Title 20. Public Health and Welfare
Chapter I. Generally, Department of Health
Subchapter H. Drugs
Part 202. Rules Governing Medical Marijuana Registration, Testing, and Labeling in Arkansas

Codification Notes. This part as promulgated prior to codification into the Code of Arkansas Rules provided as follows:

"Effective September 11, 2017"

"SECTION I. DEPARTMENT
These Rules and Regulations Governing Medical Marijuana Registration, Testing, and Labeling in Arkansas are duly adopted and promulgated by the Arkansas State Board of Health pursuant to the Department expressly conferred by the Laws of the State of Arkansas including, without limitation, Amendment No. 98 of the Constitution of the State of Arkansas of 1874, The Medical Marijuana Amendment of 2016."

"CERTIFICATION

This is to certify that the foregoing Rules and Regulations Governing Medical Marijuana Registration, Testing, and Labeling in Arkansas were adopted by the Arkansas State Board of Health at a regular session of said Board in Little Rock Arkansas as on the 27th day of April 2017.

Nathaniel Smith, MD, MPH
Secretary of Arkansas State Board of Health
Director of the Arkansas Department of Health and State Health Officer"

Subpart 1. Generally

20 CAR § 202-101. Scope and purpose.

(a) This part governs the application for and renewal of registry identification cards for qualifying patients and designated caregivers.

(b) This part also establishes:

(1) Labeling and testing standards for marijuana distributed under the Arkansas Medical Marijuana Amendment of 2016, Ark. Const. amend. 98; and

(2) How medical conditions may be added to the list of qualifying conditions.

Authority. Arkansas Constitution, Amendment 98, sec. 4.

20 CAR § 202-102. Definitions.

As used in this part:

(1) "Acquire" or "acquisition" means coming to possess marijuana by means of any legal source herein authorized, not from an unauthorized source, and in accordance with the Arkansas Medical Marijuana Amendment of 2016, Ark. Const. amend. 98, and any rules promulgated under the Arkansas Medical Marijuana Amendment of 2016, Ark. Const. amend. 98;

(2) "Activation time" means the amount of time it is likely to take for an individual to begin to feel the effects of ingesting or inhaling a marijuana item;

(3) "Amendment" means the Arkansas Medical Marijuana Amendment of 2016, Ark. Const. amend. 98;

(4) "Approved laboratory" means a laboratory that:

(A) Is accredited by the National Institute on Drug Abuse, the National Environmental Laboratory Accreditation Conference (NELAC), the International Organization for Standardization, or similar accrediting entity as determined by the Department of Health; and

(B) Has been approved by the Department of Health specifically for the testing of usable marijuana;

(5) "Assist" or "assisting" means helping a qualifying patient make medical use

of marijuana by enabling the medical use by any means authorized under the Arkansas Medical Marijuana Amendment of 2016, Ark. Const. amend. 98;

(6) "Batch" means:

(A) With regard to usable marijuana, a homogenous, identified quantity of usable marijuana, no greater than ten pounds (10 lbs.), that is harvested during a specified time period from a specified cultivation area; and

(B) With regard to oils, vapors, and waxes derived from usable marijuana, an identified quantity that is:

(i) Uniform;

(ii) Intended to meet specifications for:

(a) Identity;

(b) Strength; and

(c) Composition; and

(iii) Manufactured, packaged, and labeled during a specified time period, according to a single manufacturing, packaging, and labeling protocol;

(7) "Cardholder" means a qualifying patient or a designated caregiver;

(8) "CBD" means cannabidiol, Chemical Abstracts Service Number 13956-29-1;

(9) "CBDA" means cannabidiolic acid, Chemical Abstracts Service Number 1244-58-2;

(10) "Commission" means the Medical Marijuana Commission;

(11) "Cultivation facility" means an entity that:

(A) Has been licensed by the Medical Marijuana Commission; and

(B) Cultivates, prepares, manufactures, processes, packages, sells to, and delivers usable marijuana to a dispensary;

(12)(A) "Designated caregiver" means a person who is at least twenty-one (21) years of age, has not been convicted of an excluded felony offense, has agreed to assist a physically disabled qualifying patient with the medical use of marijuana, and who has registered with the Department of Health pursuant to the requirements of the Arkansas Medical Marijuana Amendment of 2016, Ark. Const. amend. 98, and this part.

(B) "Designated caregiver" includes, without limitation, a parent:

(i) Of a qualifying patient who is under the age of eighteen (18); and

(ii) Required to register as a designated caregiver under the Arkansas Medical Marijuana Amendment of 2016, Ark. Const. amend. 98;

(13) "Dispensary" means an entity that has been licensed by the Medical Marijuana Commission pursuant to the requirements of the Arkansas Medical Marijuana Amendment of 2016, Ark. Const. amend. 98;

(14) "Division" means the Alcoholic Beverage Control Division;

(15) "Excluded felony offense" means:

(A)(i) A felony offense as determined by the jurisdiction where the felony offense occurred.

(ii) The Department of Health shall determine whether an offense is a felony offense based upon a review of the relevant court records concerning the conviction for the offense.

(iii) An offense that has been sealed by a court or for which a pardon has been granted is not considered an excluded felony offense; or

(B) A violation of a state or federal controlled-substance law that was classified as a felony in the jurisdiction where the person was convicted, but not including:

(i) An offense for which the sentence, including any term of probation, incarceration, or supervised release, was completed ten (10) or more years earlier; or

(ii) An offense that has been sealed by a court or for which a pardon has been granted;

(16) "Harvest lot" means a specifically identified quantity of marijuana that is:

(A) Uniform in strain;

(B) Cultivated utilizing the same growing practices;

(C) Harvested at the same time at the same location; and

(D) Cured under uniform conditions;

(17) "Lot" means:

(A) An identified portion of a batch that is:

(i) Uniform; and

(ii) Intended to meet specifications for:

(a) Identity;

(b) Strength; and

(c) Composition; or

(B) In the case of a vapor, oil, or wax derived from usable marijuana, an identified quantity produced in a specified period of time in a manner that is:

(i) Uniform; and

(ii) Intended to meet specifications for:

(a) Identity;

(b) Strength; and

(c) Composition;

(18) "Medical use" means the acquisition, possession, use, delivery, transfer, or transportation of marijuana or paraphernalia relating to the administration of marijuana to treat or alleviate a qualifying patient's qualifying medical condition or symptoms associated with the qualifying patient's qualifying medical condition;

(19) "Physician" means a doctor of medicine or a doctor of osteopathic medicine who holds a valid, unrestricted, and existing license to practice in the State of Arkansas and has been issued a current and active registration from the Drug Enforcement Administration to prescribe controlled substances;

(20) "Principal display panel" means the part of a label on a package or container that is most likely to be displayed, presented, shown, or seen under customary conditions of display for sale or transfer;

(21) "Process lot" 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 harvested marijuana;

(22) "Proper identification" means a motor vehicle operator's license or other official state-issued identification of the purchaser that:

(A) Contains a photograph of the purchaser; and

(B) Includes the residential or mailing address of the purchaser, other

than a post office box number;

(23) "Qualifying medical condition" means one (1) or more of the following:

(A) Cancer, glaucoma, positive status for human immunodeficiency virus/acquired immunodeficiency syndrome, Hepatitis C, amyotrophic lateral sclerosis, Tourette syndrome, Crohn's disease, ulcerative colitis, post-traumatic stress disorder, severe arthritis, fibromyalgia, Alzheimer's disease, or the treatment of these conditions;

(B) A chronic or debilitating disease or medical condition or its treatment that produces one (1) or more of the following:

(i) Cachexia or wasting syndrome;

(ii) Peripheral neuropathy;

(iii) Intractable pain, which is pain that has not responded to ordinary medications, treatment, or surgical measures for more than six (6) months;

(iv) Severe nausea;

(v) Seizures, including without limitation those characteristic of epilepsy; or

(vi) Severe and persistent muscle spasms, including without limitation those characteristic of multiple sclerosis; and

(C) Any other medical condition or its treatment approved by the Department of Health pursuant to this part and the Arkansas Medical Marijuana Amendment of 2016, Ark. Const. amend. 98;

(24) "Qualifying patient" means a person who has been diagnosed by a physician as having a qualifying medical condition and who has registered with the Department of Health in accordance with this part and the Arkansas Medical Marijuana Amendment of 2016, Ark. Const. amend. 98;

(25) "Registry identification card" means a document issued by the Department of Health that identifies a person as a qualifying patient or a designated caregiver;

(26) "Relative percentage difference" or "RPD" means the comparison of two (2) quantities while taking into account the size of what is being compared as calculated under Appendix A, § 1(A);

(27) "Relative standard deviation" or "RSD" means the standard deviation expressed as a percentage of the mean recovery as calculated under Appendix A, § 1(A);

(28) “Sealed” means expunge, remove, sequester, and treat as confidential the record or records of a felony offense;

(29) “Segregate” means to separate and withhold from use or sale batches, lots, or usable marijuana in order to first determine its suitability for use through testing by an approved laboratory;

(30) “Testing” means the process and procedures provided by an approved laboratory for testing of usable marijuana, consistent with the provisions of this part;

(31) “Tetrahydrocannabinol (THC)” is a cannabinoid that is the primary psychoactive ingredient in usable marijuana;

(32) "THCA" means tetrahydrocannabinolic acid, Chemical Abstracts Service Number 23978-85-0;

(33) "TNI" means The NELAC (National Environmental Laboratory Accreditation Conference) Institute, a voluntary organization of state and federal environmental officials and interest groups purposed primarily to establish consensus standards for accrediting environmental laboratories;

(34) "TNI EL Standards" means the adopted 2009 TNI Environmental Lab Standards (© 2009 The NELAC Institute standards adopted by NELAC), which describe the elements of laboratory accreditation:

(A) Developed and established by the consensus principles of TNI; and

(B) That meet the approval requirements of TNI procedures and policies;

(35) "Universal symbol" means the image, established by the Department of Health and made available to licensees and registrants, indicating the container contains marijuana;

(36)(A) “Usable marijuana” means:

(i) The stalks, seeds, roots, dried leaves, flowers, oils, vapors, waxes, and other portions of the marijuana plant; and

(ii) Any mixture or preparation thereof.

(B) “Usable marijuana” does not include the weight of any ingredients other than marijuana that are combined with marijuana and prepared for consumption as food or drink;

(37) “Visiting qualifying patient” means a patient with a qualifying medical condition who:

(A) Is not a resident of Arkansas or who has been a resident of Arkansas for less than thirty (30) days; and

(B) Is in actual possession of a registry identification card or its equivalent that:

(i) Is issued under the laws of another state, district, territory, commonwealth, or insular possession of the United States; and

(ii) Pertains to a qualifying medical condition under the Arkansas Medical Marijuana Amendment of 2016, Ark. Const. amend. 98; and

(38)(A) "Written certification" means a document signed by a physician stating that in the physician's professional opinion, after having completed an assessment of the qualifying patient's medical history and current medical condition made in the course of a physician-patient relationship, the qualifying patient has a qualifying medical condition.

(B) A written certification shall specify the qualifying patient's qualifying medical condition, which also shall be noted in the physician's records.

(C) A physician shall not issue a written certificate to a patient based on an assessment performed through telemedicine.

(D) A written certification is not a medical prescription.

Authority. Arkansas Constitution, Amendment 98, sec. 4.

20 CAR § 202-103. Registry identification cards.

(a) **Qualifying patients.** The Department of Health shall issue registry identification cards to qualifying patients who submit the following:

(1) An application for a qualifying patient registry identification card that must

include the following:

(A) The qualifying patient's name and date of birth;

(B) The qualifying patient's address, unless the qualifying patient is homeless;

(C) The name, address, phone number, and Drug Enforcement Administration registration number of the physician providing the written certification;

(D) The name, address, and phone number of the qualifying patient's designated caregiver, if applicable;

(E) A signed statement by the qualifying patient that he or she will not divert marijuana to anyone who is not allowed to possess it under the Arkansas Medical Marijuana Amendment of 2016, Ark. Const. amend. 98; and

(F) A copy of a driver's license or identification card issued by the State of Arkansas;

(2)(A) The fifty-dollar application fee.

(B) The department may designate how the fee is submitted.

(C) The department may require a convenience fee if payment is submitted by credit card; and

(3) Written certification provided by the physician within thirty (30) days prior to the submittal of the application documenting that:

(A) The physician has established a physician-patient relationship with the qualifying patient as defined by the Arkansas State Medical Board;

(B) The physician has completed a full assessment of the qualifying patient's medical history and current medical condition;

(C) The date that the full assessment was completed; and

(D) Documentation that the qualifying patient has a qualifying medical condition.

(b) **Designated caregivers.**

(1) The department shall issue a registry identification card for a designated caregiver who submits the following:

(A) An application for a designated caregiver registry identification card

that must include the following:

(i) The name and date of birth of the designated caregiver;

(ii) The address of the designated caregiver;

(iii) The name and address of the qualifying patient the applicant will be assisting;

(iv) A signed statement by the designated caregiver that he or she will not divert marijuana to anyone who is not allowed to possess it under the amendment; and

(v) A copy of the applicant's driver's license or identification card issued by the State of Arkansas;

(B)(i) The fifty-dollar application fee.

(ii) The department may designate how the fee is submitted.

(iii) The department may require a convenience fee if payment is submitted by credit card; and

(C) The following documentation from the qualifying patient's physician:

(i) The qualifying patient's qualifying medical condition; and

(ii) A statement that the qualifying patient is disabled or under the age of eighteen (18).

(2)(A) The applicant shall:

(i) Complete a criminal history check form as required by the department; and

(ii) Request the Identification Bureau of the Division of Arkansas State Police to conduct a state or national criminal history check, or both, on the applicant.

(B) The applicant shall pay all appropriate fees for the state or national criminal history check, or both, as set forth by the department.

(C) The applicant shall attach the criminal history check form to the application.

(D) The department shall conduct a state or national criminal history check, or both, on the applicant and determine whether the applicant is disqualified from registration based on the report of the applicant's criminal history and forward its

determination to the applicant.

(c) The department shall not issue a registry identification card to a qualifying patient under eighteen (18) years of age unless the following conditions are met:

(1) The qualifying patient's physician has documented that he or she has explained the potential risks and benefits of the medical use of marijuana to both the qualifying patient and his or her parent, guardian, or legal custodian;

(2) The parent, guardian, or legal custodian consents in writing to the following:

(A) To allow the qualifying patient's medical use of marijuana;

(B) To assist the qualifying patient in the medical use of marijuana; and

(C) To control the acquisition of the marijuana, the dosage, and the frequency of the medical use of marijuana by the qualifying patient; and

(3) The parent, guardian, or legal custodian registers as a designated caregiver for the qualifying patient.

(d) **Visiting patients.**

(1) A visiting qualifying patient may obtain marijuana from a dispensary upon producing evidence of his or her registry identification card or its equivalent that is issued under the laws of another state, district, territory, commonwealth, or insular possession of the United States.

(2) The dispensary shall retain a copy of the registry identification card or its equivalent and his or her proper identification in a manner prescribed by the department.

(3) The dispensary shall require the visiting patient to certify, in a form required by the department, that they have been diagnosed by a physician to have one (1) or more qualifying medical conditions.

(e) **Renewal.**

(1) A registry identification card expires one (1) year after the date of issuance.

(2)(A) A registry identification card may expire on a date earlier than one (1) year after the date of issuance if the physician states in the written certification that he

or she believes the qualifying patient would benefit from the medical use of marijuana only until a specified earlier date.

(B) The specified earlier date will be the expiration date.

(3)(A) At least thirty (30) days before the expiration of the registry identification card, a qualifying patient or designated caregiver shall reapply for a registry identification card.

(B) The application for renewal shall require the same information as the initial application.

(f) **Department review of applications and renewals.**

(1) The department shall review the information contained in an application or renewal for a qualifying patient or designated caregiver registry identification card within fourteen (14) days of receiving all the information required for the application, including the written certification from the physician.

(2) The department shall deny an application or renewal if:

(A) The applicant had a previous registry identification card revoked in this state or any other jurisdiction where medical marijuana use is allowed;

(B) The written certification was not made in the context of a physician-patient relationship;

(C) The written certification was fraudulently obtained; or

(D) The application or written certification was falsified in any way.

(3) The department may revoke the registry identification card of any cardholder who:

(A) Transfers marijuana to a person who is not a qualifying patient, visiting patient, or designated caregiver with a valid registry identification card; or

(B) Knowingly violates any provision of the amendment or this part.

(4) The denial of an application, denial of an application renewal, or revocation of a registry identification card is considered a final agency action by the department, subject to judicial review by the Pulaski County Circuit Court.

(g) **Confidentiality.**

(1)(A) The department shall maintain a list of all the persons to whom

qualifying patient and designated caregiver registry identification cards have been issued.

(B) This list shall be confidential, and release of information on this list is exempt under the Freedom of Information Act of 1976, Arkansas Code § 25-19-101 et seq.

(C) Information from this list may be shared with the Alcoholic Beverage Control Division and the Medical Marijuana Commission, but only as necessary.

(2) All documentation submitted by qualifying patients or designated caregivers, including but not limited to applications and written certifications, shall remain confidential.

(3) The department shall verify to law enforcement personnel whether a registry identification card is valid without disclosing more information than is reasonably necessary to verify the authenticity of the registry identification card.

Authority. Arkansas Constitution, Amendment 98, sec. 4.

20 CAR § 202-104. Labeling.

(a)(1) The purpose of this section is to set the minimum standards for the labeling of usable marijuana that is sold to a qualifying patient or designated caregiver by a dispensary or given by a qualifying patient or designated to another qualifying patient or designated caregiver.

(2) Usable marijuana received or transferred by a dispensary, qualifying patient, or designated caregiver must meet the labeling requirements in this part.

(3) A dispensary must:

(A) Return usable marijuana that does not meet the labeling requirements in this part to the individual who transferred it to the dispensary and document to whom the item was returned, what was returned, and the date of the return; or

(B) Dispose of any usable marijuana that does not meet labeling requirements and that cannot be returned in a manner specified by the Department of Health.

(b) **Usable marijuana labeling requirements.** Prior to usable marijuana being sold or transferred to a qualifying patient or designated caregiver, the container holding the usable marijuana must have a label that has the following information:

(1) Producer's business or trade name and cultivation facility or dispensary number;

(2) Business or trade name of cultivation facility or dispensary, or cultivation facility or dispensary that packaged or distributed the product, if different from the producer;

(3) A unique identification number;

(4) Date of harvest;

(5) Name of strain;

(6) Net weight in United States customary and metric units;

(7) Concentration of THC and CBD;

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

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

(10) Universal symbol;

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

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

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

(c) **Cannabinoid concentrates and extracts.** Prior to a cannabinoid concentrate or extract being sold or transferred to a qualifying patient or designated caregiver, the container holding the concentrate or extract must have a label that has the following information:

(1) Cultivation facility's or dispensary's business or trade name and cultivation facility or dispensary number;

(2) Business or trade name of cultivation facility or dispensary that packaged

or distributed the product, if different from the cultivation facility or dispensary;

(3) A unique identification number;

(4) Product identity (concentrate or extract);

(5) Date the concentrate or extract was made;

(6) Net weight or volume in United States customary and metric units;

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

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

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

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

(11) Universal symbol;

(12) A statement that reads:

(A) "This product is not approved by the FDA to treat, cure, or prevent any disease";

(B) "For use by qualifying patients only. Keep out of reach of children.";

(C) "DO NOT EAT" in bold, capital letters; and

(D) “Marijuana use during pregnancy or breastfeeding poses potential harms.”.

(d) **General label requirement — Prohibitions and exceptions.**

(1) **Principal display panel.**

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

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

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

(2) A label required by this part must:

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

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

(C)(i) Be in no smaller than eight-point Times New Roman, Helvetica, or Arial font.

(ii) Statements required by subdivisions (c)(12)(B) and (D) of this section must be in at least eighteen-point font;

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

(E) Be unobstructed and conspicuous.

(3) Usable marijuana may have one (1) or more labels affixed to the container or packaging.

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

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

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

(ii) Cultivation facility or dispensary business or trade name and cultivation facility or dispensary number;

(iii) For cultivation facility or dispensaries, a package-unique identification number;

(iv) Concentration of THC and CBD; and

(v) Required warnings; and

(B) Must include all other required label information not listed in

subdivision (d)(4)(A) of this section on:

(i) An outer container or package; or

(ii) On a leaflet that accompanies the usable marijuana.

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

(6) The universal symbol:

(A) Must be at least forty-eight hundredths of an inch wide by thirty-five hundredths of an inch high (0.48" x 0.35");

(B) May only be used by a cultivation facility or dispensary; and

(C) May be downloaded at: https://healthy.arkansas.gov/programs-services/data-statistics-registries/medical-marijuana/.

(7) A label may not:

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

(B) Be attractive to minors.

(8) Usable marijuana that falls within more than one (1) category must comply with the labeling requirements that apply to both categories, with the exception of the "DO NOT EAT" warning if the product is intended for human consumption.

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

(10) If usable marijuana has more than one (1) test batch number, laboratory, or test analysis date associated with the usable marijuana that is being sold or transferred, each test batch number, laboratory, and test analysis date must be included on a label.

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

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

Authority. Arkansas Constitution, Amendment 98, sec. 4.

Codification Notes. "FDA" means the Food and Drug Administration.

20 CAR § 202-105. Testing standards for usable marijuana.

(a)(1) This part is applicable to cultivation facilities and dispensaries.

(2) A cultivation facility or dispensary may not:

(A) Transfer usable marijuana that is not sampled and tested in accordance with this part; or

(B) Accept the transfer of usable marijuana that is not sampled and tested in accordance with this part.

(b) **Ordering tests.** A cultivation facility or dispensary must provide a laboratory, prior to a laboratory taking samples, with the following:

(1) A written request of analysis for each test the laboratory is being requested to conduct; and

(2) Notification of whether the batch is being resampled because of a failed test and the failed test results.

(c) **Testing requirements for usable marijuana.**

(1) A cultivation facility or dispensary must test every batch of usable marijuana intended for use by a qualified patient prior to selling or transferring the usable marijuana for the following:

(A) Pesticides in accordance with 20 CAR § 202-112;

(B) Water activity and moisture content in accordance with 20 CAR § 202-114;

(C) THC and CBD concentration in accordance with 20 CAR § 202-115;

and

(D) Heavy metals in accordance with 20 CAR § 202-116.

(2) A cultivation facility or dispensary must test every batch of usable marijuana intended for use by a cultivation facility or dispensary for water activity and moisture content in accordance with 20 CAR § 202-114, unless the cultivation facility or dispensary uses a method of processing that results in effective sterilization.

(3) A cultivation facility or dispensary must test a harvest lot of marijuana or usable marijuana for microbiological contaminants:

(A) In accordance with 20 CAR § 202-111; or

(B) Upon written request by the Department of Health or the Alcoholic Beverage Control Division.

(4) In lieu of ordering and arranging for the sampling and testing required in this section, a cultivation facility may transport batches of usable marijuana to a dispensary and the dispensary may order and arrange for the sampling and testing of the batches in accordance with this part.

Authority. Arkansas Constitution, Amendment 98, sec. 4.

20 CAR § 202-106. Testing requirements for concentrates and extracts.

(a) A cultivation facility or dispensary must test every process lot of cannabinoid concentrate or extract for use by a qualified patient prior to selling or transferring the cannabinoid concentrate or extract for the following:

(1) Pesticides in accordance with 20 CAR § 202-112;

(2) Solvents in accordance with 20 CAR § 202-113;

(3) THC and CBD concentration in accordance with 20 CAR § 202-115; and

(4) Heavy metals in accordance with 20 CAR § 202-116.

(b) A cultivation facility or dispensary is exempt from testing for solvents under this section if the cultivation facility or dispensary:

(1) Did not use any solvent listed in Appendix B, Table 2; and

(2) Only used a mechanical extraction process to separate cannabinoids from

the marijuana; or

(3) Used only water, animal fat, or vegetable oil as a solvent to separate the cannabinoids from the marijuana.

(c) A cultivation facility or dispensary must test a process lot of a cannabinoid concentrate or extract for microbiological contaminants in accordance with 20 CAR § 202-111, or upon written request by the Department of Health or the Medical Marijuana Commission.

Authority. Arkansas Constitution, Amendment 98, sec. 4.

20 CAR § 202-107. Batch requirements.

(a) **Usable marijuana.**

(1) A cultivation facility or dispensary must separate each harvest lot into no larger than ten-pound batches.

(2) Notwithstanding subdivision (a)(1) of this section, a cultivation facility or dispensary may combine batches for purposes of having a batch sampled if each:

(A) Batch is intended for use by a cultivation facility or dispensary to make a cannabinoid concentrate or extract; and

(B) Harvest lot was:

(i) Cultivated utilizing the same growing practices and grown in close proximity on the licensed or registered premises;

(ii) Harvested at the same time; and

(iii) If cured prior to sampling, cured under uniform conditions.

(3) A cultivation facility or dispensary may not combine harvest lots into a batch for purposes of sampling and testing for THC or CBD.

(4) If harvest lots are combined in accordance with subdivision (a)(2) of this section, the batch must be labeled so that it identifies the different harvest lots that were combined.

(b) **Cannabinoid concentrates and extracts.** A process lot is considered a batch.

(c) A cultivation facility or dispensary must assign each batch a unique batch number and that unique batch number must be:

(1) Documented and maintained in the cultivation facility or dispensary records for at least two (2) years and available to the Department of Health upon request;

(2) Provided to the individual responsible for taking samples; and

(3) Included on the batch label as required in 20 CAR § 202-110.

(d) A cultivation facility or dispensary may not reuse a unique batch number.

Authority. Arkansas Constitution, Amendment 98, sec. 4.

20 CAR § 202-108. Sampling and sample size.

(a) **Usable marijuana.**

(1) Usable marijuana may only be sampled after it is cured, unless the usable marijuana is intended for sale or transfer to a cultivation facility or dispensary to make a cannabinoid concentrate or extract.

(2) Samples taken must in total represent a minimum of five-tenths of one percent (0.5%) of the batch, consistent with the laboratory's accredited sampling policies and procedures, described in Appendix A, §1(A).

(b) **Cannabinoid concentrates, extracts, and products.** 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 described in Appendix A, §1(A).

Authority. Arkansas Constitution, Amendment 98, sec. 4.

20 CAR § 202-109. Sampling personnel requirements – Sampling recordkeeping.

(a) Only individuals employed by a laboratory sampling under this part may take samples.

(b) Sampling may be conducted at a cultivation facility's or dispensary's premises

or the cultivation facility or dispensary may transport the batch to a laboratory for sampling under this part.

(c) Laboratory personnel that perform sampling must:

(1) Follow the laboratory's accredited sampling policies and procedures; and

(2) Follow chain of custody procedures consistent with TNI EL Standard V1M2 5.7 and 5.8.

(d) A laboratory must:

(1) Maintain the documentation required in this part for at least two (2) years; and

(2) Provide that information to the Department of Health upon request.

Authority. Arkansas Constitution, Amendment 98, sec. 4.

20 CAR § 202-110. Cultivation facility or dispensary requirements for labeling and recordkeeping.

(a) Following samples being taken from a harvest or process lot batch, a cultivation facility or dispensary must:

(1) Label the batch with the following information:

(A) The cultivation facility's or dispensary's registration number;

(B) The harvest or process lot unique identification number;

(C) The name and accreditation number of the laboratory that took samples and the name and accreditation number of the laboratory responsible for the testing, if different;

(D) The test batch or sample unique identification numbers supplied by the laboratory personnel;

(E) The date the samples were taken; and

(F) In bold, capital letters, no smaller than twelve-point font, "PRODUCT NOT TESTED.";

(2) Store and secure the batch in a manner that prevents the product from being tampered with or transferred prior to test results being reported; and

(3) Be able to easily locate a batch stored and secured and provide that location to the Department of Health or a laboratory upon request.

(b) If the samples pass testing, the product may be sold or transferred.

(c) If the samples do not pass testing, the cultivation facility or dispensary must comply with 20 CAR § 202-117.

Authority. Arkansas Constitution, Amendment 98, sec. 4.

20 CAR § 202-111. Standards for testing microbiological contaminants.

(a) Usable marijuana required to be tested for microbiological contaminants must be sampled using appropriate aseptic techniques and tested by a laboratory for total coliform count.

(b) If a laboratory detects the presence of any coliforms, the sample must be assessed for Escherichia coli (E. coli).

(c) A batch fails microbiological contaminant testing if the laboratory detects the presence of E. coli at more than one hundred colony forming units per gram (100 CFU/g) in a sample:

(1) During an initial test where no reanalysis is requested; or

(2) Upon reanalysis as described in 20 CAR § 202-117(a).

Authority. Arkansas Constitution, Amendment 98, sec. 4.

20 CAR § 202-112. Standards for testing pesticides.

(a) Usable marijuana required to be tested for pesticides must be tested by a laboratory for the analytes listed in Appendix B, Table 1.

(b) A batch fails pesticide testing if a laboratory detects the presence of a pesticide above the action levels listed in Appendix B, Table 1 in a sample:

(1) During an initial test where no reanalysis is requested; or

(2) Upon reanalysis as described in 20 CAR § 202-117(a).

Authority. Arkansas Constitution, Amendment 98, sec. 4.

20 CAR § 202-113. Standards for testing solvents.

(a) Usable marijuana required to be tested for solvents must be tested by a laboratory for the analytes listed in Appendix B, Table 2.

(b) A batch fails solvent testing if a laboratory, during an initial test where no reanalysis is requested or upon reanalysis as described in 20 CAR § 202-117(a):

(1) Detects the presence of a solvent above the action level listed in Appendix B, Table 2; or

(2) Calculates an RPD of more than twenty percent (20%) between the field primary result of the sample and the field duplicate result.

Authority. Arkansas Constitution, Amendment 98, sec. 4.

20 CAR § 202-114. Standards for testing water activity and moisture content.

(a) Usable marijuana must be tested by a laboratory for:

(1) Water activity; and

(2) Moisture content.

(b) If a sample has a water activity rate of more than sixty-five hundredths (0.65 Aw) the sample fails.

(c) If a sample has a moisture content of more than fifteen percent (15%), the result must be reported to the cultivation facility or dispensary, but the sample does not fail.

Authority. Arkansas Constitution, Amendment 98, sec. 4.

20 CAR § 202-115. Standards for THC and CBD testing.

(a) A laboratory must test for the following when testing usable marijuana for potency:

(1) THC;

(2) THCA;

(3) CBD; and

(4) CBDA.

(b) A process lot of a cannabinoid concentrate or extract fails potency testing if, based on an initial test where no reanalysis is requested or upon reanalysis as described in 20 CAR § 202-117(a), the amount of THC, as calculated pursuant to Appendix A, §1, between samples taken from the batch exceeds thirty percent (30%) RSD.

Authority. Arkansas Constitution, Amendment 98, sec. 4.

20 CAR § 202-116. Standards for testing for heavy metals.

(a) Usable marijuana must be tested by a laboratory for the metals listed in Appendix B, Table 3.

(b) A batch fails metals testing if a laboratory, during an initial test where no reanalysis is requested or upon reanalysis as described in 20 CAR § 202-117(a), detects the presence of metals above the action level listed in Appendix B, Table 3.

Authority. Arkansas Constitution, Amendment 98, sec. 4.

20 CAR § 202-117. Failed test samples.

(a)(1) If a sample fails any initial test, the laboratory that did the testing may reanalyze the sample.

(2) If the sample passes, another laboratory must resample the batch and confirm that result in order for the batch to pass testing.

(b) If a sample fails a test or a reanalysis under subsection (a) of this section, the batch:

(1) May be remediated or sterilized in accordance with this section; or

(2) If it is not or cannot be remediated or sterilized under this section, it must be destroyed in a manner specified by the Medical Marijuana Commission.

(c) If a cultivation facility or dispensary is permitted under this section to sell or transfer a batch that has failed a test, the cultivation facility or dispensary must notify the cultivation facility or dispensary to whom the batch is sold or transferred of the failed test.

(d) **Failed microbiological contaminant testing.**

(1) If a sample from a batch of usable marijuana fails microbiological contaminant testing, the batch may be used to make a cannabinoid concentrate or extract if the processing method effectively sterilizes the batch, such as a method using a hydrocarbon-based solvent or a CO_2 closed-loop system.

(2) If a sample from a batch of a cannabinoid concentrate or extract fails microbiological contaminant testing, the batch may be further processed if the processing method effectively sterilizes the batch, such as a method using a hydrocarbon-based solvent or a CO_2 closed-loop system.

(3) A batch that is sterilized in accordance with subdivision (d)(1) or (d)(2) of this section must be sampled and tested in accordance with this part and must be tested, if not otherwise required for that product, for microbiological contaminants, solvents, and pesticides.

(4) A batch that fails microbiological contaminant testing after undergoing a sterilization process in accordance with subdivision (d)(1) or (d)(2) of this section must be destroyed in a manner specified by the commission.

(e) **Failed solvent testing.**

(1) 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.

(2) A batch that is remediated in accordance with subdivision (e)(1) of this section must be:

(A) Sampled and tested in accordance with this part; and

(B) Tested, if not otherwise required for that product under this part, for solvents and pesticides.

(3) A batch that fails solvent testing that is not remediated or that if

remediated fails testing must be destroyed in a manner specified by the commission.

(f) **Failed water activity testing.**

(1) If a sample from a batch of usable marijuana fails for water activity, the batch from which the sample was taken may:

(A) Be used to make a cannabinoid concentrate or extract; or

(B) Continue to dry or cure.

(2) A batch that undergoes additional drying or curing as described in subdivision (f)(1) of this section must be sampled and tested in accordance with this part.

(g) **Failed pesticide testing.**

(1) If a sample from a batch fails pesticide testing, the batch may not be remediated and must be destroyed in a manner approved by the commission.

(2) The Department of Health must report to the Department of Agriculture all test results that show that a sample failed a pesticide test.

(h) **Failed potency testing.**

(1) Usable marijuana that fails potency testing under 20 CAR § 202-115(b) may be repackaged in a manner that enables the item to meet the standard in 20 CAR § 202-115(b).

(2) Usable marijuana that is repackaged in accordance with this section must be sampled and tested in accordance with this part.

(i) If a sample fails a test after undergoing remediation or sterilization as permitted under this section, the batch must be destroyed in a manner approved by the commission.

(j) A cultivation facility or dispensary must inform a laboratory prior to samples being taken that the batch has failed a test and is being retested after undergoing remediation or sterilization.

(k) A cultivation facility or dispensary must, as applicable:

(1) Have detailed procedures for sterilization processes to remove microbiological contaminants and for reducing the concentration of solvents; and

(2) Document all sampling, testing, sterilization, remediation, and destruction

that are a result of failing a test under this part.

Authority. Arkansas Constitution, Amendment 98, sec. 4.

Codification Notes. "CO2" means carbon dioxide.

20 CAR § 202-118. Tentative identification of compounds.

(a) 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.

(b) The Department of Health may initiate an investigation of a cultivation facility or dispensary upon receipt of a TICs report from a laboratory and may require a cultivation facility or dispensary to submit samples for additional testing, including testing for analytes that are not required by this part, at the cultivation facility's or dispensary's expense.

Authority. Arkansas Constitution, Amendment 98, sec. 4.

20 CAR § 202-119. Audit and random testing.

(a) The Department of Health may require:

(1) A cultivation facility or dispensary to submit samples identified by the department to a laboratory of the cultivation facility's or dispensary's choosing to be tested in order to determine whether a cultivation facility or dispensary is in compliance with this part; and

(2) Additional testing that is not required by this part.

(b) A laboratory doing audit testing must comply with this part, to the extent it is applicable, and if conducting testing not required by this part, may only use department-approved methods.

(c) The department must establish a process for the random testing of usable marijuana for microbiological contaminants that ensures each cultivation facility or

dispensary tests every product for microbiological contaminants at least once a year.

Authority. Arkansas Constitution, Amendment 98, sec. 4.

20 CAR § 202-120. Temporary cultivation facility or dispensary pesticide testing requirements.

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

(b) The department must ensure that samples from at least one (1) batch of every harvest lot are tested for pesticides.

(c) If any one of the randomly chosen samples from a batch of a producer cultivation facility's or dispensary's harvest lot fails a pesticide test, every batch from the harvest lot must be tested for pesticides.

(d) If the randomly chosen samples from batches of usable marijuana that are tested for pesticides all pass, the entire harvest lot:

(1) Is considered to have passed pesticide testing; and

(2) May be transferred or sold.

Authority. Arkansas Constitution, Amendment 98, sec. 4.

20 CAR § 202-121. Petitions to add medical conditions or treatments.

(a) The Department of Health will only accept petitions that are sent via United States mail:

Arkansas Department of Health
Medical Marijuana Program
4815 West Markham, Slot 50

Little Rock, AR 72205

(b) Each petition is limited to a single medical condition or disease.

(c) Each petition must include:

(1) The specific name and brief description of the proposed debilitating medical condition or disease, including any applicable ICD-10 diagnostic code or codes;

(2) The extent to which the debilitating medical condition or disease itself, and/or the treatments, cause severe suffering and impair a person's daily life;

(3) A description of the conventional medical therapies, other than those that cause suffering, available to alleviate the suffering caused by the proposed debilitating medical condition or disease;

(4) A description of the proposed benefits from the medical use of cannabis specific to the proposed debilitating medical condition or disease;

(5)(A) Evidence generally accepted by the medical community and other experts that the use of medical cannabis alleviates suffering caused by the debilitating medical disease and/or treatment.

(B) This includes but is not limited to:

(i) Full-text peer-reviewed published journals; or

(ii) Other completed medical studies; and

(6) Letters of support for the use of medical cannabis from physicians and/or other licensed healthcare providers knowledgeable about the condition or disease including, if applicable, a letter from the physician with whom the petitioner has a bona fide physician-patient relationship along with any medical, testimonial, or scientific documentation.

(d)(1) If the petition meets all requirements, it will be referred for a public hearing.

(2) Petitioners will be notified in advance of the date, time, and location of the public hearing, and will be allowed to offer verbal or written comments, as will other members of the public.

(3) Notice of the public hearing shall conform.

(e) If a medical condition, medical treatment, or disease in a petition has been

previously considered and rejected or is determined to be substantially similar to a previously rejected condition, treatment, or disease, the department may deny the petition without first referring for a public hearing unless new scientific research that supports the request is offered in the petition.

(f)(1) After reviewing the petitions, supporting evidence, and public comments, the program will issue a recommendation to the director as to which of the conditions, diseases, or treatments should be added as qualifying conditions.

(2) In considering a petition, the department shall recommend to add medical conditions or treatments to the list of qualifying medical conditions if patients suffering from the medical conditions or undergoing the treatments in question would derive therapeutic benefit from the use of marijuana, taking into account the positive and negative health effects of such use.

(g)(1) The director shall, after hearing, approve or deny a petition within one hundred twenty (120) days of submission of the petition.

(2) The director will make the final determination.

(3) If the decision is to add the condition, treatment, or disease, the department will proceed to propose rules to expand the list.

Authority. Arkansas Constitution, Amendment 98, sec. 4.

Appendix A. Sampling Policies and Procedures

Link:
https://CodeOfARRules.arkansas.gov/docs/CARCodeAppendices/Appendices/390/20CARpt.202AppendixA.pdf

Appendix B. Standards for Testing

Link:
https://CodeOfARRules.arkansas.gov/docs/CARCodeAppendices/Appendice

s/391/20CARpt.202AppendixB.pdf