

# ARKANSAS REGISTER

## Transmittal Sheet

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Effective Date \_\_\_\_\_ Code Number \_\_\_\_\_

Name of Agency Department of Health

Department Center for Health Protection/Section of Medical Marijuana

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Statutory Authority for Promulgating Rules § 4, Amendment No. 98 of the Constitution of the State of Arkansas of 1874

2017 AUG 32 PM 3:36  
MARK MARTIN  
SECRETARY OF STATE  
STATE OF ARKANSAS

**Rule Title:** Medical Marijuana Registration, Testing, and Labeling in Arkansas

**Intended Effective Date**  
(Check One)

**Date**

Emergency (ACA 25-15-204)

Legal Notice Published .....

02/08/2016

10 Days After Filing (ACA 25-15-204)

Final Date for Public Comment .....

03/10/2017

Other \_\_\_\_\_  
(Must be more than 10 days after filing date.)

Reviewed by Legislative Council .....

05/03/2017

Adopted by State Agency .....

04/27/2017

Electronic Copy of Rule e-mailed from: (Required under ACA 25-15-218)

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9/1/2017

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### CERTIFICATION OF AUTHORIZED OFFICER

I Hereby Certify That The Attached Rules Were Adopted  
In Compliance with the Arkansas Administrative Act. (ACA 25-15-201 et seq.)

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09/01/2017

Date

RECEIVED  
SEP 1 2017  
BUREAU OF LEGISLATIVE RESEARCH

**ARKANSAS STATE BOARD OF HEALTH  
DEPARTMENT OF HEALTH**



**RULES AND REGULATIONS GOVERNING MEDICAL MARIJUANA  
REGISTRATION, TESTING, AND LABELING IN ARKANSAS**

**Promulgated Under the Authority of  
Amendment No. 98 of the Constitution of the State of Arkansas of 1874  
The Medical Marijuana Amendment of 2016**

**Effective September 11, 2017**

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# **RULES AND REGULATIONS GOVERNING MEDICAL MARIJUANA REGISTRATION, LABELING, AND TESTING IN ARKANSAS**

## **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.

## **SECTION II. SCOPE AND PURPOSE**

These Rules govern the application for and renewal of registry identification cards for qualifying patients and designated caregivers. These Rules also establish labeling and testing standards for marijuana distributed under the Medical Marijuana Amendment, and how medical conditions may be added to the list of qualifying conditions.

## **SECTION III. DEFINITIONS**

- (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 Amendment and any rules promulgated under the Amendment;
- (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.
- (4) “Approved Laboratory” means a laboratory that is accredited by the National Institute on Drug Abuse (NIDA), the National Environmental Laboratory Accreditation Conference (NELAC), the International Organization for Standardization (ISO) or similar accrediting entity as determined by the Department, and that has been approved by the Department 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 Amendment.
- (6) “Batch” means, with regard to usable marijuana, a homogenous, identified quantity of usable marijuana, no greater than ten (10) pounds, that is harvested during a specified time period from a specified cultivation area, and with regard to oils vapors and waxes derived from usable marijuana, means an identified quantity that is uniform, that is intended to meet specifications for identity, strength, and composition, and that is manufactured, packaged and labeled during a specified time period according to a single manufacturing, packaging and labeling protocol.
- (7) "CBD" means cannabidiol, Chemical Abstracts Service Number 13956-29-1.

- (8) "CBDA" means cannabidiolic acid, Chemical Abstracts Service Number 1244-58-2.
- (9) "Cardholder" means a qualifying patient or a designated caregiver;
- (10) "Cultivation facility" means an entity that:
- (a) Has been licensed by the Medical Marijuana Commission;
  - (b) Cultivates, prepares, manufactures, processes, packages, sells to and delivers usable marijuana to a dispensary;
- (11)(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 Amendment and these Rules.
- (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 Amendment.
- (12) "Dispensary" means an entity that has been licensed by the Medical Marijuana Department pursuant to the requirements of the Amendment.
- (13) "Division" means the Alcoholic Beverage Control Division.
- (14) "Excluded felony offense" means:
- (a)(i) A felony offense as determined by the jurisdiction where the felony offense occurred. 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.
  - (ii) 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.
- (15) "Harvest lot " means a specifically identified quantity of marijuana that is uniform in strain, cultivated utilizing the same growing practices, harvested at the same time at the same location and cured under uniform conditions.
- (16) "Lot" mans an identified portion of a batch, that is uniform and that is intended to meet specifications for identity, strength, and composition; or in the case of a vapor, oil, or wax derived from usable marijuana, an identified quantity produced in a specified period of time in a manner that is uniform and that is intended to meet specifications for identity, strength, and composition.
- (17) "Commission" means the Medical Marijuana Commission.

(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 United States 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 batches harvested marijuana.

(22) "Proper identification" means a motor vehicle operator's license or other official state-issued identification of the purchaser that contains a photograph of the purchaser, and includes the residential or mailing address of the purchaser, other than a post office box number;

(23) “Qualifying medical condition” means one or more of the following:

(a) Cancer, glaucoma, positive status for human immunodeficiency virus/acquired immune deficiency syndrome, hepatitis C, amyotrophic lateral sclerosis, Tourette’s 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: cachexia or wasting syndrome; peripheral neuropathy; intractable pain, which is pain that has not responded to ordinary medications, treatment or surgical measures for more than six (6) months; severe nausea; seizures, including without limitation those characteristic of epilepsy; or 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 pursuant to these Rules and the Amendment.

(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 in accordance with these Rules and the Amendment.

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

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

(27) “Registry identification card” means a document issued by the Department that identifies a person as a qualifying patient or a designated caregiver.

(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 provisions of this rule.
- (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 developed and established by the consensus principles of TNI and that meet the approval requirements of TNI procedures and policies.
- (35) “Universal symbol” means the image, established by the Department and made available to licensees and registrants, indicating the container contains marijuana.
- (36)(1) “Usable marijuana” means the stalks, seeds, roots, dried leaves, flowers, oils, vapors, waxes, and other portions of the marijuana plant and any mixture or preparation thereof.
- (2) 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 is not a resident of Arkansas or who has been a resident of Arkansas for less than thirty (30) days and who is in actual possession of a 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 and pertains to a qualifying medical condition under the Amendment; and
- (38)(1) “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.
- (2) A written certification shall specify the qualifying patient's qualifying medical condition, which also shall be noted in the physician's records.
- (3) A physician shall not issue a written certificate to a patient based on an assessment performed through telemedicine.
- (4) A written certification is not a medical prescription

#### **SECTION IV. REGISTRY IDENTIFICATION CARDS**

(A) Qualifying Patients. The Department 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 Amendment; and
- (f) A copy of a driver's license or identification card issued by the State of Arkansas.

(2) The fifty dollar (\$50.00) application fee.

- (a) The Department may designate how the fee is submitted; and
- (b) The Department may require a convenience fee if payment is submitted by credit card.

(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. The Department shall issue a registry identification card for a designated caregiver who submits the following:

(1) An application for a Designated Caregiver registry identification card that must include the following:

- (a) The name and date of birth of the designated caregiver;
- (b) The address of the designated caregiver;
- (c) The name and address of the qualifying patient the applicant will be assisting;



(d) 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;

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

(2) The fifty dollar (\$50.00) application fee;

(a) The Department may designate how the fee is submitted; and

(b) The Department may require a convenience fee if payment is submitted by credit card.

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

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

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

(4)(a) The applicant shall complete a criminal history check form as required by the Department and shall request the Identification Bureau of the Department 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; and

(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.

(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.

(a) 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.

(b) 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 or more qualifying medical conditions.

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

(1) A registry identification card may expire on a date earlier than one 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. The specified earlier date will be the expiration date.

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

(F) Department Review of Applications and Renewals. 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.

(1) 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; or

(c) The written certification was fraudulently obtained; or

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

(2) 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 these rules.

(3) 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) The Department shall maintain a list of all the persons to whom qualifying patient and designated caregiver registry identification cards have been issued.

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

(b) 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.

## **SECTION V. LABELING**

(A) 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.

(1) Usable marijuana received or transferred by a dispensary, qualifying patient or designated caregiver must meet the labeling requirements in these rules.

(2)(a) A dispensary must return usable marijuana that does not meet labeling requirements in these rules 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.

(B) Usable Marijuana Labeling Requirements

(1) 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:

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

(b) 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;

(c) A unique identification number;

(d) Date of harvest;

- (e) Name of strain;
- (f) Net weight in U.S. customary and metric units;
- (g) Concentration of THC and CBD;
- (h) Activation time expressed in words or through a pictogram;
- (i) Name of the lab that performed any test, any associated test batch number and any test analysis date;
- (j) Universal symbol;
- (k) A warning that states: "For use by qualified patients only. Keep out of reach of children.";
- (l) A warning that states: "Marijuana use during pregnancy or breastfeeding poses potential harms."; and
- (m) A warning that states: "This product is not approved by the FDA to treat, cure, or prevent any disease".

(C) Cannabinoid Concentrates and Extracts

(1) 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:

- (a) Cultivation facility or dispensary's business or trade name and cultivation facility or dispensary number;
- (b) Business or trade name of cultivation facility or dispensary that packaged or distributed the product, if different from the cultivation facility or dispensary;
- (c) A unique identification number;
- (d) Product identity (concentrate or extract);
- (e) Date the concentrate or extract was made;
- (f) Net weight or volume in U.S. customary and metric units;
- (g) If applicable, serving size and number of servings per container or amount suggested for use by the qualifying patient at any one time;

- (h) Concentration or amount by weight or volume of THC and CBD in each amount suggested for use and in the container;
- (i) Activation time, expressed in words or through a pictogram;
- (j) Name of the lab that performed any test, any associated test batch number and any test analysis date;
- (k) Universal symbol;
- (l) A statement that reads:
  - (i) "This product is not approved by the FDA to treat, cure, or prevent any disease";
  - (ii) "For use by qualifying patients only. Keep out of reach of children.";
  - (iii) "DO NOT EAT" in bold, capital letters; and
  - (iv) "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 these rules must:

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

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

- (c) Be in no smaller than 8 point Times New Roman, Helvetica or Arial font;
  - (i) Statements required by subsections (C)(1)(I)(ii) and (iv) must be in at least 18 point.
- (d) Be in English, though it can also be in other languages; and
- (e) Be unobstructed and conspicuous.

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

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

(a) May have a label on the container that contains usable marijuana and on any packaging that is used to display usable marijuana for sale or transfer to a 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 subsection (4)(a) on an outer container or package, or on a leaflet that accompanies the usable marijuana.

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

(6) The universal symbol:

(a) Must be at least 0.48 inches wide by 0.35 inches high.

(b) May only be used by a cultivation facility or dispensary.

(c) May be downloaded at:  
<http://www.healthy.arkansas.gov/Pages/MedMarijuana.aspx>.

(7) A label may not:

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

(b) Be attractive to minors.

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

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

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

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

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

## **SECTION VI. TESTING STANDARDS FOR USABLE MARIJUANA**

(A) These rules are applicable to cultivation facilities and dispensaries.

(1) A cultivation facility or dispensary may not:

(a) Transfer usable marijuana that is not sampled and tested in accordance with these rules; or

(b) Accept the transfer of usable marijuana that is not sampled and tested in accordance with these rules.

(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 re-sampled 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 § XIII.
- (b) Water activity and moisture content in accordance with § XV.
- (c) THC and CBD concentration in accordance with § XVI.
- (d) Heavy Metals in accordance with § XVII.

(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 § XV, 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 in accordance with § XII, or upon written request by the Department or Division.

(4) In lieu of ordering and arranging for the sampling and testing required in this rule, 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 these rules.

**SECTION VII. 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:



- (a) Pesticides in accordance with § XIII.
  - (b) Solvents in accordance with § XIV.
  - (c) THC and CBD concentration in accordance with § XVI.
  - (d) Heavy Metals in accordance with § XVII
- (B) A cultivation facility or dispensary is exempt from testing for solvents under this rule 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 § XII, or upon written request by the Department or the Commission.

## **SECTION VIII. BATCH REQUIREMENTS**

- (A) Usable marijuana.
- (1) A cultivation facility or dispensary must separate each harvest lot into no larger than 10 pound batches.
  - (2) Notwithstanding subsection (A)(1) of this section, a cultivation facility or dispensary may combine batches for purposes of having a batch sampled if each batch is intended for use by a cultivation facility or dispensary 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.
  - (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 subsection (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.

(1) 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 years and available to the Department upon request;

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

(3) Included on the batch label as required in § XI.

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

## **SECTION IX. 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 0.5 percent 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.

(1) 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).

## **SECTION X. SAMPLING PERSONNEL REQUIREMENTS; SAMPLING RECORDKEEPING**

(A) Only individuals employed by a laboratory sampling under these rules may take samples.

(B) Sampling may be conducted at a cultivation facility or dispensary's premises or the Cultivation facility or dispensary may transport the batch to a laboratory for sampling under these rules.

(C) Laboratory personnel that perform sampling must:

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

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

(D) A laboratory must maintain the documentation required in these rules for at least two years and must provide that information to the Department upon request.

## **SECTION XI. 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 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 12 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.

(3) Be able to easily locate a batch stored and secured and provide that location to the Department 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 § XVIII.

## **SECTION XII. STANDARDS FOR TESTING MICROBIOLOGICAL CONTAMINANTS**

(A) Usable marijuana required to be tested for microbiological contaminants must be sampled using appropriate aseptic technique 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 100 colony forming units per gram in a sample:

- (1) During an initial test where no reanalysis is requested; or
- (2) Upon reanalysis as described in § XVIII(A).

## **SECTION XIII. 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 § XVIII(A).

## **SECTION XIV. 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 § XVIII(A):

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

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

#### **SECTION XV. 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 0.65  $A_w$  the sample fails.

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

#### **SECTION XVI. 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.

(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 § XVIII(A):

(1) The amount of THC, as calculated pursuant to Appendix A, §1, between samples taken from the batch exceeds 30 percent RSD.

#### **SECTION XVII. 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 § XVIII(A) detects the presence of metals above the action level listed in Appendix B, Table 3.

## **SECTION XVIII. FAILED TEST SAMPLES**

(A) If a sample fails any initial test, the laboratory that did the testing may reanalyze the sample. 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 rule; or

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

(C) If a Cultivation facility or dispensary is permitted under this rule 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<sub>2</sub> closed loop system.

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

(3) A batch that is sterilized in accordance with subsection (D)(1) or (D)(2) of this section must be sampled and tested in accordance with these rules 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 subsection (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 subsection (E)(1) of this section must be sampled and tested in accordance with these rules and must be tested if not otherwise required for that product under these rules, for solvents and pesticides.

(3) A batch that fails 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 subsection (F)(1) of this section must be sampled and tested in accordance with these rules.

(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 must report to the Arkansas 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 §§ XVI(B)(1) or (C)(1) may be repackaged in a manner that enables the item to meet the standard in §§ XVI(B)(1) or (C)(1).

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

(I) If a sample fails a test after undergoing remediation or sterilization as permitted under this rule, 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.

(2) Document all sampling, testing, sterilization, remediation and destruction that are a result of failing a test under these rules.

## **SECTION XIX. 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 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 these rules, at the cultivation facility or dispensary's expense.

## **SECTION XX. AUDIT AND RANDOM TESTING**

(A) The Department may require a cultivation facility or dispensary to submit samples identified by the Department to a laboratory of the cultivation facility or dispensary's choosing to be tested in order to determine whether a cultivation facility or dispensary is in compliance with these rules, and may require additional testing that is not required by these rules.

(B) A laboratory doing audit testing must comply with these rules, to the extent they are applicable, and if conducting testing not required by these rules, 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.

## **SECTION XXI. TEMPORARY CULTIVATION FACILITY OR DISPENSARY PESTICIDE TESTING REQUIREMENTS**

(A) Notwithstanding these rules, if the Department 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 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 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 is considered to have passed pesticide testing and may be transferred or sold.

## **SECTION XXII. PETITIONS TO ADD MEDICAL CONDITIONS OR TREATMENTS**

(A) The Department will only accept petitions that are sent via U.S. 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(s);

(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) 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 (this includes but is not limited to full-text peer-reviewed published journals or other completed medical studies); and

(6) Letters of support for the use of medical cannabis from physicians and/or other licensed health care 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) If the petition meets all requirements, it will be referred for a public hearing. 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. 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) 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. 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) The Director shall, after hearing, approve or deny a petition within one hundred twenty (120) days of submission of the petition. The Director will make the final determination. If the decision is to add the condition, treatment or disease, the Department will proceed to propose regulations to expand the list.

**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 on the 27<sup>th</sup> day of April, 2017.



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

## **APPENDIX A**

### **SECTION I. MARIJUANA ITEM SAMPLING PROCEDURES AND TESTING**

#### **(A) Sampling**

(1) A laboratory must prepare usable marijuana sampling policies and procedures that contain all of the information necessary for collecting and transporting samples from usable marijuana in a manner that does not endanger the integrity of the sample for any analysis required by this rule. These policies and procedures must be appropriate to the matrix being sampled.

(2) Care should be taken by laboratory personnel while sampling to avoid contamination of the non-sampled material. Sample containers must be free of analytes of interest and appropriate for the analyses requested.

(3) A sufficient sample size must be taken for analysis of all requested tests and the quality control performed by the testing laboratory for these tests.

(4) A laboratory must comply with any recording requirements for samples and subsamples in the policies and procedures and at a minimum:

(a) Record the location of each sample and subsample taken.

(b) Assign a field identification number for each sample, subsample and field duplicate that have an unequivocal link to the laboratory analysis identification.

(c) Assign a unique identification number for the test batch in accordance with Section X and TNI EL standard requirements.

(d) 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 must include identification for all samples, subsamples, preservations, sample containers, tests, and subsequent extracts or digestates.

(e) Place the laboratory identification code as a durable mark on each sample container.

(f) Enter a unique identification number into the laboratory records. This number must 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.

(5) Combining subsamples.

(a) Subsamples collected from the same batch must be combined into a single sample by a laboratory prior to testing.

(b) Subsamples and samples collected from different batches may not be combined.

(c) Field duplicates may not be combined with the primary samples.

(B) THC and CBD testing validity. When testing a sample for THC and CBD a laboratory must comply with additional method validation as follows:

(1) Run a laboratory control standard in accordance with TNI standards requirements within acceptance criteria of 70 percent to 130 percent recovery.

(2) Analyze field duplicates of samples within precision control limits of plus or minus 20 percent RPD, if field duplicates are required.

(C) Calculating total THC and total CBD.

(1) Total THC must be calculated as follows, where M is the mass or mass fraction of delta-9 THC or delta-9 THCA:

$$M \text{ total delta-9 THC} = M \text{ delta-9 THC} + (0.877 \times M \text{ delta-9 THCA}).$$

(2) Total CBD must be calculated as follows, where M is the mass or mass fraction of CBD and CBDA:

$$M \text{ total CBD} = M \text{ CBD} + (0.877 \times M \text{ CBDA}).$$

(3) Each test report must include the total THC and total CBD.

(D) Report total THC and total CBD as Dry Weight. A laboratory must report total THC and Total CBD content by dry weight calculated as follows:

$$P \text{ total THC(dry)} = P \text{ total THC(wet)} / [1 - (P \text{ moisture}/100)]$$

$$P \text{ total CBD(dry)} = P \text{ total CBD(wet)} / [1 - (P \text{ moisture}/100)]$$

(E) Calculating RPD and RSD.

(1) A laboratory must use the following calculation for determining RPD:

$$RPD = \frac{(\text{sample result} - \text{duplicate result})}{(\text{sample result} + \text{duplicate result})/2}$$

(2) A laboratory must use the following calculation for determining RSD:

$$\%RSD = \frac{s}{x} \times 100\%$$

$$s = \sqrt{\frac{\sum_{i=0}^n (x_i - \bar{x})^2}{(n - 1)}}$$

(3) For purposes of this section:

- (a) s = standard deviation.
- (b) n = total number of values.
- (c)  $x_i$  = each individual value used to calculate mean.
- (d)  $\bar{x}$  = mean of n values.

(4) 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.

(F) Tentative Identification of Compounds (TIC).

(1) If a laboratory is using a gas chromatography mass spectrometry instrument for analysis when testing cannabinoid concentrates or extracts for solvents and determines that a sample may contain compounds that are not included in the list of analytes the laboratory is testing for, the laboratory must attempt to achieve tentative identification.

(2) Tentative identification is achieved by searching NIST 2014 or an equivalent database (>250,000 compounds).

(3) A laboratory shall report to the cultivation facility or dispensary and the Department or the Division, depending on which agency has jurisdiction, up to five tentatively identified compounds (TICS) that have the greatest apparent concentration.

(4) Match scores for background subtracted or deconvoluted spectra should exceed 90 percent compared to library spectrum.

(a) The top five matches over 90 percent must be reported by the lab

(b) TIC quantitation is estimated by comparing analyte area to the closest internal standard area and assuming a response factor (RF) =1.

(G) A laboratory must provide:

(1) Any pesticide test result to the Department of Agriculture upon the Department of Health's request.

(2) A sample or a portion of a sample to the Department of Agriculture upon the Department of Health's request and document the chain of custody from the laboratory to the Department of Agriculture.

(H) A laboratory performing tests for a cultivation facility or dispensary must enter any information required by the Division.

(I) A laboratory performing tests for a cultivation facility or dispensary must comply with the documentation requirements in § X.

(J) The Department may, in its discretion, deviate from TNI Standards in order to comply with these rules based on the state's needs.

## **SECTION II Reporting Usable marijuana Test Results**

(A) Within 24 hours of completion of the laboratory's data review and approval procedures, a laboratory must report all failed tests for testing required, except for failed water activity, whether or not the lab is reanalyzing the sample under § XVIII:

(1) To the Department electronically if performing testing for a cultivation facility or dispensary.

(B) The laboratory must report all test results required under these rules that have not been reported under subsection (A) of this section in a manner prescribed by the Department.

(C) A laboratory must determine and include on each test report its limit of quantification (LOQ) for each analyte listed in Appendix B, Table 1 and Appendix B, Table 2.

(D) When reporting pesticide testing results, the laboratory must include in the report any target compound that falls below the LOQ that has a signal to noise ratio of greater than 3:1 and meets identification criteria with a result of "detected."

(E) A test report must include any associated test batch numbers and the date each test was completed.

(F) A laboratory that is reporting failed test results to the Department must report the failed test at the same time or before reporting to the cultivation facility or dispensary.

(G) In addition to reporting failed test results, a laboratory conducting testing for a cultivation facility or dispensary must report to the Department electronically at any pesticide testing report with a "detected" as described in subsection (D) of this section.

(H) Test results expire after one year.



## APPENDIX B

Table 1. Pesticide analytes and their action levels

Analyte	Chemical Abstract Services (CAS) Registry Number	Action Level ppm
Abamectin	71751-41-2	0.5
Acephate	30560-19-1	0.4
Acequinocyl	57960-19-7	2
Acetamiprid	135410-20-7	0.2
Aldicarb	116-06-3	0.4
Azoxystrobin	131860-33-8	0.2
Bifenazate	149877-41-8	0.2
Bifenthrin	82657-04-3	0.2
Boscalid	188425-85-6	0.4
Carbaryl	63-25-2	0.2
Carbofuran	1563-66-2	0.2
Chlorantraniliprole	500008-45-7	0.2
Chlorfenapyr	122453-73-0	1
Chlorpyrifos	2921-88-2	0.2
Clofentezine	74115-24-5	0.2
Cyfluthrin	68359-37-5	1
Cypermethrin	52315-07-8	1
Daminozide	1596-84-5	1
DDVP (Dichlorvos)	62-73-7	0.1
Diazinon	333-41-5	0.2
Dimethoate	60-51-5	0.2
Ethoprophos	13194-48-4	0.2

Analyte	Chemical Abstract Services (CAS) Registry Number	Action Level ppm
Etofenprox	80844-07-1	0.4
Etoxazole	153233-91-1	0.2
Fenoxycarb	72490-01-8	0.2
Fenpyroximate	134098-61-6	0.4
Fipronil	120068-37-3	0.4
Fonicamid	158062-67-0	1
Fludioxonil	131341-86-1	0.4
Hexythiazox	78587-05-0	1
Imazalil	35554-44-0	0.2
Imidacloprid	138261-41-3	0.4
Kresoxim-methyl	143390-89-0	0.4
Malathion	121-75-5	0.2
Metalaxyl	57837-19-1	0.2
Methiocarb	2032-65-7	0.2
Methomyl	16752-77-5	0.4
Methyl parathion	298-00-0	0.2
MGK-264	113-48-4	0.2
Myclobutanil	88671-89-0	0.2
Naled	300-76-5	0.5
Oxamyl	23135-22-0	1
Paclobutrazol	76738-62-0	0.4
Permethrins <sup>1</sup>	52645-53-1	0.2
Phosmet	732-11-6	0.2
Piperonyl_butoxide	51-03-6	2
Prallethrin	23031-36-9	0.2

<sup>1</sup> Permethrins should be measured as

cumulative residue of cis- and trans-permethrin isomers (CAS numbers 54774-45-7 and 51877-74-8 respectively).

Analyte	Chemical Abstract Services (CAS) Registry Number	Action Level ppm
Propiconazole	60207-90-1	0.4
Propoxur	114-26-1	0.2
Pyrethrins <sup>2</sup>	8003-34-7	1
Pyridaben	96489-71-3	0.2
Spinosad	168316-95-8	0.2
Spiromesifen	283594-90-1	0.2
Spirotetramat	203313-25-1	0.2
Spiroxamine	118134-30-8	0.4
Tebuconazole	80443-41-0	0.4
Thiacloprid	111988-49-9	0.2
Thiamethoxam	153719-23-4	0.2
Trifloxystrobin	141517-21-7	0.2

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<sup>2</sup> Pyrethrins should be measured as the cumulative residues of pyrethrin 1, cinerin 1, and jasmolin 1 (CAS

numbers 121-21-1, 25402-06-6, and 4466-14-2 respectively).

Table 2. List of solvents and their action levels

Solvent	Chemical Abstract Services (CAS) Registry Number	Action Level (µg/g)
1,2-Dimethoxyethane	110-71-4	100
1,4-Dioxane	123-91-1	380
1-Butanol	71-36-3	5000
1-Pentanol	71-41-0	5000
1-Propanol	71-23-8	5000
2-Butanol	78-92-2	5000
2-Butanone	78-93-3	5000
2-Ethoxyethanol	110-80-5	160
2-methylbutane	78-78-4	5000 <sup>3</sup>
2-Propanol (IPA)	67-63-0	5000
Acetone	67-64-1	5000
Acetonitrile	75-05-8	410
Benzene	71-43-2	2
Butane	106-97-8	5000 <sup>3</sup>
Cumene	98-82-8	70
Cyclohexane	110-82-7	3880
Dichloromethane	75-09-2	600
2,2-dimethylbutane	75-83-2	290 <sup>4</sup>
2,3-dimethylbutane	79-29-8	290 <sup>4</sup>
1,2-dimethylbenzene	95-47-6	See Xylenes
1,3-dimethylbenzene	108-38-3	See Xylenes

Solvent	Chemical Abstract Services (CAS) Registry Number	Action Level (µg/g)
1,4-dimethylbenzene	106-42-3	See Xylenes
Dimethyl sulfoxide	67-68-5	5000
Ethanol	64-17-5	5000
Ethyl acetate	141-78-6	5000
Ethylbenzene	100-41-4	See Xylenes
Ethyl ether	60-29-7	5000
Ethylene glycol	107-21-1	620
Ethylene Oxide	75-21-8	50
Heptane	142-82-5	5000
n-Hexane	110-54-3	290
Isopropyl acetate	108-21-4	5000
Methanol	67-56-1	3000
Methylpropane	75-28-5	5000 <sup>3</sup>
2-Methylpentane	107-83-5	290 <sup>4</sup>
3-Methylpentane	96-14-0	290 <sup>4</sup>
N,N-dimethylacetamide	127-19-5	1090
N,N-dimethylformamide	68-12-2	880
Pentane	109-66-0	5000
Propane	74-98-6	5000 <sup>3</sup>
Pyridine	110-86-1	200
Sulfolane	126-33-0	160
Tetrahydrofuran	109-99-9	720
Toluene	108-88-3	890
Xylenes <sup>5</sup>	1330-20-7	2170

<sup>3</sup> Limit based on similarity to pentane

<sup>4</sup> Limit based on similarity with n-hexane

<sup>5</sup> Combination of: 1,2-dimethylbenzene, 1,3- dimethylbenzene, 1,4-dimethylbenzene, and ethyl benzene

*Table 3. List of Metals and their action levels*

<b>Metal</b>	<b>Action Level (µg/kg)</b>
Arsenic (inorganic)	200
Cadmium	200
Lead	500
Mercury (total)	100

**QUESTIONNAIRE FOR FILING PROPOSED RULES AND REGULATIONS  
WITH THE ARKANSAS LEGISLATIVE COUNCIL AND JOINT INTERIM COMMITTEE**

**DEPARTMENT/AGENCY** Department of Health  
**DIVISION** Center for Health Protection/Section of Medical Marijuana  
**DIVISION DIRECTOR** Renee Mallory  
**CONTACT PERSON** Robert Brech  
**ADDRESS** 4815 West Markham, St., Slot 31, Little Rock, AR  
**PHONE NO.** 501-661-2297 **FAX NO.** 501-661-2357 **E-MAIL** robert.brech@arkansas.gov  
**NAME OF PRESENTER AT COMMITTEE MEETING** Robert Brech  
**PRESENTER E-MAIL** robert.brech@arkansas.gov

**INSTRUCTIONS**

- A. Please make copies of this form for future use.**
- B. Please answer each question completely using layman terms. You may use additional sheets, if necessary.**
- C. If you have a method of indexing your rules, please give the proposed citation after “Short Title of this Rule” below.**
- D. Submit two (2) copies of this questionnaire and financial impact statement attached to the front of two (2) copies of the proposed rule and required documents. Mail or deliver to:**

**Donna K. Davis  
Administrative Rules Review Section  
Arkansas Legislative Council  
Bureau of Legislative Research  
One Capitol Mall, 5<sup>th</sup> Floor  
Little Rock, AR 72201**

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1. What is the short title of this rule? MEDICAL MARIJUANA REGISTRATION, TESTING, AND LABELING
2. What is the subject of the proposed rule? Medical marijuana
3. Is this rule required to comply with a federal statute, rule, or regulation? Yes  No   
If yes, please provide the federal rule, regulation, and/or statute citation. \_\_\_\_\_
4. Was this rule filed under the emergency provisions of the Administrative Procedure Act? Yes  No   
If yes, what is the effective date of the emergency rule? \_\_\_\_\_

When does the emergency rule expire? \_\_\_\_\_

Will this emergency rule be promulgated under the permanent provisions of the Administrative Procedure Act? Yes  No

5. Is this a new rule? Yes  No

If yes, please provide a brief summary explaining the regulation. These rules govern the application for and renewal of registry identification cards for qualifying patients and designated caregivers. These rules also establish labeling and testing standards for marijuana distributed under the Medical Marijuana Amendment of 2016, and how medical conditions may be added to the list of qualifying conditions.

Does this repeal an existing rule? Yes  No

If yes, a copy of the repealed rule is to be included with your completed questionnaire. If it is being replaced with a new rule, please provide a summary of the rule giving an explanation of what the rule does. \_\_\_\_\_

Is this an amendment to an existing rule? Yes  No

If yes, please attach a mark-up showing the changes in the existing rule and a summary of the substantive changes. **Note: The summary should explain what the amendment does, and the mark-up copy should be clearly labeled "mark-up."**

6. Cite the state law that grants the authority for this proposed rule? If codified, please give the Arkansas Code citation. Amendment No. 98 of the Constitution of the State of Arkansas of 1874, The Medical Marijuana Amendment of 2016, § 4

7. What is the purpose of this proposed rule? Why is it necessary? To implement the Board of Health's responsibilities under the Amendment.

8. Please provide the address where this rule is publicly accessible in electronic form via the Internet as required by Arkansas Code § 25-19-108(b).  
<http://www.healthy.arkansas.gov/aboutADH/Pages/RulesRegulations.aspx>

9. Will a public hearing be held on this proposed rule? Yes  No

If yes, please complete the following:

Date: 03/10/2017

Time: 2:00 p.m.

Place: Auditorium of the Arkansas  
Department of Health

10. When does the public comment period expire for permanent promulgation? (Must provide a date.)  
It expired on 3-10-2017

11. What is the proposed effective date of this proposed rule? (Must provide a date.)  
9/11/2017

12. Do you expect this rule to be controversial? Yes  No



If yes, please explain.

The Department is not aware of any significant controversy at this time regarding this rule; however, the subject of medical marijuana continues to be controversial.

13. Please give the names of persons, groups, or organizations that you expect to comment on these rules? Please provide their position (for or against) if known.

Melissa Fults - Drug Policy Education Group  
Storm Nolan - Arkansas Cannabis Industry Association  
Steve Johnson  
Robert Reed  
Paul Danielson  
Brian Nichol, Anesthesiologist & Pain Management Physician  
Deborah Beuerman  
Donna Will  
Gene Ribley  
Daniel Sanders  
Dante Jacuzzi  
Steve Jacobie  
Christopher L. Travis  
Justice J. Brooks

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**FINANCIAL IMPACT STATEMENT**

**PLEASE ANSWER ALL QUESTIONS COMPLETELY**

**DEPARTMENT**      Department of Health  
**DIVISION**        Center for Health Protection/Section of Medical Marijuana  
**PERSON COMPLETING THIS STATEMENT**   Robert Brech  
**TELEPHONE NO.**   501-661-2297   **FAX NO.**   501-661-2357   **EMAIL:**   robert.brech@arkansas.gov

To comply with Ark. Code Ann. § 25-15-204(e), please complete the following Financial Impact Statement and file two copies with the questionnaire and proposed rules.

**SHORT TITLE OF THIS RULE**    Medical Marijuana Registration, Testing, and Labeling

- 1. Does this proposed, amended, or repealed rule have a financial impact?      Yes       No
- 2. Is the rule based on the best reasonably obtainable scientific, technical, economic, or other evidence and information available concerning the need for, consequences of, and alternatives to the rule?      Yes       No
- 3. In consideration of the alternatives to this rule, was this rule determined by the agency to be the least costly rule considered?      Yes       No

If an agency is proposing a more costly rule, please state the following:

- (a) How the additional benefits of the more costly rule justify its additional cost;  
N/A
- (b) The reason for adoption of the more costly rule;  
N/A
- (c) Whether the more costly rule is based on the interests of public health, safety, or welfare, and if so, please explain; and;  
N/A
- (d) Whether the reason is within the scope of the agency's statutory authority; and if so, please explain.  
N/A

4. If the purpose of this rule is to implement a federal rule or regulation, please state the following:

- (a) What is the cost to implement the federal rule or regulation?

**Current Fiscal Year**

**Next Fiscal Year**

General Revenue \_\_\_\_\_  
Federal Funds \_\_\_\_\_  
Cash Funds \_\_\_\_\_  
Special Revenue \_\_\_\_\_  
Other (Identify) \_\_\_\_\_

General Revenue \_\_\_\_\_  
Federal Funds \_\_\_\_\_  
Cash Funds \_\_\_\_\_  
Special Revenue \_\_\_\_\_  
Other (Identify) \_\_\_\_\_

Total \_\_\_\_\_

Total \_\_\_\_\_

(b) What is the additional cost of the state rule?

**Current Fiscal Year**

**Next Fiscal Year**

General Revenue \_\_\_\_\_

General Revenue \_\_\_\_\_

Federal Funds \_\_\_\_\_

Federal Funds \_\_\_\_\_

Cash Funds \_\_\_\_\_

Cash Funds \_\_\_\_\_

Special Revenue \_\_\_\_\_

Special Revenue \_\_\_\_\_

Other (Identify) \_\_\_\_\_

Other (Identify) \_\_\_\_\_

Total \_\_\_\_\_

Total \_\_\_\_\_

5. What is the total estimated cost by fiscal year to any private individual, entity and business subject to the proposed, amended, or repealed rule? Identify the entity(ies) subject to the proposed rule and explain how they are affected.

**Current Fiscal Year**

**Next Fiscal Year**

\$ 0

\$ \$2,500,000

There will be a cost, but only to the individuals and corporations that choose to participate in the medical marijuana industry. The labeling and minimum testing standards are necessary to protect the public. It is expected that marijuana testing and labeling standards could cost cultivation facilities and dispensaries approximately \$1,000,000. The Department also expects to raise approximately \$1,500,000 from fees paid by registrants.

6. What is the total estimated cost by fiscal year to state, county, and municipal government to implement this rule? Is this the cost of the program or grant? Please explain how the government is affected.

**Current Fiscal Year**

**Next Fiscal Year**

\$ 90,000

\$ \$780,000

The rule implements fees to pay for the cost of implementing and the ongoing costs to operate the program. It is estimated to cost \$780,000 the first full year and \$1,500,000 thereafter.

7. With respect to the agency's answers to Questions #5 and #6 above, is there a new or increased cost or obligation of at least one hundred thousand dollars (\$100,000) per year to a private individual, private entity, private business, state government, county government, municipal government, or to two (2) or more of those entities combined?

Yes  No

If YES, the agency is required by Ark. Code Ann. § 25-15-204(e)(4) to file written findings at the time of filing the financial impact statement. The written findings shall be filed simultaneously with the financial impact statement and shall include, without limitation, the following:

(1) a statement of the rule's basis and purpose;

- (2) the problem the agency seeks to address with the proposed rule, including a statement of whether a rule is required by statute;
- (3) a description of the factual evidence that:
  - (a) justifies the agency's need for the proposed rule; and
  - (b) describes how the benefits of the rule meet the relevant statutory objectives and justify the rule's costs;
- (4) a list of less costly alternatives to the proposed rule and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule;
- (5) a list of alternatives to the proposed rule that were suggested as a result of public comment and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule;
- (6) a statement of whether existing rules have created or contributed to the problem the agency seeks to address with the proposed rule and, if existing rules have created or contributed to the problem, an explanation of why amendment or repeal of the rule creating or contributing to the problem is not a sufficient response; and
- (7) an agency plan for review of the rule no less than every ten (10) years to determine whether, based upon the evidence, there remains a need for the rule including, without limitation, whether:
  - (a) the rule is achieving the statutory objectives;
  - (b) the benefits of the rule continue to justify its costs; and
  - (c) the rule can be amended or repealed to reduce costs while continuing to achieve the statutory objectives.

## Written Findings

A statement of the rule's basis and purpose:

These rules establish labeling and testing standards for marijuana distributed under the Medical Marijuana Amendment. It also establishes the fee to be paid by registrants.

The problem the agency seeks to address with the proposed rule, including a statement of whether a rule is required by statute;

The rules seek to ensure that medical marijuana products sold in Arkansas are free from unacceptable levels of pesticides, solvents and heavy metals. Labeling standards are critical to inform the public of medical marijuana potency and to convey important health warnings.

A description of the factual evidence that:

(a) Justifies the agency's need for the proposed rule; and

As a plant product, it is imperative that the products be adequately tested and labeled to ensure its safety.

(b) Describes how the benefits of the rule meet the relevant statutory objectives and justify the rule's costs;

This is a newly approved constitutional amendment and program. By utilizing recommendations from the Association of Public Health Laboratories, the Department developed these rules. The costs associated with testing will be paid to private companies to perform the necessary tests.

A list of less costly alternatives to the proposed rule and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule;

The Department is not aware of any alternatives.

A list of alternatives to the proposed rule that were suggested as a result of public comment and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule;

There were comments suggesting that the testing of 10 pound batches was too costly and perhaps the testing 100 pound batches should be allowed. However, the Department considers it imperative that products ingested, especially through inhalation, must be tested and determined free from contaminants. The Department will consider larger batches in the future should it be determined to be a safe and effective.

A statement of whether existing rules have created or contributed to the problem the agency seeks to address with the proposed rule.

N/A

If existing rules have created or contributed to the problem, an explanation of why amendment or repeal of the rule creating or contributing to the problem is not a sufficient response; and

N/A

An agency plan for review of the rule no less than every ten (10) years to determine whether, based upon the evidence, there remains a need for the rule, including without limitation whether:

The rule is achieving the statutory objectives;

The benefits of the rule continue to justify its costs; and

The rule can be amended or repealed to reduce costs while continuing to achieve the statutory objectives.

Since this is a new program, the Department intends to continually update and improve the rules as evidence surfaces and updates and improvements become apparent and necessary.