EXHIBIT D

DEPARTMENT OF HEALTH, CENTER FOR HEALTH PROTECTION

SUBJECT: Medical Marijuana Registration, Testing, and Labeling in Arkansas

DESCRIPTION: 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.

PUBLIC COMMENT: A public hearing was held on March 10, 2017. The public comment period expired on March 10, 2017. The department submitted the following summary of the comments received:

*See attached

FINANCIAL IMPACT: To parties subject to the regulations, 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.

On costs to the state, the rule implements fees to pay for the cost of implementing and the ongoing costs to operate the program. The estimated cost is $1,500,000 the first year.

LEGAL AUTHORIZATION: Section 4(a)(2)(A) and (B) of Amendment 98 of the Arkansas Constitution (Amendment) states that the Department of Health shall adopt rules necessary to carry out the purposes of the Amendment and also to perform its duties under the amendment.

Arkansas Code Annotated § 25-15-105(b)(1) states that an agency shall not assess a fee or penalty without specific statutory authority. The current rule assesses a fifty dollar ($50) application fee for registry identification cards to qualifying patients and caregivers as well as possible convenience fees for the use of a credit card. Section 18 9(2)(A) of the Amendment authorizes the department to generate revenue from registry identification card applications and renewal fees, as well as fees for replacement registry identification cards.

COMMENT: Melissa Fults; Drug Policy Education Group

The biggest concern I have is adding the qualifying conditions. There is no appeals process that's in here. I feel this is going to be necessary because there are a lot of patients that have been left out of having this medicine available to them.

RESPONSE:

With this rule and with every rule I think there will be an appeals process. Under the Administrative Procedure Act should you not be happy with the final decision of the agency there is a mechanism that you can take that to the board. If you are unhappy with the board's decision you can then take it to circuit court. From there you can take it to the Arkansas Supreme Court.

COMMENT: Storm Nolan; Arkansas Cannabis Industry Association

Our main goal here is to make sure this is set up well for Arkansans, patients and of course the industry. Which is going to be a symbiotic relationship. If the industry doesn't do well then that won't be good for patients. Three main points:

1. Patients obtaining cards. I want to draw your attention to how Colorado does it. We feel very strongly that online application is crucial to make it easy for Arkansans to submit all the documents online. The physician submits their portion of the application online then the patient completes their portion. Have a backup mailing option. Colorado promises a card in 2-3 business days. The reason that's important is we're talking about people suffering.

2. Application fee. You have it set at $50.00 right now. The amendment calls for a reasonable fee and of course there is a wide range of debate what a reasonable fee would be. For the average Arkansan $50.00 is a lot of money. We are talking medicine not driver's license or something like that. You don't have to pay a fee to pick up your Oxycontin at Walgreen's. Colorado also has an option to waiver the fee if you or your family are below the 185% of the federal poverty line.

3. Our next point is the ease of adding additional qualifying medical conditions. Amendment 98 that passed reads, "if patients suffering from the medical condition would derive therapeutic benefit from the use of marijuana taking into account the positive and negative health effects of such use". Pretty cut and dry there. Merriam Webster defines therapeutic "as having a beneficial effect on body and mind". Your section 22(C)(1) in your rules is very lengthy and starts out with requiring that this being a debilitating medical condition which

again is a far greater hurdle than "therapeutic benefit" as outlined in the Amendment. Those two definitions don't seem to line up together. Go on to the next part of (C)(1) this condition must cause severe suffering and impaired daily life. Again far above what's contemplated in the original Amendment. (C)(5) which requires the petitioner to submit evidence generally excepted by the medical community, this includes full text peer published journals. As you probably know since marijuana is a scheduled 1 drug in our country it is hard to come by a peer reviewed article about the benefits of medical marijuana. Very high hurdles for adding conditions.

4. Last point is about testing. The way I read it I believe testing will be allowed on site at a cultivation facility and dispensary. Sample size requirement is .5% of a batch. The largest batch size allowed is 10 lbs. that brings it up to about 0.8 of an oz. Which is a lot of money. Which would be around $250.00 to $300.00. Other states like Washington limits the maximum to 10 grams. What we would propose the rule to say is .5% up to a maximum of 10 grams for testing.

RESPONSE:

There will be an online process we're working on now. Assuming you are a regular patient and don't have anything special that would take more time to review, you would be able to submit it online and be able to upload documents to it.

The $50.00 fee is based on how many registrants we think we are going to have and simply divided into the cost we think It's going to take to run the program. Unfortunately, the program has to be paid for and I think we have estimated the cost conservatively. We may not have to keep it at $50.00 but until we start the program and get it up and running that's where it's going to be. If there is a way to lower it, we will.

As for the medical conditions, I agree it's not going to be a simple process. Those things are listed in the constitutional amendment because you will be dealing with doctors at the Health Department, and at the State Board of Health. It will be interesting to see how that works but I don't think it's going to be as easy as saying, "I have a condition and I think it will help me."

As far as the size of the batch or size of the sample we know there's going to be some growing pains. It's going to take us a while due to this all being new to us. If it turns out that those sample sizes are too large and they don't have to be that large. Then I suspect we will dial back on that as well. I think we will go forward with these rules to meet the constitutional amendment. I wouldn't be surprised if we don't open it up fairly quickly to address some of the minor issues that have come up.

COMMENT: Steven Johnson

I was able to sit in on more of the Commission meetings than I was on meetings with the AR Dept. of Health. The commission was deciding on how many dispensaries and cultivation centers to have throughout the state, as well as their locations. Essentially looking at the supply and how to supply Arkansans. I was wondering during those decisions where they were going to determine the demand for that medicine? I think Colorado has a pretty good example of how they did it. They set up an online patient/physician registry. Patients could go onto the registry stating they are a patient needing cannabis medicine once it was available. Physicians could also go onto the registry and state they would be willing to recommend medical marijuana to their patients.

Some statistics concerning Colorado regarding their registry. As of Dec. 31, 2016, 342,976 new patients applied since the registry began. That's essentially 6% of the population of Colorado. Of the total number of active patients 94,577, 3.6% had designated a primary caregiver or medical marijuana center. In Dec. 2016 148 physicians had recommended medical marijuana for active patients.

In conclusion, as to where the supply of medical cannabis in AR should be, I think it would be a good idea if the Health Department or another dept. could set up some kind of online registry comparable to Colorado and other states such as Hawaii and Maine. This would give Arkansas patients and physicians interested in medical cannabis an opportunity to register. The data from that registration could show the need for dispensary locations so supply and demand could be met.

RESPONSE:

We have in the past on a number of programs taken a map of Arkansas and placed dots where certain things are happening in correlation to population. I suspect we will be asked to provide such information to the Commission. We will do all we can to get the information the Commission needs to them as soon as possible.

COMMENT: Robert Reed

Some of the other states have had problems with their labeling having to be relabeled a number of times. In the first 3 years of Colorado's program they had to change their labeling 6 times. Since then they have had to change their labeling 3 times. What safeguards do we have in place to keep from having to change our labeling a number of times the first few years as this can be quite expensive?

RESPONSE:

This is a new program and I suspect that there will be changes made. Most of the labeling came out of Oregon but we did add some things that some of the professionals wanted. I suspect that as the program grows and moves forward that changes to the labeling standards may be made. People will be given notice that labeling changes are coming. Changes cannot be made overnight. The process to change the rule is usually, at least a 6-month period of time. It is a long process especially with the legislative reviews.

COMMENT: Paul Danielson

My concern is generally over the regulations and about driving up the cost to the extent that it will defeat the purpose of having medical marijuana in the first place. People will not be able to afford it. This will drive them to the streets and into the black market. I want to focus on pesticide testing and batch requirements. The way the rule is written there will be significant cost involved with testing and batch requirements. This will impose significant expense which will be passed on to the consumer.

My understanding of testing for pesticides in Colorado and Washington is extremely time consuming and expensive. In Washington it cost $350.00 per 5 lb. batch with a 10-day waiting period. I think there are better more scientific ways you could test. For example, test in the aggregate, for a 100 lb. crop, 10 lb. sample from each. Take a sample from each 10 lb. batch. Test it in the aggregate. The results would be at far less expense. Also on page 23 section 21 you have random testing. I think this would meet the same requirements at less expense. It would serve the same purpose and protect the public.

Requirements likewise for every 10 lbs. for pesticides and other quality assurances just does not make sense to me. You can't test every plant. Again you test in the aggregate, get an average and you'll achieve the same result at significant less cost.

Bottom line is if we regulate this to the point that it cost so much that people can't afford it. You then defeat the whole purpose and it will drive people back to the streets into the black market.

RESPONSE:

Although some standards came out of Oregon, most came out of a publication from The American Public Health Laboratory Association. They published a document of what their recommendations were. I think once we get into testing and it turns out that certain pesticides never show up or can never show up I suspect, that we will go in and make changes at that time, or perhaps make changes on the batch requirements.

It was not our intent to drive up the cost. We were challenged with the responsibility of making sure there was proper testing and that products were safe. That was our goal and I hope we didn't go too far.

COMMENT: Brian Nichol; Anesthesiologist & Pain Management Physician

Good afternoon, I really look forward to having some alternatives to the current modalities available to my patients. One concern I had was already addressed concerning the rather expensive and it seems excessive testing that maybe required. You did mention that you're following the Oregon model. As I recall, Oregon had some issue when it went to this testing in 2016 to where there were not enough accredited laboratories to handle the volume and provide it to the dispensaries in a timely fashion. As the Arkansas Department of Health is going to require accredited laboratories to do the testing, how many laboratories are available now to handle the testing that's going to be required by the Arkansas Department of Health?

Another question I have is about the identification cards. I understand that The Alcoholic Beverage Control Board and The Arkansas Department of Health are going to work in concert to develop a seed to patient inventory control system so that dispensaries can make sure that patients aren't going over their 2-week allotments. Has anyone started working on that system because it sounds complicated and time consuming to implement?

RESPONSE:

In the rule there are certain accrediting agencies listed, if you are accredited by those listed than you would be approved. The health dept. would have the authority to add others if we need to too have the capacity necessary. I'm told there will be additions. I know that some laboratories are already talking about moving into AR to do the testing. If it turns out that there are no laboratories to do the testing, then we will have to make adjustments. Although, it is my understanding that there will be laboratories available.

We've been working in-house, utilizing our programmers to get a system in place for registration. There will be a RFP (request for proposal), from what I understand, that will go out for a seed to sale type system that will be integrated. Again this is all new to us and I hope that it all works. I think that we will have the system up and running before any medical marijuana is available for sale.

COMMENT: Deborah Beuerman

I was wondering could I make CBD oil at home? Can I make waxes at home? Can I make edibles at home? Are there particular extraction methods allowed or not allowed? Some of them are explosive. I wondered why you

referred to medical marijuana as a serving? Drugs are usually referred to as dosages and if it's a serving how can I determine how much of a serving is if I'm making stuff at home? There is also a comment in one of the sections that says "Do not eat" is required this label for a serving. A serving usually means something you eat so why would you have a serving that you would not eat? I wondered can a designated caregiver also be a patient? I wonder how an infant can understand all the benefits and risks that must be explained to them by a physician before they receive a medical marijuana card? Are there any restrictions on delivery methods? Smoking is harmful and we don't want children smoking medical marijuana. How can they get their dosage? Edibles and topical creams maybe attractive to children which may cause problems. Is there a limit to the amount of THC that can be in a product? 30% can be rather harmful, can we go that high?

As far as laboratories you may have already answered. Are there approved labs in AR now? You said that you will get the number needed so are these labs that are already setup that are going to be pressed into service or pay to be medical marijuana labs? What are the requirements for the lab setup? Who will pay for the labs? I'm concerned about the taxpayer having to foot these expensive bills. What kind of training is required for the employees of the labs? Who sets the standards for the labs? Who inspects the labs? Who enforces all the laws the labs will have to follow?

I like the standards for adding qualifying conditions. I wonder what kind of standards were put into selecting the conditions for the amendment?

One other testing question, you mentioned in microbes you will test for E coli, why would you not test for other molds and aspergillus?

Is it legal to transport seeds, federally legal?

RESPONSE:

Many of what you mentioned will be under the Medical Marijuana Commission. My opinion, which should not be taken as fact, it won't do you any good if you are arrested. The only way you can be in possession of marijuana is if you bought it at a dispensary. If you were to buy raw plant material from a dispensary and then were caught with an oil, I'm not sure you would be covered because you did not buy the oil at a dispensary. I would just caution you about making things at home. The idea is that these products would be made in a controlled environment. They would be tested and would at least be as safe as possible.

As for the delivery method of administering medical marijuana that will be under Alcohol Beverage Control. Many of this is split up and is a bit confusing but the way it was drafted the Health Department has certain responsibilities, the Medical Marijuana Commission had certain responsibilities and the Alcohol Beverage Control had certain responsibilities. We really had no say in the matter.

As for the medical conditions listed in the Constitutional Amendment you would have to ask the people who drafted the amendment of how they chose the medical conditions.

The laboratories standards and procedures will be up to the laboratories. These will not be public health laboratories. We have one public health laboratory which may do some testing if there is a problem, but these will be private laboratories that the cultivation centers and dispensaries will have to hire. If they are accredited by these entity's, they would have to meet the accreditation standards of those entities. I can tell you that the health dept. does some lab certifications although it is very limited. Those standards are very strict and if not met they would lose their accreditation and their ability to test. There are some laboratories already in the state that are accredited by those entities. Whether or not they will be testing any medical marijuana I don't know, I suspect that they will. What's happened in other states is that companies have moved in to do the testing.

Federally, none of this is legal. If you read the amendment in the title it says, "this violates federal law". What the amendment does say is that seeds could be imported from a cultivation center in another state. The seeds alone. It's very clear that you cannot import a plant. We're going to get the cultivation centers up and running, built, licensed and inspected then grow the marijuana before it's available.

COMMENT: Donna Will

My comment is for the person who just wants to have their medical marijuana. You're making this very complicated for sick people who may not have the funds to get this, and causing them to have a lot of hoops to jump through. I'm a California patient who recently purchased a home in Arkansas and I'm looking forward to having medical marijuana available as I have several qualifying conditions. People have commented to where this is going, that you're creating a situation to how the black market isn't going to end. Medical marijuana isn't going to get better and I'm hoping for less regulations and that the commission will work with people. I'm hoping that we do not have to pass another bill in AR to have a cottage industry. I think it's very important that caregivers and patients are able to grow their own medicine for several reasons. They know where it came from, they know there are no pesticides and there are no problems with testing.

In 1996 California passed the Compassionate Use Act which gave Californian's the right to use medical marijuana. It has taken them 20 years to make a list of the licensing and 20 years to get around to packaging.

In California, doctors can recommend medical marijuana due to the fact that they cannot prescribe it due to it being a scheduled one narcotic. The way Arkansas has it written you're asking these doctors to certify something. They can recommend but I don't think they can legally under their license certify the use of medical marijuana. The question I have is how can they legally do that?

RESPONSE:

It's true that doctors cannot legally prescribe marijuana because it is classified as a scheduled I narcotic under federal law. In Arkansas it is a schedule VI. That's how Arkansas is set up. Only a doctor with a DEA registration can participate in the program. They would subject themselves to some penalties should they try to prescribe marijuana. What they are going to do in AR is they're going to do a written certification that certifies that the patient has one of the qualifying medical conditions. As far as the labeling we have learned from a lot of different states. We tried to steal as much labeling information as we could from them to see what would work best.

It is unfortunate that it is going to take as long as it is to get marijuana grown and ready for sale. The way it's setup the only thing that can be imported into Arkansas is the seeds. This means that first the cultivation centers and dispensaries are going to have to be picked by the commission. They are going to have to be licensed. If the cultivation center and dispensaries are growing the marijuana, they have to have time for the marijuana to be planted and grown to maturity. It will then have to be tested. This is why we think it will be several months before any marijuana is available for sale.

COMMENT: Gene Ribley

My question has to do with chronic conditions like glaucoma and paralysis. Would there not be a way to provide a cardholder a lifetime card or something to that affect to cut down on bureaucracy?

RESPONSE:

Actually that was discussed, there was a bill I believe, that was filed that would have dealt with that. The problem right now is that we have got to figure out how many registrants there are. We have to figure out how much it will cost to run the program. You cannot get lifetime prescriptions for other types of medicine. Hopefully, if your doctor recommends medical marijuana they will do the written certification and will follow up to make sure that it's actually helping you. So the feeling is that it is important that you go back to see your

doctor and get reevaluated. For now the amendment is very clear, it is valid for one year or less if the doctor gives you a written certification.

COMMENT: Daniel Sanders

My questions refer to the testing side of things. It was covered a little earlier there's nothing in regards to fungi visual examination, there's nothing to do in regards to mycotoxins. It is very important in regards to patients that are immune deficient and or immune impaired. This is something that needs to be seriously added because if you get one case of someone getting seriously sick from a tainted batch that's a huge gray mark not only for the state of Arkansas but to anyone else down in this area trying to bring it to the state. I know a prior commenter talked about sampling size. Myself, I worked in a lab for nearly 3 years. Sampling size is an important thing. It's very hard to get a representative batch of 5 or 10 lbs. of marijuana when it can be representative of someone picking from this lot or that lot or up here or down there. It's something that needs to be very strongly regulated. $300.00 to $600.00 to have it tested, that's nothing when you have it spread across 5 to 10 lbs. I have a whole list of things regarding testing that would be great to cover but I'd rather forward it to you. I would say that coming from the Dept. of Health those are actually very big issues that should be mandated because it's almost nationally mandated. Oregon is one of a few places that doesn't test for salmonella, doesn't test for fungi and they do not test for mycotoxins.

RESPONSE:

Please forward it to me. Like anything else people think the testing goes too far. Some people think it doesn't go far enough. Obviously, any cultivation center or dispensary they're perfectly free to do any of the testing that they want to ensure their patients are safe. I would encourage them to do so. Businesses can always decide to be more proactive with their testing. You can send me any comments to robert.brech@arkansas.gov

COMMENT: Dante

I would like to comment about testing. Something you may want to know. Approved laboratory means a laboratory that has been accredited by the National Institute of Drug Abuse. There is no accreditation for the National Institute of Drug Abuse. The other thing is people wanted to know how many people were accredited. That would be the NELAC accreditation. There are only 3 in the state and two of them said they were thinking about doing this but neither have started looking at doing testing. The other is in Bentonville and they didn't want to do it.

The other point was we were only talking about bringing seeds in. This probably needs to be expanded to include clones. One of the reasons is that if you only bring in seeds you don't have any assurance that there

aren't any male seeds included. If there are male seeds and you can't tell until later on in the crop, they can slip through and ruin an entire crop. What other states usually do is provide a 4 or 5- day window that people can bring these in and then it is shut.

Another thing in the amendment is the definition on a mature plant. It's very different than what it is in other states. It includes sticks, stones and everything else other than. The only thing a mature plant is, is a bud for the most part.

RESPONSE:

There is a lot of uncertainty right now in the medical marijuana industry altogether. Nobody was quite certain what the Trump administration would do. Attorney General Sessions who was just confirmed in office made very strong comments against marijuana. I wouldn't be surprised if there weren't some people being a little bit careful about investing a lot of money. The federal government could shut this down tomorrow, it's that simple.

As for the gender of the seeds imported I don't think this is anything the board of health can deal with through the rules. It's in the amendment and I don't think there's anything we can do about that.

As for the definition, we'll look at that. I don't think the mature plant definition is in our rule. It could be in the commission rules. I will check and see but I don't recall.

COMMENT: Steve Jacobie

The Health Department has posted, for public comment, that only persons with an AR ID can consume marijuana products. In my opinion, this regulation is inconsistent with the Arkansas Medical Marijuana's Amendment's provision that "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.

RESPONSE:

A person will need to produce an Arkansas ID to obtain an Arkansas registry identification card. Visiting patients may obtain marijuana under the Section IV(D).

COMMENT: Christopher L. Travis

The Proposed Rules fail to address how the Department will perform all the duties the Amendment delegates to the Dept. Specifically, the Proposed Rules should be amended to address how the Dept. will comply with the following sections of the Amendment 5(f)(2)(B), 5(h), 8(m)(4)(A)(i), 8(m)(4)(C), 10(b)(8)(D)(ii), and 10(b)(8)(E).

The Dept. should amend the current definition of "Approved laboratory" in subsection III(4) of the current version of the Proposed Rules in the following ways:

1. Because the Amendment does not authorize the Dept. to regulate or approve laboratories, the Dept. should delete the concept of a laboratory approval process from the definition of "Approved Laboratory" in subsection III(4) of the Proposed Rules.

With respect to testing, the Amendment only authorizes the Dept. to adopt rules governing, "labeling and testing standards for the marijuana distributed to qualifying patients" and "any other matters necessary for the department's fair, impartial, stringent, and comprehensive administration of this amendment." Amendment 98, § 4(b)(2)&(3).

The authority to adopt a rule establishing "testing standards" encompasses the authority to adopt a rule to set standard testing methodologies and necessarily implies the authority to establish the required results of tests conducted pursuant to those standards. The Department's authority to regulate "testing standards" does not encompass also regulating the laboratories that conduct the standardized tests. Said another way, it is not "necessary" for the Dept. to regulate laboratories under rules governing "testing standards." Any rule regulating or approving laboratories exceeds the scope of the Department's rulemaking authority pursuant to the Amendment.

2. In addition, the Dept. should amend the definition of " approved laboratory" to (i) delete the reference to an accreditation by the National Institute on Drug Abuse (NIDA) because NIDA does not issue accreditations and (ii) to delete the reference to the International Organization for Standardization (ISO) because an ISO accreditation is necessary for obtaining accreditation by the National Environmental Laboratory Accreditation Conference "NELAC), which makes a separate ISO accreditation redundant.

3. If the Dept. believes the regulation and approval of laboratories is "necessary" to allow the Dept. to adopt and implement a rule governing the "testing standards for marijuana distributed to qualifying patients," the Dept. should comply with the AR Administrative Procedure Act and promulgate a proposed rule governing the procedure and standards by which a laboratory can apply for and be approved as an "Approved Laboratory."

An amended "Approved Laboratory" definition could read as follows:

"Approved Laboratory" means a laboratory that is accredited by the National Environmental Laboratory Accreditation Conference (NELAC).

The Dept. defines the phrase "cultivation facility" in subsection III(10) of the proposed Rules. Throughout the Proposed Rules, however, the Dept. utilizes the undefined phrase, "cultivation center." To avoid ambiguity and comport with the Amendment, the Dept. should revise the Proposed Rules to consistently use the defined

The Dept. utilizes the phrase "cannabinoid concentrate or extract" several times throughout the Proposed Rules, but the Dept. failed to define that phrase in the Proposed Rules. The Dept. should amend the Proposed Rules to create a new definition for the phrase, "cannabinoid concentrate or extract," which the Dept. should define as follows:

phrase "cultivation facility."

"Cannabinoid concentrate or extract" means any product derived or extracted by a cultivation facility or a dispensary through the processing of usable marijuana, including, without limitation, oils, vapors, and waxes."

The Dept. should amend the definition of "batch" in Section III(6) of the Proposed Rules in the following ways for the following reasons:

1. The Dept. should delete the word "homogenous" in the first line of that definition and the words "that is harvested during a specified time period from a specified cultivation area" in the second and third lines of that definition because the word and that phrase cause the definition of "batch" to be ambiguous.

Pursuant to the current Proposed Rules, with regard to unprocessed, usable marijuana, (i) a "harvest lot" will be the largest unit of usable marijuana, (ii) a "batch" will be the next largest unit, an (iii) a "lot" will be the smallest unit. That is, a harvest lot may contain multiple batches, and a batch may contain multiple lots.

A harvest lot-by definition in subsection III(15) of the Proposed Rules-must be " 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." Pursuant to Section VIII(A)(1) of the Proposed Rules, a cultivation facility or dispensary must "separate each harvest lot into no larger than 10 lb. batches." Therefore, a batch of unprocessed, usable marijuana can only be created from a harvest lot.

Because a harvest lot must be (i) uniform, (ii) cultivated utilizing the same growing practices, (iii) harvested at the same time and the same location, and (iv) cured under uniform conditions, every batch from a single harvest lot will necessarily be homogenous and will have been harvested during a specified time period from a specified cultivation area, and the Department's inclusion of those words in the definition of "batch" is unnecessary, redundant, and ambiguous.

2. In the 2nd line of the current version of the definition of "batch" the Dept. should replace the words, "that is harvested during a specified time period from a specified cultivation area," with the words, "from a harvest lot". As described above, creating a definition for a harvest lot and then failing to utilize that defined term in a consistent manner creates ambiguity.

3. In the 3rd and 4th lines of the current version of the definition of "batch," the Dept. should replace the words "oils, vapors and waxes derived from usable marijuana" with the words "cannabinoid concentrate or extract" that should have the meaning described in previous comment above.

An amended definition could read as follows:

(6) "Batch" means, with regard to usable marijuana, an identified quantity, no greater than ten (10) lbs., from a harvest lot and, with regard to cannabinoid concentrate or extract, 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.

The Dept. should amend the Proposed Rules to define the word "strain," which the Dept. used in the definition of "harvest lot" in Section III(15) and in Section V(B)(b)(1)(e). The Department's failure to define the word "strain" in the Proposed Rules makes the Proposed Rules ambiguous.

The Dept. should amend the definition of "lot" in Section III(16) of the Proposed Rules in the following ways for the following reasons:

1. The Dept. should change the word "mans" in the 1st line to word "means."

2. For the same reasons as stated regarding the word "homogenous" in the definition of "batch," the Dept. should delete the word "uniform" from the definition of "lot." A lot comes for a batch, and a batch comes from a harvest lot. A harvest lot must-by definition-be uniform, so there is no need to reiterate that a lot must be "uniform."

3. In the 2nd line of the current version of the definition of "lot," the Dept. should replace the words "a vapor, oil, or wax derived from usable marijuana" with the words "cannabinoid concentrate or extract".

4. In the 3rd line of the current version of the definition of "lot", the Dept. should insert the words, "of a batch" after the word "quantity". Alternatively, depending upon the Department's resolution of the ambiguity between the definitions of "process lot" and "batch," the Dept. may need to insert the words, "of a process lot" after the word "quantity".

An amended definition could read as follows:

(16) "Lot" means an identified portion of a batch that is intended to meet specifications for identity, strength, and composition; or in the case of cannabinoid concentrate or extract, and identified quantity of a batch [or of a process lot] produced that is intended to meet specifications for identity strength, and composition.

1. The Dept. should amend the definition of "process lot" in Section III(21) to clarify whether a "process lot" is a portion of a batch or whether a batch is a portion of a process lot. For instance, the definition of "process lot" concludes with the concept that a process lot comes from the same batch or batches of harvested marijuana, which implies that a batch is a larger quantity than a process lot. However, in Section VIII 9B)(1), the Proposed Rules state, "a process lot is considered a batch." The Proposed Rules as written are ambiguous.

2. The Dept. should clarify the meaning of the words "the same type" in the definition of "process lot" with regard to cannabinoid concentrate or extract or delete the word " the same type" because the phrase " the same type" has no commonly understood meaning and creates ambiguity.

3. The Dept. should replace the words, "the same batch of batches harvested marijuana" in the last line of the definition of "process lot" with the following words, "the same batch of batches." The definition of "batch" includes the concept of harvested marijuana, and failure to utilize defined words and phrases in a consistent manner causes the definition of "process lot" to be ambiguous.

An amended definition of "process lot" could read as follows:

(21)"Process lot" means any amount of cannabinoid concentrate or extract processed at the same time using the same extraction methods, standards operation procedures, and from the same batch or batches.

The Dept. should delete the definition "proficiency testing," in subsection III(22) in the current version of the Proposed Rules because—in addition to never being used in the Proposed Rules—does not regulate any subject matter over which the Amendment grants the Dept. rule-making authority.

The Dept. should amend the definition of "usable marijuana" in Section III(37)(1) to delete the words, "oils, vapors, waxes", which would be included in the definition of cannabinoid concentrate or extract as stated in Comment 5. Although the Amendment utilizes those words in its definition of "usable marijuana," inclusion of those derivative products in the definition of "batch" in Section III(6) of the Proposed Rules, the Dept. defines "batch" "with regard to oils, vapors and waxes derived from usable marijuana...." Because oils, vapors and waxes constitute usable marijuana pursuant to the definition of "usable marijuana," the definition of batch could be

read to refer to oils, vapors and waxes derived from oils, vapors and waxes, which does not appear to be the Department's intent.

An amended definition of "usable Marijuana" could read as follows:

(37)(1) "Usable marijuana" means the stalks, seeds, roots, flowers, 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.

The Proposed Rules do not create a distinction between usable marijuana that has passed the required testing and usable marijuana before such testing has occurred. The Department's failure to address that distinction in the Proposed Rules makes the Proposed Rules ambiguous. To remove that ambiguity, the Dept. should create a new defined phrase "finished marijuana," which could read as follows:

"Finished marijuana" means usable marijuana that has passed all testing required by these rules.

The Proposed Rules, likewise, do not create a distinction between cannabinoid concentrate or extract that has passed the required testing and cannabinoid concentrate or extract before such testing has occurred. To remove that ambiguity, the Dept. should create a new defined phrase "finished cannabinoid concentrate or extract," which could be defined as follows:

"Finished cannabinoid concentrate or extract" means cannabinoid concentrate or extract that has been tested pursuant to these rules."

Rules in the following ways for the following reasons"

1. Replace the words, "Qualifying Patient" with the word "applicant" in the following subsections: (A)(1)(a); (A)(1)(d).

2. Move subsection IV(A)(1)(c) to subsection IV(A)(3). A physician supplying a written certification to support a person's application for a qualifying patient registry identification card would certainly know his or her own name, address, phone number and Drug Enforcement Administration number, while the applicant will be unlikely to know or have ready access to that information.

3. Replace the words "a designated caregiver" in the 2nd line of subsection IV(B) with the words "an applicant".

4. Replace the words "designated caregiver" with the word "applicant" in the following subsections: (B)(1)(a); and (B)(1)(d).

5. In subsection IV(B)(1)(c), the Dept. should replace the words "the qualifying patient" with the words "a qualifying patient". The Amendment in Section 2(6)(A), uses the word "a" in defining a designated caregiver, which allows for the possibility that a single designated caregiver could provide services to multiple qualifying patients. However, the Proposed Rules limit designated caregiver to providing care to a single qualifying patient, which exceeds to Department's authority under the Amendment.

6. The Dept. should delete subsections IV(A)(1)(f) and IV(B)(1)(e) because the Amendment does not require either a qualified patient or a designated caregiver to present a driver's license or other identification card issued by the state of Arkansas. Requirements for identification cards exceed the Department's regulatory authority pursuant to the Amendment. Additionally, limiting the required of Arkansas, could violate either the dormant commerce clause or the full faith and credit clause of the United States Constitution.

7. the Dept. should replace the current version of subsection IV(B)(3)(a) with the following, "(a) a copy of either a Qualifying Patients current registry identification card or pending application for a Qualifying Patient registry identification card; and".

8. In the 2nd line of the current version of subsection IV(B)(4)(a), the Dept. should insert the words, "the Department" before the word "shall". This change would match the remainder of subsection IV(B)(4), which requires the Dept. to conduct all background searches.

9. The Dept. should delete subsection IV(D)(1)(b) of the Proposed Rules because requiring a visiting qualifying patient to certify—on some unknown Department-approved form—that they have been

Pursuant to the Amendment, an out-of-state person or new Arkansas resident may only qualify as a visiting qualifying patient if the person's out-of-state registration card "pertains to a qualified medical condition." Therefore, the only proof the amendment requires a visiting qualifying patient to present is stated in Section 3(I)(2)(A): "a visiting qualifying patient may obtain marijuana from a

Draft 4-27-2017
This draft is a working document. All information contained herein is s
from the final document. The information contained in this document sl
of the agency or the Governor.

EXHIBIT D

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 May 8, 2017

Draft 4-27-2017
This draft is a working document. All information contained herein is subject to change and may differ substantially from the final document. The information contained in this document should not be considered the position or views of the agency or the Governor.

Table of Contents

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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 involving violence;

(A) Murder;

(B) Manslaughter;

(C) Kidnapping;

(D) Rape;

(E) Mayhem;

(F) Assault to do great bodily harm;

(G) Robbery;

(H) Burglary;

(I) Housebreaking;

(J) Breaking and entering; and

(K) Larceny;

(ii) However, 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 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, heptatits 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 a full 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 qualifying patient's records.

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)(l)(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 www._____.

(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 Aw 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_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 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.

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 total delta-9 THC= M delta-9 THC + (0.877 x M delta-9 THCA).

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

M total CBD= M CBD + (0.877 x M 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 total THC(dry)= P total THC(wet)/ [1-(P moisture/100)]

P total CBD(dry)= P total CBD(wet)/ [1-(P 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:

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

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

(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) 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 at www._____ 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 www._____ 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
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
Flonicamid	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[1]	52645-53-1	0.2
Phosmet	732-11-6	0.2
Piperonyl_butoxide	51-03-6	2
Prallethrin	23031-36-9	0.2

[1] 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[2]	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

[2] 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[3]
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[3]
Cumene	98-82-8	70
Cyclohexane	110-82-7	3880
Dichloromethane	75-09-2	600
2,2-dimethylbutane	75-83-2	290[4]
2,3-dimethylbutane	79-29-8	290[4]
1,2-dimethylbenzene	95-47-6	See Xylenes
1,3-dimethylbenzene	108-38-3	See Xylenes
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[3]
2-Methylpentane	107-83-5	290[4]
3-Methylpentane	96-14-0	290[4]
N,N-dimethylacetamide	127-19-5	1090
N,N-dimethylfromamide	68-12-2	880
Pentane	109-66-0	5000
Propane	74-98-6	5000[3]
Pyridine	110-86-1	200
Sulfolane	126-33-0	160
Tetrahydrofuran	109-99-9	720
Toluene	108-88-3	890
Xylenes[5]	1330-20-7	2170

[3] Limit based on similarity to pentane
[4] Limit based on similarity with n-hexane
[5] Combination of: 1,2-dimethylbenzene, 1,3- dimethylbenzene, 1,4-dimethylbenzene, and ethyl benzene

Table 3. List of Metals and their action levels

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