 6. Broken glass;
- 7. Sawdust; or
- 8. Other materials or methods approved by the Department that will render the cannabis waste unusable and unrecognizable.
- 8.1.12 Licensure and/or permitting may <u>also</u> be required through the Mississippi Department of Environmental Quality <u>for cannabis disposal entities as well as local permitting, may also be required</u> dependent upon <u>the</u> location of the cannabis disposal entity.

Source: Miss. Code Ann. §§ 41-137-1 – 41-137-67.

Subpart 9 ADVERTISING AND MARKETING

- 9.1 Prohibition Against Advertising and Marketing.
- 9.1.1 Medical cannabis establishments participating in the Medical Cannabis Program licensed by the Department pursuant to this Part, or entities acting on their behalf, are prohibited from advertising and marketing in any media, including but not limited to:
 - A. Broadcast or electronic media:
 - 1. Radio
 - 2. Television
 - 3. Unsolicited internet pop-up advertising
 - 4. Social media
 - B. Print media:

1. Newspaper

C. Other forms:

- 1. Mass text/messaging communications.
- 2. Mass email communications.
- 3. Medical cannabis or medical cannabis products shall not be displayed in windows or public view.
- 4. Advertisement in any manner that can be viewable or otherwise perceived as a public space, including, but not limited to, adopt a highway signs, and electronic interstate signs.
- 5. Solicited/paid patient and/or caregiver reviews/testimonies/endorsements.
- 6. Solicited/paid practitioner reviews/testimonies/endorsements.
- 9.1.2 No Medical Cannabis Establishment Licensees shall not engage in advertising that contains any statement or illustration that:
 - A. Depicts the actual consumption of cannabis or cannabis products;
 - B. Promotes the overconsumption of cannabis or cannabis products;
 - C. Makes any health, medicinal, or therapeutic claims about cannabis or cannabis products;
 - D. Makes safety claims of any type;
 - E. Includes the image of a cannabis leaf or bud; or
 - F. Includes any image designed or likely to appeal to minors, including cartoons, toys, animals, or children or any other likeness, images, characters, or phrases that are designed in any manner to be appealing to children and/or youth.

9.2 Branding Requirements.

9.2.1 Medical cannabis establishments <u>licensed by the Department pursuant to this Part</u> are permitted to participate in branding activities as described in Rules 3.3.2.9.2.2 and 3.3.5.9.2.3 in order to publicize their businesses. Additionally, the business name, <u>location(s)</u>, and contact information of all licensed medical cannabis establishments will be made available by the Department through a public website.

- 9.2.2 Permissible branding activities include:
 - 1. Establishment of a website and/or social media presence that provides general information on the licensed entity's contact information, retail dispensing locations, and a list of products available.
 - 2. Listings in business directories (inclusive of phone books, cannabis-related or medical publications):
 - 3. Display of cannabis in company logos and other branding activities; and,
 - 4. Sponsorships of health or not-for-profit charity or advocacy events.
- 9.2.3 Branding must shall not target minors, pregnant women, breastfeeding women, or promote non-medical use of cannabis.
- 9.2.4 Branding, in the form of business signage, for all <u>licensed</u> medical cannabis establishments is subject to local zoning and permitting requirements.

9.3 Use of Inducements.

- 9.3.1 Medical Cannabis Establishments <u>Licensees</u> may utilize inducements to assist qualified patients. Inducements <u>must shall</u> not persuade or influence the use of medical cannabis outside of practitioner recommendations and/or limitations or the amounts allowed by the Mississippi Medical Cannabis Act. Examples of inducements include, but are not limited to:
 - 1. The use of discount cards;
 - 2. The use of coupons;
 - 3. The use of "punch cards" to offer discounts/free products;
 - 4. Promotion of sales/discounts on medical cannabis of any type;
 - 5. The use of "buy one, get one" discount approaches; and,
 - 6. The use of any type of "daily deal", "weekly deal", "monthly deal", etc.
- 9.3.2 Any and all medical cannabis and/or medical cannabis products that are part of an inducement program as defined in Rule 3.4.1 9.3.1, remain subject to seed-to-sale tracking requirements, any practitioner limitation included on the qualified patient's written certification, and MS Medical Cannabis Equivalency Unit

MMCEU allotment limitations of set forth in the Mississippi Medical Cannabis Act.

9.4 Education Regarding the Risks and Benefits of Medical Cannabis.

- 9.4.1 Education on the risks and benefits of the use of medical cannabis between a registered practitioner and/or medical cannabis establishment and a qualified patient, caregiver, parent, or legal guardian is permissible. This education is not considered advertising or marketing.
- 9.4.2 Education on the risks and benefits of the use of medical cannabis between a registered practitioner and/or medical cannabis establishment and a qualified patient, caregiver, parent, or legal guardian can also include written or video educational materials that are inclusive of the medical cannabis establishment's brand.
- 9.4.3 Education provided to a qualified patient, caregiver, parent, or legal guardian by a registered practitioner and/or medical cannabis establishment that includes instruction/direction on the safe use of medical cannabis and/or medical cannabis products is permissible.
- 9.4.4 Except as otherwise provided in this Part tThe use of pictures and/or images of cannabis and/or cannabis products must-shall be limited to patient education materials.
- 9.4.5 Patient Education. A registered practitioner or medical cannabis establishment may provide educational materials about cannabis to qualifying patients and/or their designated caregivers, parents and/or legal guardians. Educational materials must shall adhere to the following:
 - A. Information about the potential risks and side effects of medical cannabis use, including the risk of poisoning and the number for the closest poison control center must shall be included;
 - B. Information to assist in the selection of cannabis, describing the potential differing effects of various strains of cannabis, as well as various forms and routes of administration, purported effectiveness of various methods, and the differences in the anticipated time frames for the forms to take affect may be

included;

- C. Materials offered to registered qualifying patients and their personal caregivers to enable them to track the strains used and their associated effects may be included;
- D. Information on tolerance, dependence, and withdrawal may be included;
- E. Information regarding substance abuse signs and symptoms, as well as referral information for substance abuse treatment programs; and,
- F. Other warnings, instructions, and/or directions on the safe use of medical cannabis and/or medical cannabis products which the registered practitioner and/or medical cannabis establishment deems appropriate.

Source: Miss. Code Ann. §§ 41-137-1 – 41-137-67.

Subpart 10 VARIANCE REQUESTS

- 10.1.1 Through a variance, the Department may waive provisions of this Part on its own initiative or by request from licensed medical cannabis establishments. The Department shall not consider Variance Requests related to provisions that are purely statutory.
- 10.1.2 Requests for variance from the rules of any provision of this Part shall be made in writing and will be granted or denied by the State Health Officer. Variance Requests must shall include:
 - 1. A list of each rule for which a variance is requested, with citation to the specific rule(s);
 - 2. An explanation of why the rule cannot be met at the time of the request or why meeting the rule would impose an undue burden on the licensed medical cannabis establishment; and,
 - 3. The requested relief.

Denial of variance requests shall be issued by the Department in writing and shall include the specific reasons for the denial.

- 10.1.3 The Variance Request <u>must_shall</u> be submitted by the primary contact of the licensed medical cannabis establishment in a complete-format approved by the Department.
- 10.1.4 Variance Requests are not guaranteed for approval and will not be approved to circumvent any relevant rule, regulation or standards promulgated under the Act or any portion thereof. The medical cannabis establishment making the Variance Request should continue to meet Department-published rules in this Part while the #Request is under consideration and pending.

Source: Miss. Code Ann. §§ 41-137-1 – 41-137-67.

Subpart 11 Enforcement and Penalties

- 11.1 Suspension or Revocation of License, Fines or Other Penalties.
- 11.1.1 The Department may take the following actions against licensees, alone or in combination, in any case in which it finds that the a licensee has failed to comply with the requirements established by the Mississippi Medical Cannabis Act and/or the rules, regulations or standards promulgated in furtherance of such act:
 - A. Impose monetary penalties;
 - B. Issue an Administrative Hold;
 - C. Suspend a license;
 - D. Revoke a license;
 - E. Accept the voluntary surrender of a license;
 - F. Confiscate or seize cannabis plants, cannabis and/or cannabis products;
 - G. Order destruction of cannabis plants, cannabis and/or cannabis products;
 - H. Recall cannabis and/or cannabis products; or
 - I. Accept the voluntary surrender of cannabis plants, cannabis and/ cannabis products.

The following schedule of disciplinary actions included as APPENDIX B to this Part shall be used when administratively disciplining medical cannabis establishments for violating statutory and/or regulatory requirements. The Department reserves the right to increase penalties based on aggravating

circumstances and/or the medical cannabis establishment's history of violations and corrective actions.

- 11.1.2 Suspension. In addition to the schedule of disciplinary actions included as APPENDIX B to this Part, the Department may suspend the license of a medical cannabis establishment if necessary to protect public health, safety, or welfare. A suspension shall not exceed a period longer than six (6) months. A medical cannabis establishment may continue to possess and cultivate cannabis as otherwise authorized to do so under its license during a suspension, but it may not dispense, transfer or sell cannabis.
- 11.2.3 The Department may seize, destroy, confiscate or place an administrative hold on any cannabis plants, cannabis and/or cannabis products under, but not limited to, the following circumstances:
 - A. Failure to log and/or tag in the seed-to-sale system;
 - B. Alteration of cannabis and/or cannabis products in a manner that fails to comply with this Part;
 - C. Failure to package and label in accordance with this Part in general and Section 11 specifically;
 - D. Such items are cultivated, harvested, manufactured or transferred in a manner, or otherwise in a form, not compliant with the rules/regulations in this Part or the Mississippi Medical Cannabis Act Use; or
 - E. <u>Improper use</u>, handling, storage, transport, transfer or other possession of such items.
- 11.2.4 Administrative Holds. The Department may order an administrative hold of cannabis plants, cannabis and/or cannabis products to prevent destruction of evidence, diversion or other threats to public safety, while permitting a licensee to retain its inventory pending further investigation, pursuant to the following procedure:
 - A. If during an investigation or inspection of a licensee, an employee or agent of the Department develops reasonable grounds to believe certain cannabis plants, cannabis or cannabis products constitute evidence of acts in violation of the rules/regulations in this Part, the Mississippi Medical Cannabis Act or constitute a threat to the public health or safety, the Department may issue a notice of administrative hold of any such cannabis plants, cannabis or

- cannabis products. The notice of administrative hold shall provide a documented description of the cannabis plants, cannabis and/or cannabis products subject to the administrative hold and a concise statement regarding the reasons for issuing the administrative hold.
- B. The Department will identify the cannabis plants, cannabis and/or cannabis products subject to the administrative hold in the seed-to-sale system. The licensee shall continue to comply with all inventory tracking requirements of the seed-to-sale system.
- C. The licensee shall completely and physically segregate the cannabis plants, cannabis and/or cannabis products subject to the administrative hold in a limited access area of the licensed premises under investigation, where it shall be safeguarded by the licensee.
- D. While the administrative hold is in effect, the licensee is prohibited from selling, giving away, transferring, transporting or destroying the cannabis plants, cannabis and/or cannabis products subject to the administrative hold, except as otherwise authorized by this Part.
- E. While the administrative hold is in effect, the licensee must safeguard the cannabis plants, cannabis and/or cannabis products subject to the administrative hold, must maintain the licensed premises in reasonable condition according to health, safety and sanitary standards, and must fully comply with all security requirements, including but not limited to all surveillance, lock and alarm requirements in this Part.
- F. Nothing herein shall prevent a licensee from voluntarily surrendering cannabis plants, cannabis and/or cannabis products that is subject to an administrative hold, except that the licensee shall follow the procedure authorized by the Department to complete the voluntary surrender.
- G. Nothing herein shall prevent a licensee from the continued possession, cultivation or harvesting of the cannabis plants, cannabis and/or cannabis products subject to the administrative hold.
- H. At any time after the initiation of the administrative hold, the Department may lift the administrative hold or seek other appropriate relief.

11.1.5 Emergency Decision and Order.

A. The Department may issue an emergency decision and order for temporary, interim relief to prevent or avoid immediate danger to the public health, safety, or welfare. Such circumstances include, but are not limited to, the

following:

- 1. The Department has information that cannabis and/or cannabis products at a licensee's premises have a reasonable probability of causing serious adverse health consequences or death.
- 2. To prevent the sale, transfer, or transport of contaminated or illegal cannabis and/or cannabis products in possession of a licensee.
- 3. The Department observes or has information that conditions at a licensee's premises exist that present an immediate risk to worker or public health and safety.
- 4. To prevent illegal diversion of cannabis and/or cannabis products, or other criminal activity at a licensee's premises.
- 5. To prevent the destruction of evidence related to illegal activity or violations of the Act.
- 6. To prevent misrepresentation to the public, such as selling untested cannabis and/or cannabis products or providing inaccurate information about cannabis and/or cannabis products.
- B. <u>Temporary</u>, interim relief may include a suspension or administrative hold by one or more of the following:
 - 1. An order temporarily suspending a license.
 - 2. An order to segregate or isolate specific cannabis and/or cannabis products.
 - 3. An order prohibiting the movement of cannabis and/or cannabis products to or from the premises.
 - 4. An order prohibiting the sale of specific cannabis and/or cannabis products.
 - 5. An order prohibiting the destruction of specific cannabis and/or cannabis products.
- C. The emergency decision and order issued by the Department shall include a brief explanation of the factual and legal bases of the emergency decision that justify the Department's determination that emergency action is necessary, and the specific actions ordered. The emergency decision and order shall be effective when issued or as otherwise provided by the decision and order.
- D. To issue an administrative hold that prohibits activity related to specified cannabis and/or cannabis products, the Department shall comply with the

following:

- 1. Provide notice of the administrative hold that includes a description of the cannabis and/or cannabis procuts subject to the administrative hold.
- 2. Following notice, the Department shall identify the cannabis and/or cannabis products subject to the administrative hold in the seed-to-sale system.
- E. A licensee subject to an administrative hold shall comply with the following:
 - 1. Within 24 hours after receipt of notice of the administrative hold, physically segregate all designated cannabis and/or cannabis products in a limited-access area of the licensed premises. The licensee shall ensure that all cannabis and/or cannabis products subject to the administrative hold are safeguarded and preserved in a manner that prevents tampering, degradation, or contamination.
 - 2. While the administrative hold is in effect, the licensee shall not sell, donate, transfer, transport, gift, or destroy the cannabis and/or cannabis products subject to the hold.
 - 3. A licensee may voluntarily surrender cannabis and/or cannabis products that are subject to an administrative hold. The licensee shall identify the cannabis and/or cannabis products being voluntarily surrendered in the seed-to-sale system.
- F. To issue a temporary suspension, the Department shall specify in the order that the licensee shall immediately cease conducting all commercial cannabis activities under its license, unless otherwise specified in the order. If the order permits the cannabis to be harvested, the licensee shall place the harvested cannabis into separate batches.
- G. The emergency decision and order for temporary, interim relief shall be issued in accordance with the following procedures:
 - 1. The Department shall give notice of the emergency decision and order and an opportunity to be heard to the licensee prior to the issuance, or effective date, of the emergency decision and order, if practicable.
 - 2. Notice and hearing under this section may be oral or written and may be provided by telephone, personal service, mail, facsimile transmission, electronic mail, or other electronic means, as the circumstances permit.
 - 3. Notice may be given to the licensee, any person meeting the definition of owner for the license, or to a manager or other personnel at the licensed premises.

- 4. Upon receipt of the notice, the licensee may request a hearing within three
 (3) business days by submitting a written request for hearing to the
 Department through electronic mail, facsimile transmission, or other
 means. The hearing shall commence within five (5) business days after
 receipt of the written request for hearing, unless a later time is agreed
 upon by the Department and the licensee.
- 5. The hearing may be conducted in the same manner as a hearing under Rule 11.1.7; however, the timeframes provided in Rule 11.1.7 shall not apply to a hearing under this rule. Pre-hearing discovery or cross-examination of witnesses is not required under this section.
- 6. The emergency decision and order shall be affirmed, modified, or set aside as determined appropriate by the Department within five (5) business days after the hearing.
- H. After formal proceedings are held to resolve the underlying issues giving rise to the temporary, interim relief, a licensee aggrieved by a final decision of the Department may appeal the decision as set forth in Section 11.2.
- I. The Department's authority provided by this rule may be used in addition to any civil, criminal, or other administrative remedies available to the Department.
- 11.1.6 Notification Notice: At the time of denial of an application for licensure or the imposition of any monetary penalty and prior to imposition of non-monetary sanctions, suspension or revocation of a license, or denial of an application for licensure, written notice of the contemplated action shall be given to the licensee at the address on record with the licensing agency. Such notice shall specifying the reason(s) for the proposed action and shall notify the licensee of the right to a hearing on the matter.

The Department shall provide its initial notice of <u>denial</u>, suspension, revocation, fine or other sanction by personal delivery, <u>or</u> mailing by certified mail, signature required, <u>or by electronic mail to the applicant or licensee</u>, as <u>applicable</u>, to the <u>medical cannabis licensee</u> at the address <u>listed in its application</u> on record with the <u>licensing agency Department</u>.

11.1.7 Request for an Administrative Appeal/Hearing. The Mississippi State Department of Health will provide to a licensee/aggrieved party an opportunity for a prompt and fair appeal process when the licensee/aggrieved party is dissatisfied with an administrative decision imposing fines and/or other

<u>penalties/</u>sanctions, <u>denial,</u> suspension, or revocation of a license and wishes to appeal the administrative decision.

- A. Upon written request by the licensee/aggrieved party and within twenty (20) days of receipt of the initial notice of administrative action, the licensee/aggrieved party may file a request for an appeal which is handled through the means of an administrative hearing with the Department. Once a licensee/aggrieved party requests an appeal, the State Health Officer shall be notified by the Department and shall appoint a qualified Hearing Officer within thirty (30) days to set a date, time and place for the administrative hearing convenient for all parties.
- B. If the licensee/aggrieved party fails to appeal the initial notice within the prescribed time, the decision becomes final and cannot be further appealed.
- C. A court reporter shall attend and transcribe the proceeding.
- D. Hearings before a Hearing Officer are considered confidential and are not open to the public.
- E. An informal review may be granted for any situation, but is not required before seeking an administrative appeal, and if requested, does not toll the time limit to request an appeal/administrative hearing.
- F. The parties may continue to attempt to resolve issues informally once the formal appeals process has begun.
- G. The licensee/aggrieved party shall be entitled to legal representation at the hearing at his/her own expense but may also choose to represent himself/herself. The burden shall be on the licensee/aggrieved party at the hearing to prove that the agency—Department's decision was: (a) arbitrary or capricious; (b) unsupported by substantial evidence; (c) beyond the power of the administrative agency—Department to make; or (d) violated a statutory or constitutional right of the aggrieved party.
- H. A continuance for an administrative hearing may only be requested by a showing of good cause and may be granted at the discretion of the Hearing Officer. A request for a continuance must shall be made within ten (10) days of the date for which it is needed unless it is due to an emergency.
 - 1. Within thirty (30) calendar days of the hearing, or such period as determined during the hearing, written findings of fact together with a recommendation from the Hearing Officer shall be forwarded to the State Health Officer for review. The State Health Officer may adopt, modify, or reject the Hearing Officer's recommendation or decide what, if any, action is to be taken on the matter. The decision by the State Health

- Officer will be made within fourteen (14) calendar days of receipt of the recommendation from the Hearing Officer and will be considered the Final Decision or Final Order by the Department.
- 2. Written notice of the decision shall be provided to the licensee/aggrieved party at the address on record with the Department. Licensee/aggrieved party has a duty to update his/her address as necessary to receive correspondence in a timely manner.
- 3. Appeal of the Department's Final Order shall be accomplished as provided by the appropriate statute.
- 4. If the licensee/aggrieved party fails to appeal the Final Order within the prescribed time, the decision becomes final and cannot be further appealed.
- 5. For the *Rules and Procedures for State Level Administrative Hearings* refer to APPENDIX AC of this Part.

11.2 Appeal of Final Decisions or Orders.

- Any person or entity who disagrees with or is aggrieved by the Final Decision or Final Order of the Department concerning the imposition of fine(s) and/or other sanction(s), including but not limited to, denial of an application for licensure, suspension, or revocation of a license may appeal same in the circuit court of the county in which he/she resides. If the aggrieved party is a nonresident of this state, he/she may appeal to the Circuit Court of the First Judicial District of Hinds County, Mississippi. The appeal shall be filed no later than twenty (20) calendar days after the issuance of the Final Decision or Order by the Department.
- The review by the circuit court shall be based on the record made before the Department. Before filing an appeal petition in circuit court, the appellant shall obtain from the Department an estimate of the cost to prepare the entire record of the Department and shall pay to the Department the amount of the estimate. The circuit court shall dismiss with prejudice any petition filed where it is shown that the petitioner failed to pay prior to filing the petition the estimated cost for preparation of the record. TheOn appeal to the circuit court, appellant shall have the burden of proving that the decision of the Department was: (a) arbitrary or capricious; (b) unsupported by substantial evidence; (c) beyond the power of the administrative agency to make; or (d) violated some statutory or constitutional right of the licensee/aggrieved party.

- 11.2.3 Any person or entity aggrieved by the decision of the circuit court may appeal to the Mississippi Supreme Court.
- If a medical cannabis establishment is allowed to continue to operate during the appeal process, it will remain under the regulation of the Department and will be subject to all current licensure regulations to include, but not limited to, inspection of the facility, review of facility and/or records, submission of all required or requested documents, and payment of all applicable fees and/or monetary penalties. However, the medical cannabis establishment may not dispense, transfer or sell cannabis during this period.
- 11.2.5 A cannabis testing <u>facility entity</u> may continue to possess cannabis under its license during a suspension but shall not receive, transfer or test cannabis during the suspension period.

Source: Miss. Code Ann. §§ 41-137-1 – 41-137-67.

APPENDIX A

Table 1

Key to Table 1:

- CAS Number = Chemical Abstract Services Registry number
- CFU = Colony-forming unit, a method to estimate the number of viable bacteria or fungal cells in a sample.

A. Microbial Contaminants			
Analyte	Maximum Allowable Contaminants	Required Action	
Total Escherichia coli	100 CFU/g	Remediate and retest, or Destroy	
Total coliform	100 CFU/g	Use to make a concentrate or extract if the processing	

		method effectively sterilizes the batch and retested or destroy	
Shiga toxin- producing Escherichia coli	Detectable in 1 gram	Remediate and retest, or Destroy	
Salmonella spp.	Detectable in 1 gram	Destroy	
Aspergillus flavus,	Inhalable: Detectable in 1 gram	Remediate and retest, Remediate and use for preparing an extract or a concentrate, or destroy Use to make a concentrate or extract if the processing method effectively sterilizes the batch and retest or destroy	
Mycotoxins: Aflatoxin B1, B2, G1, and G2 Ochratoxin A	Marijuana Cannabis product, except a marijuana cannabis product intended for topical application, prepared from an extract or concentrate of medical marijuana:cannabis	Destroy	
Total Mold and Yeast	1000 CFU/g	Use to make a concentrate or extract f the processing method effectively sterilizes the batch and retest or destroy	
B. Heavy Metals			
	Maximum Allowable Concentration (ppm)	Required Action	
Analyte	Inhaled Inhaled Other		

Arsenic	0.4	0.2		1.5	
Cadmium	0.4	0.2		0.5	D P
Lead	1.0	0.5		0.5	Remediate and retest, or Destroy
Mercury	0.2	0.1		3.0	
Total Chromium	1.2	0.6		2.0	*Copper is required for vaping products only
<u>Nickel</u>	1.0	0.5		<u>N/A</u>	vaping products only
<u>Copper</u>	N/A	3.0*		<u>N/A</u>	
	C.	Residual S	Solv	ents	
Analyte	CAS Nui	nber	A	Iaximum Allowable ncentration	Required Action
Acetone	67-64	-1]	1,000 ppm	
Acetonitrile	75-05	-8		410 ppm	
Benzene	71-43-2			2 ppm	
Butanes (measured as the cumulative residue of n- butane and iso- butane)	106-97-8 and respecti		5,0	000 ppm	
Chloroform	67-66-3		1	60 ppm	1

Dichloromethane	75-09-2	600 ppm	
Ethanol	64-17-5	5,000 ppm	
Ethyl Acetate	141-78-6	5,000 ppm	
Ethyl Ether	60-29-7	5,000 ppm	
Heptane	142-82-5	5,000 ppm	
Hexanes (measured as the cumulative residue of n-hexane, 2- methylpentane, 3- methylpentane, 2,2- dimethylbutane, and 2,3- dimethylbutane)	110-54-3, 107-83-5, and 79-29-8	290 ppm	Remediate and retest, or
Isopropyl Acetate	108-21-4	5,000 ppm	Destroy
Methanol	67-56-1	3,000 ppm	
Pentanes (measured as the cumulative residue of n-pentane, iso- pentane, and neo- pentane)	109-66-0, 78-78-4, and 463-82-1	5,000 ppm	
2-Propanol (IPA)	67-63-0	5,000 ppm	
Propane	74-98-6	5,000 ppm	
Toluene	108-88-3	890 ppm	
Xylenes (measured as the cumulative residue of 1,2-dimethylbenzene, 1,3-dimethylbenzene, and 1,4- dimethylbenzene, And the non-xylene, ethyl benzene)	1330-20-7 (95-47- 6,108- 38-3, and 106-42- 3, and 100-41-4)	2,170 ppm	Remediate and retest, or
dimethylbenzene, and 1,4- dimethylbenzene, and the non- xylene, ethyl benzene)			Destroy

D. Pesticides, Fungicides, Growth Regulators

		Maximum	
		Allowable	
Analyte	CAS Number	Concentration	Required Action
Abamectin	71751-41-2	0.5 ppm	
Acephate	30560-19-1	0.4 ppm	
Acequinocyl	57960-19-7	2.0 ppm	
Acetamiprid	135410-20-7	0.2 ppm	
Aldicarb	116-06-3	0.4 ppm	
Azoxystrobin	131860-33-8	0.2 ppm	
Bifenazate	149877-41-8	0.2 ppm	
Bifenthrin	82657-04-3	0.2 ppm	
Boscalid	188425-85-6	0.4 ppm	
Carbaryl	63-25-2	0.2 ppm	
Carbofuran	1563-66-2	0.2 ppm	
Chlorantraniliprole	500008-45-7	0.2 ppm	
Chlorfenapyr	122453-73-0	1.0 ppm	
Chlormequat chloride	7003-89-6	0.2 ppm	
Chlorpyrifos	2921-88-2	0.2 ppm	
Clofentezine	74115-24-5	0.2 ppm	
Cyfluthrin	68359-37-5	1.0 ppm	
Cypermethrin	52315-07-8	1.0 ppm	
Daminozide	1596-84-5	1.0 ppm	
DDVP (Dichlorvos)	62-73-7	0.1 ppm	
Diazinon	333-41-5	0.2 ppm	
Dimethoate	60-51-5	0.2 ppm	
Ethoprophos	13194-48-4	0.2 ppm	Destroy
Etofenprox	80844-07-1	0.4 ppm	
Etoxazole	153233-91-1	0.2 ppm	
Fenoxycarb	72490-01-8	0.2 ppm	
Fenpyroximate	134098-61-6	0.4 ppm	
Fipronil	120068-37-3	0.4 ppm	
Flonicamid	158062-67-0	1.0 ppm	
Fludioxonil	131341-86-1	0.4 ppm	
Hexythiazox	78587-05-0	1.0 ppm	
Imazalil	35554-44-0	0.2 ppm	
Imidacloprid	138261-41-3	0.4 ppm	
Kresoxim-methyl	143390-89-0	0.4 ppm	
Malathion	121-75-5	0.2 ppm	

Delta-9- tetrahydrocann abinol (Δ9- THC)	Label claim is not within +/- 20 % of tested value		Revise label as necessary
Tetrahydro- cannabinolic acid (THC-A)			
Analyte	Labeling		Required Action
_	E. Potency	7	
Trifloxystrobin	141517-21-7	0.2 ppm	
Thiamethoxam	153719-23-4	0.2 ppm	
Thiacloprid	111988-49-9	0.2 ppm	
Tebuconazole	107534-96-3	0.4 ppm	
Spiroxamine	118134-30-8	0.4 ppm	
Spirotetramat	203313-25-1	0.2 ppm	
Spiromesifen	283594-90-1	0.2 ppm	
Spinosad	168316-95-8	0.2 ppm	
Pyridaben	96489-71-3	0.2 ppm	
Pyrethrins (measured as the cumulative residue of pyrethrin 1, cinerin 1 and jasmolin 1)	8003-34-7(121-21-1, 25402-06-6, and 4466-14-2)	1.0 ppm	
Propoxur	114-26-1	0.2 ppm	
Propiconazole	60207-90-1	0.4 ppm	_
Prallethrin	23031-36-9	0.2 ppm	_
Piperonyl_butoxide	51-03-6	2.0 ppm	_
Phosmet	732-11-6	0.2 ppm	Destroy
Permethrins (measured as the cumulative residue of cis- and trans-isomers)	52645-53-1(54774-45-7 and 51877-74-8)	0.2 ppm	
Paclobutrazol	76738-62-0	0.4 ppm	
Oxamyl	23135-22-0	1.0 ppm	
Naled	300-76-5	0.5 ppm	
Myclobutanil	88671-89-0	0.2 ppm	
Methyl parathion	298 -00 - 0	0.2 ppm	
Methomyl	16752-77-5	0.4 ppm	
Methiocarb	2032-65-7	0.2 ppm	
Metalaxyl	57837-19-1	0.2 ppm	

Cannabidiolic acid (CBD-A)		
Cannabidiol (CBD)		
Terpenoids (primary and secondary)	Label claim is not within +/- 10 % of tested value	Revise label as necessary
F. M	Ioisture Content and Water Activity T	esting
Measurement	Allowable Measurement	Required Action
Water activity	> 0.65 Aw	Destroy
Moisture content	> than 15%	Remediate and retest

Table 2

Quality Control Sample	Acceptance Criteria	<u>Frequency</u>
Positive control	Produces expected result, positive result	Per Batch
Negative control	Produces expected result, negative result	Per Batch
<u>Duplicate sample</u>	Results shall concur	Per Run
Analyst or technician Quantitative Performance Plate count comparisons monthly	Within 10% for all analysts	<u>Monthly</u>

Table 3

Quality Control Sample	Acceptance Criteria	Corrective Action
Positive control	Produces expected result, positive result	Re-prep and reanalyze the entire analytical batch, once. If problem persists, locate and remedy the source of unexpected result, then re-prep samples and reanalyze with a new set of controls.
Negative control	Produces expected result, negative result	Re-prep and reanalyze the entire analytical batch, once. If problem persists, locate and remedy the source of unexpected result, then re-prep samples and reanalyze with a new set of controls.
Laboratory replicate sample	Sample results must <u>shall</u> concur	Reanalyze sample and associated replicate sample once. If problem persists, re-prep samples and reanalyze.

Table 4

Quality Control Sample	Acceptance Criteria	Corrective Action
Method Blank Sample	Not to exceed LOQ	Reanalyze entire analytical batch once. If method blank is still greater than the LOQ for any analyte, locate the source of contamination then re-prep samples and reanalyze.
<u>Laboratory</u> <u>Control Sample</u>	<u>RPD ≤20%</u>	Reanalyze the entire analytical batch, once. If problem persists, re-prep samples and reanalyze or re-run the initial calibration curve.
Duplicate Sample	<u>RPD ≤20%</u>	Reanalyze sample and associated replicate sample once. If problem persists, re-prep samples and reanalyze.
Laboratory Control Sample	Percent recovery 70% to 130%	Reanalyze the entire analytical batch, once. If problem persists, re-prep samples and reanalyze or re-run the initial calibration curve.

Laboratory replicate samples	RPD ≤30%	Reanalyze sample and associated replicate sample once. If problem persists, re-prep samples and reanalyze.
Matrix Spike Sample/ <u>Matrix</u> <u>Spike</u> <u>Duplicate</u>	Percent recovery 70% to 130% RPD \(\leq 20\)%	Reanalyze sample and associated matrix spike sample once. If problem persists, re-prep samples and reanalyze.
CCV	Percent recovery 70% to 130% RPD ≤20% except for lowest point, which can be +/- 30%	Reanalyze all samples that followed the last CCV that met the acceptance criteria. If CCV still fails, re-run the initial calibration curve and all samples in the analytical sequence.

APPENDIX B

SCHEDULE OF DISCIPLINARY ACTIONS

Violation	Penalty Offense	Unit of Measurement
Failure of an employee to possess an active work permit	\$5,000	Each employee found without an active work permit.
Employment of someoneperson under the age of 21	\$5,000	Each employee found under the age of 21.
Failure to assist Department during recall of product	\$5,000	Each directive from the Department regarding recall.
Failure to comply with security requirements	\$5,000	Each security deficiency related to Rules in this Part.
On-site use of cannabis by employee(s) of medical cannabis establishment	\$5,000	Each employee found using cannabis on premises of the medical cannabis establishment.
Failure to sufficiently maintain records	\$10,000	Each deficiency/finding related to recordkeeping to Rules in this Part.
Unlawful acquisition, transfer, purchase or sale of cannabis and/or cannabis product(s) unless otherwise listed	\$10,000	Each instance of acquisition, transfer, purchase or sale.
Failure to accurately track inventory	\$10,000 and/or one- week suspension and/or destruction of product	Each untagged plant, package and/or batch at the time of the Department's finding.
Falsification of records	\$10,000 and/ <u>or</u> one week suspension	Each instance of falsification of records required underelated to recordkeeping to Rules in this Part.
Refusal to permit access by Department staff as required by law	Two-week suspension	Instance/Occurrence documented at the time of requested access.
Threat against law enforcement and/or Department staff	Two-week suspension	Instance/Occurrence documented at the time of the threat.
Cultivation activities during a license suspension period	Revocation	Cultivation activities that would include (but not limited to) any planting, drying, harvesting, and/or packaging during the dates of

		suspension and any administrative appeal.
Processing activities during a license suspension period	Revocation	Activities related to processing during the dates of suspension and any administrative appeals.
Transportation activities during a license suspension period	Revocation	Transportation activities that would include during the dates of suspension and any administrative appeal.
Disposal/Destruction activities during a license suspension period	Revocation	Any disposal activities during the dates of suspension and any administrative appeal.
General <u>Ppenalty</u> if <u>for any</u> <u>violation/infraction</u> not specifically listed <u>in this Table</u>	\$5,000	Each instance and/or finding to be specifically identified by the Department.

APPENDIX C

RULES AND PROCEDURES FOR ADMINISTRATIVE HEARINGS

- Hearing Officer: The Hearing Officer shall be appointed by the State Health Officer or his/her designee. The Hearing Officer shall preside at the hearing, shall be charged with maintaining order at the hearing, and shall rule on all questions of evidence and procedure in accordance with the provisions of these rules.
- 2. Appearance by Licensee/Aggrieved party: The licensee/aggrieved party shall appear at the date and time set for the hearing, and failure to do so without reasonable notice to the Department may result in admission of the charges and adverse action taken against the licensee.
- 3. Representation by Counsel: The licensee/aggrieved party may, but is not required to be, represented by counsel at the hearing at his/her own expense and shall have the right to cross-examine all witnesses, present evidence, written or oral, on his/her own behalf, and to refute any testimony or evidence presented by the Department.
- 4. Confidentiality of Hearings: Administrative hearings before a Hearing Officer are considered confidential and are not open to the public.
- 5. Rules of Evidence and Discovery: Formal rules of evidence and procedure, including Discovery, do not apply in administrative hearings; however, the rules of evidence may be used as a guide during the hearing. A record of the hearing shall be made by a court reporter.
- 6. Attendance of Witnesses: The licensee/aggrieved party or counsel for the Department may make a written request to the Hearing Officer at least ten (10) days prior to the hearing to ensure the attendance of a witness or the production of documents through the issuance of an administrative subpoena. The issuance of the subpoena shall be at the discretion of the Hearing Officer.
- 7. Order of Proceedings: The Department shall present its case first, followed by the licensee/aggrieved party, and any rebuttal evidence by either party. At the request of either party, all prospective witnesses shall be excluded from the proceedings except while actually testifying.
- 8. Standard of Proof: In order for the Department's decision to be upheld overturned, the Hearing Officer must-shall find that the regulatory violation has been proved by clear and convincing evidence and/or that the disciplinary action is supported by substantial evidence is (a) arbitrary or capricious; (b) unsupported by evidence; (c) beyond the power of the administrative agency to make; or (d) violated some statutory or constitutional right of the aggrieved party.
- 9. Recommendation and Final Decision/Final Order: Within thirty (30) days of the hearing, or such period as determined at the hearing considering the amount of testimony and evidence and the complexity of the issues, the Hearing Officer shall submit his/her "Findings of Fact, Conclusions of Law and Recommendation" to the State Health Officer, outlining the proof presented and containing his/her recommendation to the State Health Officer as to the

appropriate action to be taken. The State Health Officer shall issue his/her Final Order adopting, modifying, or rejecting the Recommendation within fourteen (14) days of receipt of the recommendation. This Final Order becomes the final appealable order of the Mississippi State Department of Health as to those proceedings.

- 10. Appeal of the Department's Final Order shall be accomplished as provided by the appropriate statute.
- 11. Any person or entity who disagrees with or is aggrieved by the Final Decision or Final Order of the Department concerning the imposition of fine(s) and/or other sanction(s). suspension, or revocation of a license may appeal same in the circuit court of the county in which he/she resides. If the aggrieved party is a nonresident of this state, he/she may appeal to the Circuit Court of the First Judicial District of Hinds County, Mississippi. The appeal shall be filed no later than twenty (20) calendar days after the issuance of the Final Decision or Order by the Department.
- 12. Any person or entity aggrieved by the decision of the circuit court may appeal to the Mississippi Supreme Court.
- 13. If the licensee/aggrieved party fails to appeal the Final Order within the prescribed time, the decision becomes final and cannot be further appealed.

Source: Miss. Code Ann. §§ 41-137-1 – 41-137-67.

APPENDIX D

Medical Cannabis Testing Requirements by Product Type

Product Type	Potency	Pesticides &Chemical Residue	Residual Solvents	Heavy Metals	Microbiological Impurities	Water Activity	<u>Foreign</u> <u>Matter</u>	Homogeneity
Bud/Flower, Shake/Trim or raw pre-roll	✓	✓		<u> ✓</u>	✓	✓	<u>~</u>	
Non-Solvent Concentrate*	<u> ✓</u>	<u> </u>		<u>✓</u>	<u>~</u>		✓	
<u>Concentrate</u>	✓	<u>√</u>	✓	✓	<u>√</u>		<u>√</u>	
<u>Infused Flower</u>	<u> ✓</u>	<u> ✓</u>	✓	✓	<u>√</u>	✓	✓	
Infused Non-Edible Liquids	<u>~</u>	<u>~</u>	✓	<u>✓</u>	<u>~</u>		✓	<u> ✓</u>
<u>Infused</u> <u>Non-Edible Solids</u>	✓	<u> </u>	✓	<u> </u>	✓	✓	✓	<u> </u>
Infused Edible	<u>√</u>	<u>√</u>	<u>✓</u>	✓	<u>√</u>	<u>√</u>	<u>√</u>	<u>√</u>
Inhalable Concentrates, Infused Pre-Roll or Other Compound Concentrate Products***	<u> </u>	<u>~</u>	<u> </u>	<u>~</u>	<u>✓</u>	<u> </u>	<u> </u>	

^{*} Extraction using ice water, rosin press or dry ice

^{**} Moonrock, Caviar joint, infused pre-roll, tarantula, etc.

APPENDIX E

Final packaging, for testing purposes, does not require complete regulatory labeling, but at minimum must include the product name and form, specific unique lot number, net contents and target potencies.

Product Type	Description	Sample Packaging
Cannabis Flower	Loose cannabis flower whole or ground.	Samples must be in packaging/containers as it would be sold to the consumer. (Jar, bag, etc.) Remainder of the batch can be
		<u>packed</u> <u>after receiving passing compliance</u> <u>testing results.</u>
		Samples must be packed in final packaging (Bag, doob tube, other compliant containers).
Pre-Rolled Cannabis Flower	Cannabis flower loaded, rolled and ready for consumption.	Pre-roll lots in their entirety must be rolled prior to testing and can be stored in a manner to ensure general sanitary practices and product stability. Remainder of the batch can be packaged after receiving
		passing compliance testing results.
Oil for Vaporization	Pre-filled vape cartridges and prefilled disposable pens.	Samples must be in the layer of packaging in which the product comes in contact (Prefilled cartridge or disposable pen).
		Remainder of the batch must be stored in manner to ensure general sanitary practices and product stability. Remainder of the batch can
		be packaged after passing compliance testing results.
Topicals	All products intended for topical use containing >3% THC. Some examples are	Samples must be in packaging/containers as it would be sold to the patient.
	balms, lotions, and body oils.	Remainder of the batch must be stored in manner to ensure general sanitary practices and product stability. Remainder of the batch can be packaged after passing compliance testing results.
Wax, Shatter, Resin	Concentrated cannabis extracted using a solvent. Some examples are budder, crumble,	Samples must be in packaging/containers as it would be sold to the patient.
	sauce, shatter, crystals, and crumble.	Remainder of the batch must be stored in manner to ensure general sanitary practices and product stability. Remainder of the batch can

		be packaged after passing
		compliance testing results
		compliance testing results
	<u>Includes:</u>	
	 Any cannabis edible product that 	
	is intended to be chewed and relies	
	upon a gelling agent such as, but not	
	limited to, gelatin, agar, or pectin to	Samples must be in
Gel-based foods, Water-	maintain its shape or texture. Some	packaging/containers as it would be
Soluble Edibles,	examples are fruit chews, gummies,	sold to the patient (bottles, mylar
Tablets, Capsules, Solid Chocolates, a	and chewable gel capsules.Tablets, capsules, and	bags, jars, vials, etc).
nd Lozenges	lozenges.	Remainder of the batch must be
<u>iiu Lozenges</u>	 Edible products which are 	stored in a manner to ensure general
	intended to be dissolved in water	sanitary practices and product
	before consumption. Some examples	stability. Remainder of the batch can
	are dissolving powders and	be packaged after receiving
	effervescent tablets.	compliance testing results.
		<u> </u>
		Samples must be in the layer of
		packaging in which the product
		comes in contact (bottle, vial,
		<u>dropper, etc).</u>
	Homogeneous oral liquids including tinctures,	
Oral Liquids	oral solutions, syrups, and	Remainder of the batch must be
	<u>oral emulsions.</u>	stored in manner to ensure general
		sanitary practices and product
		stability. Remainder of the batch can
		be packaged after passing
		compliance testing results.
		Samples must be sent in the bottled/canned form ready for
		consumption.
		<u>consumption.</u>
<u>Beverages</u>	All beverages and syrups.	Remainder of the batch must be
		stored in manner to ensure general
		sanitary practices and product
		stability. Remainder of the lot can be
		packaged after passing compliance
		testing results.