ADMINISTRATIVE RULES & REGULATIONS SUBCOMMITTEE
OF THE
ARKANSAS LEGISLATIVE COUNCIL

Room A, MAC
Little Rock, Arkansas

Tuesday, June 13, 2017
1:00 p.m.

A. Call to Order.

B. Reports of the Executive Subcommittee.

C. Department of Correction Quarterly Report for Quarter Ending March 31, 2017. (Solomon Graves)

D. Rules Regarding Medical Marijuana.

1. <u>DEPARTMENT OF FINANCE AND ADMINISTRATION, ALCOHOLIC BEVERAGE CONTROL ADMINISTRATION</u> (Mary Robin Casteel)

a. <u>SUBJECT</u>: Rule 2017-1: ABC Medical Marijuana Rules

<u>DESCRIPTION</u>: This establishes oversight requirements for marijuana cultivation facilities and dispensaries in Arkansas, including requirements for the following: recordkeeping; security; personnel; manufacturing, processing, packaging, and dispensing of usable marijuana to qualifying patients and designated caregivers; procedures for suspending or terminating licenses; procedures for inspections and investigations; advertising restrictions; and procedures for disposal of marijuana.

<u>PUBLIC COMMENT</u>: A public hearing was held on March 31, 2017. The public comment period expired on April 8, 2017. The department received the following comments:

Issue: Cultivation of Medical Marijuana by Dispensaries

Comments:

- Dispensaries should not be allowed to cultivate
- Delay issuance of dispensary permits

- Exclude immature plants and seedlings from allowable plant count
- Define mature plant as a "flowering plant" instead of a plant greater than 8 inches.
- Clarify when a plant must be tagged: 8 inches tall, 8 inches wide

Board Response: Amendment 98 allows dispensaries to grow up to 50 mature marijuana plants at any given time, in addition to seedlings. The Board originally defined mature plant as a plant that is greater than 8 inches tall. After receiving and considering comment, the Board amended its proposed rule in attempt to, on one hand, ensure the definition of mature plant did not entirely hinder a dispensary's ability to grow medical marijuana, and on the other hand, ensure proper limits were in place to control the amount of marijuana plants that could be possessed at any given time by a dispensary. The Board made three notable changes in this regard. First, it amended the definition of immature and mature plant. Mature plants are now defined as "flowering plants". Immature plants are non-flowering plants, including seedlings. Second, the Board limited the number of immature plants that may be possessed by a dispensary at any given time to 150 immature plants. Finally, the Board imposed a limitation on harvesting mature plants. Dispensaries may harvest no more than 50 mature marijuana plants per month.

Issue: Restrictions on contractors at cultivation facilities and dispensaries.

Comments:
- Less restrictive requirements for notification of contractors on site
- Remove hour restrictions on contractors

Board Response: The Board's proposed rules limited the hours in which contractors are allowed to be on-site at cultivation facility or dispensary to 8 a.m. to 8 p.m. The board amended its rules to remove restrictions on the hours during which contractors may be present in a dispensary or cultivation facility. The Board declined to remove its rule requiring facilities to notify the Alcoholic Beverage Control Administration if a contractor must be present on the premises for more than two consecutive days.

Issue: Inventory tracking, tagging of plants for tracking purposes

Comments:
- Implement an inventory tracking system that requires RFID technology
- Clarify when a plant must be tagged: 8 inches tall, 8 inches wide
- Clarify how plants will be tagged and labeled

Board Response: The Board's proposed rules require all seeds and plants to be batched and tagged for tracking purposes. The proposed rule also requires individual plants to be tagged when they reach a height 8 inches.

The Board amended its rules to provide clarification for the tagging of plants. The amended rule requires a plant to be tagged at the earliest of three events: a plant reaches 8 inches tall, a plant reaches 8 inches in width, or a plant reaches maturity. The ABC is currently working with the Arkansas Department of Health to implement an inventory tracking system. Clarifications for tagging and labeling cannot be made until the tracking system is developed.

Issue: Construction issues

Comments:

- A greenhouse with barbed wire around it should be sufficient for securing a cultivation facility.
- Amend the requirement that aisles must be kept around each plant group in a production area to allow for the use of "sliding tables".
- Clarification on requirement of biometric locks
- Require cultivation facilities to have a separate, secure area for loading marijuana for transport.

Board Response: The Board declined to change its rules for the security of the structure in which medical marijuana will be cultivated, except to mirror changes made by the 91st General Assembly. The Board did amend its rule concerning aisles in production areas. The new rule will allow for the use of sliding tables, but maintains a requirement that production areas remain accessible for observation and inventory purposes. The Board also clarified that biometric locks must be used on external doorways and gates.

Issue: Transport and Delivery of Marijuana

Comments:

- Requiring two employees for transport and delivery is not necessary.
- Requiring two employees for transport and delivery creates unnecessary costs.
- Allow deliveries to "residence" inns or "long-term stay" hotels

Board Response: The Board declined to amend this provision. Providing safe transport and preventing the diversion of medical marijuana is a priority for the Board, and any inconvenience on the licensee is not outweighed by the safety risks that exist for solo transports. The Board declined to amend its rules to allow for delivery to hotels designated as "residence" or "long-term stay" hotels.

Issue: Inconsistency between ABC rule and MMC rule concerning coupons or discounts.

Comments:

- The Medical Marijuana Commission encourages applicants to provide a compassionate care plan for serving patients. ABC proposed rules would prohibit any such plan from offering lower priced products for patients who are unable to afford medical marijuana.

Board Response: The Board amended its rules to allow for coupons or discounts as part of a compassionate care plan approved by the Medical Marijuana Commission.

Issue: Types of Medical Marijuana

Comments:

- Generic shapes of bars and consumables should be allowed.
- Ban marijuana smoking, and only allow in pill form or oil.
- Amend restriction on use of caffeine in edibles, because it is unreasonable.

Board Response: The Board maintained its restrictions on edible forms of marijuana and clarified its rule concerning production of edibles that may appeal to minors. Specifically, the Board elaborated that edible marijuana should not be made to resemble any product, branded or generic, that appeals to minors, including cookies, brownies, and candy. The Board did not ban the smoking of marijuana; however, pursuant to legislation, amended its rules to prohibit dispensaries from selling paraphernalia used in the smoking of marijuana.

Issue: Environmental and employee safety considerations

Comments:

- Issues regarding wastewater, discarded material, and recyclables.
- Air contamination issues, including odors
- Product and chemical storage considerations
- Consideration of odors emanating from facilities

Board Response: The Board did not make any changes to the operational rules for cultivation facilities and dispensaries in response to these comments. The rules, as proposed, address many of these concerns.

Issue: Amendments of certain definitions within the definition portion of the rules.

Comments:

- Amend definition of "approved laboratory"
- Amend definition of "mature plant"
- Amend definition of "inventory tracking system"
- Define the word "strain"
- Amend definition of "batch"
- Amend definition of "process lot"

- Define “marijuana items”, or replace with “usable marijuana”.
- Define “elevation drawings”
- Amend “immature plant” to “immature marijuana plant”
- Amend definition of “shipping container”

Board Response: The Board made some changes to its definitions as discussed earlier in this summary. The Board declined to make other changes.

This rule was approved as an emergency rule on May 3, 2017. The proposed effective date for permanent promulgation is pending legislative review and approval.

FINANCIAL IMPACT: The cost to general revenue for the current fiscal year is estimated at $170,756 and for the next fiscal year at $281,057. However, license fees and taxes will offset the total projected cost, so the estimated cost increase to the state is less than $10,000.

LEGAL AUTHORIZATION: This rule was approved as an emergency rule on May 3, 2017, in order to comply with the constitutional requirement that rules be in place by May 8, 2017.

Amendment 98 § 8(b) of the Arkansas Constitution authorizes the Alcoholic Beverage Control Division (“ABC”) to adopt rules necessary to carry out the purposes of the amendment and to perform its duties under the amendment.

2. DEPARTMENT OF HEALTH, CENTER FOR HEALTH PROTECTION (Robert Brech)

a. 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:

NAME: Robert Brech, General Counsel ADH
COMMENT: Good afternoon, today we’re here for the public comment & public hearing which is also the end of the public comment period for

the Board of Health's Rules and Regulations concerning Medical Marijuana registration, labeling and testing in Arkansas. To give those who are not familiar with the process or would like some information as to what happens after this meeting. We will take the public comments and answer them if time permits. This is really an opportunity for you to give public comments about the rules. Should we determine that one of the comments should lead to a subsequent change of the rule. We would have to take that change back to the Board of Health and the process would start over and have another public comment period. This is done so the public can be informed of any changes to the rule. If there are no subsequent changes made, all Board of Health Rules and Regulations by statute have to be heard by The Public Health Committee, both on the Senate and the House side. Assuming we get a positive review from those committees, we would then go to the Rules Subcommittee of the Legislative Counsel. Assuming we get a favorable review at that point it will be a matter for scheduling. We suspect we'll probably schedule a special meeting of the Board of Health to finalize the rules. Once some paperwork is done and we get everything filed with the appropriate entities it will go into effect ten days after that. What we are expecting at this point is to be affective May 1st. We will begin taking applications for registration cards June 1st. We will not be issuing cards right away. Cultivation Centers and Dispensaries will not have had time to be up and running and no Medical Marijuana will be available for some time. We will issue registration cards 30 days prior to marijuana being available for sale. There's two reasons for waiting to release the cards. One is that if you don't buy the marijuana from a dispensary in Arkansas, it wouldn't be legal for you to possess it. We don't want people to have the feeling they can walk around possessing marijuana that was not purchased from a dispensary. The second reason is that these cards will be valid for 1 year from the time issued or your doctor provides written certification of a time less than one year. If we were to issue cards in June and no marijuana is available for sale until January or February of 2018 most of the time frame on the card would have run out and we don't want that to happen.

I would like to point out that most of the registration information in the rule came out of the Amendment. As far as the labeling and testing standards for the most part came out of the state of Oregon's rules. We started with New Mexico which didn't work out too well so we shifted to Oregon. As far as the heavy metal testing, they came out of the state of Massachusetts.

NAME: Melissa Fults- Drug Policy Education Group
COMMENT: 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: (Robert Brech) -- 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.

NAME: Storm Nolan-Arkansas Cannabis Industry Association
COMMENT: 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.

RESPONSE: (Robert Brech) -- 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.

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.

RESPONSE: (Robert Brech) -- 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.

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.

RESPONSE: (Robert Brech) -- 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."

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: (Robert Brech) -- 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.

NAME: Steve Johnson
COMMENT: 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: (Robert Brech) -- 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.

NAME: Robert Reed
COMMENT: 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: (Robert Brech) -- 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.

NAME: Paul Danielson

COMMENT: 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: (Robert Brech) -- 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.

NAME: Brian Nichol, Anesthesiologist & Pain Management Physician
COMMENT: 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: (Robert Brech) -- 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.

NAME: Deborah Beuerman
COMMENT: 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?

RESPONSE: (Robert Brech) -- 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.

NAME: Donna Will
COMMENT: 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: (Robert Brech) -- 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.

NAME: Deborah Beuerman
COMMENT: Is it legal to transport seeds, federally legal?

RESPONSE: (Robert Brech) -- 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.

NAME: Gene Ribley
COMMENT: 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: (Robert Brech) -- 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.

NAME: Daniel Sanders
COMMENT: 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: (Robert Brech) -- 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

NAME: Dante
COMMENT: 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: (Robert Brech) -- 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.

RESPONSE: (Robert Brech) -- There will not be a transcript word for word. There will be some minutes that will be created. We will put together with some sort of breakdown of the questions and the answers.

NAME: Steve Jacobie
COMMENT: 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).

NAME: Christopher L. Travis
COMMENT: 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).

RESPONSE: The Board's rules are not typically meant for duties mandated to the Department. The Department will comply with the Amendment.

COMMENT: 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).

RESPONSE: The Department interprets the Amendment such that any testing standards adopted must necessarily be performed by a laboratory that can reasonably be expected to be able to do the tests.

COMMENT: 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 phrase "cultivation facility."

RESPONSE: The rules will be changed to reflect cultivation facility only.

COMMENT: 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: "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."

RESPONSE: The Department will take this under advisement in any future revisions of the rules.

COMMENT: 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.

RESPONSE: The Department will take this under advisement in any future revisions of the rules.

COMMENT: 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.

RESPONSE: The Department will take this under advisement in any future revisions of the rules.

COMMENT: 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.

RESPONSE: The Department will take this under advisement in any future revisions of the rules.

COMMENT: 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.

RESPONSE: The Department will take this under advisement in any future revisions of the rules.

COMMENT: 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.

RESPONSE: The definition will be deleted.

COMMENT: 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.

RESPONSE: The Department will take this under advisement in any future revisions of the rules.

COMMENT: 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.

RESPONSE: The Department will take this under advisement in any future revisions of the rules.

COMMENT: 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."

RESPONSE: The Department will take this under advisement in any future revisions of the rules.

COMMENT: The Dept. should amend the current version of Section IV in the current version of the Proposed Rules in the following ways for the following reasons"

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

RESPONSE: The Department will take this under advisement in any future revisions of the rules.

COMMENT: 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.

RESPONSE: The Department will take this under advisement in any future revisions of the rules. It is noteworthy that the DEA number is typically found on prescriptions.

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

RESPONSE: The Department will take this under advisement in any future revisions of the rules.

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

RESPONSE: The Department will take this under advisement in any future revisions of the rules.

COMMENT: 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.

RESPONSE: While a caregiver may provide care to more than one person, they must register for each patient. This will allow them to obtain marijuana for their patient at the dispensary.

COMMENT: 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 identification cards to only those issued by the State of Arkansas, could violate either the dormant commerce clause or the full faith and credit clause of the United States Constitution.

RESPONSE: The Department disagrees and is simply complying with the guidance from the Department of Justice.

COMMENT: 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".

RESPONSE: The Department will take this under advisement in any future revisions of the rules.

COMMENT: 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.

RESPONSE: The applicant must request that the check be performed.

COMMENT: 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 diagnosed by a physician to have one or more qualified medical conditions is ambiguous and exceeds the Department's authority under the Amendment. Section 2(18) of the Amendment defines a visiting qualifying patient as follows:

A patient with a qualified medical condition who is not a resident of Arkansas or who has been a resident of Arkansas for less than 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 qualified medical condition under this section.

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 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." The Dept. exceeds its authority under the Amendment if it requires evidence in addition to the registry identification card or its equivalent, which pursuant to the Amendment must on his face pertain to a qualified medical condition.

RESPONSE: The key phrase in the Amendment is "and pertains to the qualifying medical condition under this section." The Department has interpreted this in the friendliest fashion to visiting patients. Without disqualifying the visiting patient should their state have a more liberal listing of conditions, the visiting patient only has to certify that they have a condition that would qualify for a registration card in Arkansas.

COMMENT: At the end of the 2nd line of the current version of subsection IV(G)(1)(a), the Dept. should insert the following language, "and shall not be subject to disclosure except to authorize employees of the Department, Division and Commission." This limitation is found in Section 5(f)(2)(B) of the Amendment and this addition is necessary to make the Proposed Rules comply with the Amendment. The Department's failure to include this additional limitation on disclosure would exceed the Department's authority under the Amendment.

RESPONSE: The Board's rules are not typically meant for duties mandated to the Department. The Department will comply with the Amendment.

COMMENT: The Dept. should modify the current version of Section V in the Proposed Rules in the following ways for the following reasons:

In Sections V(A), V(A)(1), V(A)(2)(b), V(B), and V(B)(1) of the current version of the Proposed Rules, the Dept. should replace the words, "usable marijuana" with either the new defined phrase described in Comment 12 above, "finished marijuana" or other defined term the Dept. adopts to refer to usable marijuana that has been tested and approved for sale.

RESPONSE: The Department will take this under advisement in any future revisions of the rules.

COMMENT: The Dept. should clarify the meaning of "in a manner specified by the Dept." in subsection V(A)(2)(b). As written, that subsection is ambiguous.

RESPONSE: The Department will take this under advisement in any future revisions of the rules.

COMMENT: In subsection V(D)(1)(a), the Dept. should replace the words "usable marijuana" with either the new defined phrase described in comment 10 above, "finished marijuana" or other defined term the Dept. adopts to refer to usable marijuana that has been tested and approved for sale.

RESPONSE: The Department will take this under advisement in any future revisions of the rules.

COMMENT: In subsections V(D)(1)(a) and V(D)(2)(a), the Dept. should insert the words, "or cannabinoid concentrate or extract" after the word "marijuana".

RESPONSE: The Department will take this under advisement in any future revisions of the rules.

COMMENT: In subsection V(D)(2)(d), the Dept. should insert the word "also" after the word "can".

RESPONSE: The change will be made.

COMMENT: In subsection V(D)(2)(a), the Dept. should replace the word "marijuana" with either the new defined phrase described in

Comment 12 above, “finished marijuana” or whatever defined term the Dept. adopts to refer to usable marijuana that has been tested and approved for sale.

RESPONSE: The Department will take this under advisement in any future revisions of the rules.

COMMENT: The Dept. should clarify the meaning of “unobstructed and conspicuous” in subsection V(D)(2)(e) to avoid Section V(D)(2) being vague and ambiguous.

RESPONSE: The Department will take this under advisement in any future revisions of the rules.

COMMENT: In subsections V(D)(3), V(D)(4), V(D)(4)(a), V(D)(4)(a)(i), V(D)(4)(b), V(D)(5), V(D)(8), V(D)(10), and V(D)(11), the Dept. should replace the words, “usable marijuana” with either the new defined phrase described in Comment 12 above, “finished marijuana” or other defined term the Dept. adopts to refer to usable marijuana that has been tested and approved for sale.

RESPONSE: The Department will take this under advisement in any future revisions of the rules.

COMMENT: Also in subsections V(D)(3), V(D)(4), V(D)(4)(a), V(D)(4)(a)(i), V(D)(4)(b), V(D)(5), V(D)(8), V(D)(10), and V(D)(11), the Dept. should insert the words, “or cannabinoid concentrate or extract” after the word “marijuana”.

RESPONSE: The Department will take this under advisement in any future revisions of the rules.

COMMENT: The Dept. should clarify the meaning of “attractive to minors” in Subsection V(D)(7)(b). As written, this subsection is vague and ambiguous.

RESPONSE: The Department will take this under advisement in any future revisions of the rules.

COMMENT: In subsection V(D)(12), the Dept. should clarify the meaning of the phrase, “exit packaging”.

RESPONSE: This should be self-explanatory.
COMMENT: The Dept. should amend Section VI of the current version of the Proposed Rules in the following ways for the following reasons:

The Dept. should amend the subsection VI(A) to allow for pre-sampling and pre-testing transportation of usable marijuana as allowed by subsection X(B). Failure to do so creates ambiguity and conflict between the subsections.

The Dept. should amend subsection VI(C)(4) to make it clear that the transportation allowed by the subsection does not violate the prohibition on transfers prior to sampling and testing created by subsection VI(A)(1).

RESPONSE: Section VI(C)(4) does make it clear that the transportation allowed by the subsection does not violate the prohibition on transfers prior to sampling and testing created by subsection VI(A)(1).

COMMENT: The Dept. should amend subsection VII(B)(3) of the current version of the Proposed Rules by replacing the words, "used only water, animal fat or vegetable oil" with the words "used only water, animal fat, vegetable oil, olive oil, coconut oil or any other naturally-occurring oil".

RESPONSE: The Department will take this under advisement in any future revisions of the rules.

COMMENT: The Dept. should amend Section VIII of the current version of the Proposed Rules in the following ways for the following reasons:

In subsection VIII(A), the Dept. should create a new subsection VIII(A)(1) that reads as follows:

(1) For each harvest lot produced by a cultivation facility of dispensary, the cultivation facility or dispensary must record the following information"

(i) the strain;

(ii) the growing practices utilized to cultivate the usable marijuana;

(iii) the time of the harvest;

(iv) the location of the harvest;

(v) and the conditions utilized to cure the harvest.

RESPONSE: The Department will take this under advisement in any future revisions of the rules.

COMMENT: In the current version of subsection VIII(A)(1), the Dept. should delete the words, "no larger than 10 lbs." because the definition of batch is subsection III(6) already limits a batch to no more than 10 lbs.

RESPONSE: The Department will take this under advisement in any future revisions of the rules.

COMMENT: In the current version of subsection VIII(A)(2), the Dept. should insert "from multiple harvest lot" after the word "batches".

RESPONSE: The Department will take this under advisement in any future revisions of the rules.

COMMENT: Also, in the 4th line of the current version of subsection VIII(A)(2), the Dept. should insert a period after the word "extract" and delete the remainder of that line as well as subsections VIII(A)(2)(a), (b) and (c). The facts required by those subsections are included in the definition of "harvest lot" and relisting them in this subsection is redundant and creates ambiguity.

RESPONSE: The Department will take this under advisement in any future revisions of the rules.

COMMENT: In the 1st line of subsection VIII(A)(3), before the word "batch," the Dept. should insert the word "single" to clarify that a single batch may only come from a single harvest lot for purposes of sampling and testing the THC or CBD.

RESPONSE: The Department will take this under advisement in any future revisions of the rules.

COMMENT: The Dept. should amend the current version of Section XI in the following ways for the following reasons:

In subsection XI(A), the Dept. should delete the words, "harvest or process lot" because the definition of batch makes those words redundant and creates ambiguity.

RESPONSE: The Department will take this under advisement in any future revisions of the rules.

COMMENT: The Dept. should clarify subsection XI(A)(2) to inform cultivation facilities or dispensaries of the manner in which the Dept. expects them to store and secure batches. The current version of subsection XI(A)(2) is ambiguous.

RESPONSE: The Department will take this under advisement in any future revisions of the rules.

COMMENT: In the subsection XI(B), the Dept. should replace the word "product" with the words, "usable marijuana or cannabinoid concentrate or extract".

RESPONSE: The Department will take this under advisement in any future revisions of the rules.

COMMENT: In the current version of Section XII(A) of the Proposed Rules, the Dept. should insert the words "or cannabinoid concentrate or extract" after the words "usable marijuana".

In the current version of Section XIV(A) of the Proposed Rules, the Dept. should replace the words "usable marijuana" with the words "cannabinoid concentrate of extract". The only time the Proposed Rules mention required testing for microbiological contaminants is in Section VII(A)(b), and that Section refers only to cannabinoid concentrate or extracts. Therefore, the Department's use of "usable marijuana" in Section XII(A) creates ambiguity.

To avoid ambiguity and make clear that cannabinoid concentrates or extracts, pursuant to subsection VII(A)(c) must be tested for THC and CBD, in the current version of Section XVI of the Proposed Rules, the Dept. should insert the words, "or cannabinoid concentrate or extract" after the words, "usable marijuana".

To avoid ambiguity and make clear that cannabinoid concentrates or extracts, pursuant to subsection VII(A)(d) must be tested for heavy metals, in the current version of Section XVII(A) of the Proposed Rules, the Dept. should insert the words, "or cannabinoid concentrate or extract" after the words, "usable marijuana".

The Dept. should amend the current version of Section XVIII in the current version of the Proposed Rules in the following ways for the following reasons:

The Dept. should replace the word "Commission" with the word "Department" throughout Section XVIII. The Proposed Rules, in subsection III(18), define the "Commission" to mean the Medical Marijuana Commission. Pursuant to Section 4(b)(2) of the Amendment, the Department should be the entity regulating the destruction of usable marijuana and cannabinoid concentrate or extract that fails required testing.

RESPONSE: The Department will take this under advisement in any future revisions of the rules.

COMMENT: Because the current language is vague and ambiguous, the Dept. should clarify the meaning of the wards, "in a manner specified by the Commission" in subsections (B)(2), (D)(4), (E)(3), (G)(1), and (I) of Section XVIII.

RESPONSE: The Department will take this under advisement in any future revisions of the rules.

COMMENT: In the current version of Section XVIII(H)(1) and (2) of the Proposed Rules, the Dept. should insert the words, "or cannabinoid concentrate or extract" after the words, "usable marijuana".

RESPONSE: The Department will take this under advisement in any future revisions of the rules.

COMMENT: The Dept. should amend or clarify Section XX of the current version of the Proposed Rules in the following ways for the following reasons:

In the 3rd line of subsection XX(A), the Dept. should insert the words, "in accordance with these rules" after the word "tested" to clarify that the random audit tests will be consistent with the tests otherwise required by the Proposed Rules.

RESPONSE: The Department will take this under advisement in any future revisions of the rules.

COMMENT: In subsection XX(B), the Dept. should clarify the meaning of the words, "approved methods". As written, the current version of that rule is ambiguous.

RESPONSE: The Department will take this under advisement in any future revisions of the rules.

COMMENT: In the 1st line of subsection XX(C) the Dept. should insert the words "cannabinoid concentrate or extract" after the words "usable marijuana".

RESPONSE: The Department will take this under advisement in any future revisions of the rules.

COMMENT: In addition, the Dept. should clarify the meaning of the 'process for the random testing" referred to in subsection XX(C).

RESPONSE: The Department will take this under advisement in any future revisions of the rules.

COMMENT: To avoid ambiguity and to make clear that cannabinoid concentrate or extracts, pursuant to subsection VII(A)(a) must be tested for pesticides, in the current version of Section XXI(A) of the proposed Rules, the Dept. should insert the words, "or cannabinoid concentrate or extract" after the words, "usable marijuana".

RESPONSE: The Department will take this under advisement in any future revisions of the rules.

COMMENT: In appendix A of the current version of the Proposed Rules, the Dept. should insert the words "or cannabinoid concentrate or extract" after the words "usable marijuana.

RESPONSE: The Department will take this under advisement in any future revisions of the rules.

NAME: Justice J. Brooks, I
COMMENT: The better option is to define "visiting qualifying patient" as it is defined in The Arkansas Medical Marijuana Amendment of 2016 and adopt a rule that bars access to the medical marijuana program for three years to Patients that receive a misdemeanor conviction or citation for a marijuana-related crime in another state. The schematics of this structure allows all qualified persons that visit Arkansas for medical tourism to participate in this state's medical marijuana program, while adequately helping to prevent the diversion of marijuana to other states. It also protects Arkansas's strategic advantage in the emerging medical-tourism industry, without implicating the Cole Memo enforcement priorities.

RESPONSE: The Department will continue to follow the guidance in the Cole Memo.

This rule was approved as an emergency rule on May 3, 2017, in order to comply with the constitutional requirement that rules be in place by May 8, 2017. The proposed effective date is pending legislative review and approval.

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: This rule was approved as an emergency rule on May 3, 2017, in order to comply with the constitutional requirement that rules be in place by May 8, 2017.

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.

3. MEDICAL MARIJUANA COMMISSION (Mary Robin Casteel)

a. SUBJECT: Rule 2017-1: AMMC Rules

DESCRIPTION: This establishes the standards under which marijuana cultivation and dispensaries may operate in Arkansas.

PUBLIC COMMENT: A public hearing was held on March 31, 2017. The public comment period expired on March 31, 2017. The department received the following comments:

Amendment 98 § 8(c)(2) of the Arkansas Constitution states that "[s]ixty percent (60%) of the individuals owning an interest in a dispensary or cultivation facility" shall be current residents of Arkansas who have resided in the state for the previous seven (7) consecutive years. However, the Commission's rules place the residency requirement on an individual owning at least sixty percent (60%) thereby basing the residency requirement on ownership interest and not on the number of individuals owning an interest.

Michael Harry, Bureau Staff Attorney, asked what is the Commission's stance on whether or not this is in opposition to Amendment 98? What is the Commission's stance on the constitutionality of this provision with regards to the Commerce Clause of the U.S. Constitution. Additionally, the amendment also limits the amount of plants a dispensary may cultivate to 50 mature plants, however the rules allow for 50 mature plants and 150 immature plants. What is the Commission's stance on whether this is in opposition to Amendment 98?

RESPONSE:
A. The Commission, in undertaking the constitutionally required promulgation of rules to implement the licensing of cultivation facilities and dispensaries, considered this requirement seriously. Specifically, in providing clarification on the 60% ownership requirement, the Commission considered the intent of the Amendment, the public comments received on the proposed rules, and the Department of the Treasury Financial Crimes Enforcement Network ("FinCEN") Suspicious Activity Guidelines.

The amendment, titled the Arkansas Medical Marijuana Amendment of 2016, at its core intends to create a medical marijuana program for the State of Arkansas that complies with existing Federal guidance. Because marijuana remains classified a Schedule I Controlled Substance and is illegal under Federal law, specific attention must be paid to what guidance there is to prevent the implemented program from running afoul of Federal limitations. The Amendment took pains to ensure that the activities of the Arkansas medical marijuana Cultivation Facilities and Dispensaries included an Arkansas ownership majority. In reviewing the language, the Commission determined that the language of the Amendment requiring a majority Arkansas owners should be administered in a way that minimizes attempts to circumvent Federal guidance and implement the will of the people – requiring a 60% ownership by Arkansans. The potential for two Arkansans to own 1% each of a Cultivation Facility while a non-Arkansan owned 98% appeared to be contrary to the intent of the Amendment.

The public comments received by the Commission regarding the proposed rules repeatedly emphasized the importance of making this a program for Arkansas by Arkansans. The comments restated the perception of the voters that the Amendment was intended to ensure majority Arkansas ownership. The Commission clarified the requirement of 60% ownership in light of the comments and the intent of the Amendment discussed above.

Finally, marijuana remains illegal at the Federal level, including medical marijuana, as it is classified as a Schedule I controlled substance. Guidance from the Department of Justice and the Department of Treasury

specify that interstate activity could jeopardize a Medical Marijuana program where medical marijuana is being diverted to States that have not approved it or ownership and management of producers or vendors of medical marijuana are not residents of the State in which they operate. See *Guidance Regarding Marijuana Enforcement*, Memorandum of Dep. Att'y Gen. James Cole 1- 2 (DOJ, Aug. 9, 2013) ("Cole Memo I"); *Guidance Regarding Marijuana Related Financial Crimes*, Memorandum of Dep. Att'y Gen. James Cole (DOJ, Aug. 9, 2013) ("Cole Memo II"); and *BSA Expectations Regarding Marijuana-Related Businesses*, FIN-2014-G001(FinCEN, February 14, 2014)("FinCEN Memo"). The FinCEN Memo specifically notes that a Suspicious Activity Report red flags for banking institutions that are providing banking services to marijuana-related businesses are a marijuana business that is owned or managed by individuals who are not residents of the State in which it operates and a marijuana-business engaging in interstate financial activity.

The Commission is constitutionally mandated by the Arkansas Medical Marijuana Amendment to implement the rules regarding licensure of Cultivation Facilities and Dispensaries. *See* Ark. Medical Marijuana Amendment § 8(d). These rules are required to address the requirements for licensure and what must be demonstrated by applicants. *Id.* In determining what would be required to demonstrate "60% of the individuals owning an interest" as meaning "60% Arkansas ownership," the Commission was undertaking its constitutionally mandated duty and providing clarity to the language that they have been charged with administering. The interpretation is not clearly contrary to the language of the amendment and is a reasonable interpretation to be made by the Commission as charged by the Amendment.

B. Regarding the constitutionality of the limitation, the Commerce Clause of the United States Constitution, U. S. Constitution, art. 1, § 8, cl. 3, does not prohibit the regulation of intrastate commercial activity nor does it prohibit a valid regulation that incidentally burdens the flow of commerce among the States. Specifically, the Commerce Clause has been described as limiting a State's ability to regulate interstate commerce, or commerce among the various states. *See e.g.*, *United States v. Lopez*, 514 U.S. 549 (1995). Commerce Clause jurisprudence has repeatedly emphasized that it is when a State reaches outside of its borders to control the instrumentalities and channels of interstate commerce, or local activities that bear a substantial impact on interstate commerce that a violation occurs. *United States v. Morrison*, 529 U.S. 598 (2000). Here, the regulation regarding ownership of entities who will be engaging in intrastate commerce does not rise to the level of a constitutional prohibition. To regulate purely intrastate actions under the Commerce Clause, the activity must somehow impact or relate to the national market and commerce among the several states as described more fully below.

There is no legal interstate market for medical marijuana. Medical marijuana, while authorized by over twenty states, is not authorized at the federal level and interstate transport or sale of marijuana is still prohibited.

The Dormant Commerce Clause does not prevent or prohibit the interpretation proffered by the Commission regarding the administration of the Arkansas Medical Marijuana Amendment. The Dormant Commerce Clause prohibits states from favoring in state business over out of state businesses or otherwise creating isolationist of protectionist economic legislation. While the Arkansas Medical Marijuana Amendment on its face favors in state economic interests over out of state economic interests, there is an articulable State interest that cannot be met by a less discriminatory method – namely the insulation of the State Medical Marijuana Program from Federal enforcement action and the interest in ensuring that the Arkansas Medical Marijuana Amendment, as approved by the voters of the State, goes into effect.

Legislation enacted for purely protectionist purposes faces "a virtual[] per se rule of invalidity" however, "where other legislative objectives are credibly advanced and there is no patent discrimination against interstate trade," a Court will balance the local interest against the incidental burden on interstate commerce. *Philadelphia v. New Jersey*, 437 U.S. 617, 624 (1978). A State may not discriminate against "articles of commerce" unless there is a valid reason apart from the origin of the articles for the legislation. *Id.* (quoting *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970)). There is no valid justification for a state to economically isolate itself from the common market of goods when such isolationism is merely meant to preserve or enhance in-State economic activities.
The applicable test has been described as: Where the statute regulates evenhandedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits. *Huron Cement Co. v. Detroit*, 362 U.S. 440, 443 . If a legitimate local purpose is found, then the question becomes one of degree. And the extent of the burden that will be tolerated will of course depend on the nature of the local interest involved, and on whether it could be promoted as well with a lesser impact on interstate activities.

Pike, 397 U.S. at 142. It is the national market for goods that is protected against burdensome regulation, and not the particular activities of any interstate company. *Exxon Corp. v. Maryland*, 437 U.S. 117 (1978) (State may constitutionally prohibit petroleum producers from operating retail service stations).

There is no legal interstate market for medical marijuana, but the involvement of interstate activities raises the Federal concerns involved.

See Cole Memo I at 1- 2 (Listing federal priorities on Marijuana enforcement to include preventing diversion of marijuana into a state that has not authorized it; preventing the involvement of criminal enterprises, gangs, and cartels; and preventing marijuana businesses from being used as a front for other illegal activities). Similarly, the *FinCEN Memo* specifies that a red flag for a banking service provider to potentially file a priority Suspicious Activity Report is when the manager or owner of a marijuana-business does not reside in the state where the business operates. The proffered rule does not burden any interstate commerce that relates to medical marijuana because there is no legal interstate market in medical marijuana and the ownership requirements do not inhibit or address a national market for medical marijuana. Specifically, the potential for diversion across state lines and the transfer of funds generated from an activity illegal at the federal level across state lines warrant investigation or potential enforcement actions by the Federal government against a state medical marijuana program. *Id.*

A less discriminatory standard cannot achieve these State interests because the greater the level of non-Arkansan involvement, the greater the very problem sought to be avoided – Federal prohibition of the Arkansas Medical Marijuana program within the confines of the State of Arkansas. This goes beyond mere economic protectionism, as there is no attempt to prohibit all non-Arkansan ownership, but instead provides the method by which the State interest in ensuring the Arkansas Medical Marijuana Amendment of 2016 may be administered under the existing Federal guidelines may be achieved. *Cf. Gonzalez v. Raich*, 545 U.S. 1 (2005) (rejecting a Commerce Clause challenge to the application of the Controlled Substances Act on intrastate medical marijuana cultivation). *Cole Memo I* at 4 ("Even in jurisdictions with strong and effective [Marijuana] regulatory systems, evidence that particular conduct threatens federal priorities will subject that person or entity to federal enforcement action…"); *Cole Memo II* at fn. 2 ("For example, financial institutions should recognize that a marijuana-related business operating in a state that has not legalized marijuana would likely result in the proceeds going to a criminal organization"; and *FinCEN Memo* (Heightened regulatory danger of marijuana business owners not being located in same state as marijuana business)

The legitimate local public interest is the even-handed administration of the Arkansas Medical Marijuana Amendment within the limitations demonstrated by Federal guidance protecting the health and welfare of the Qualified Patients under this system – no less restrictive method is available as less restrictive methods are exactly what the Federal government has stated warrant scrutiny and enforcement against such programs. The limitation on ownership of Cultivation Facilities and

Dispensaries as promulgated by the Medical Marijuana Commission is constitutional and consistent with the Amendment.

ABC - II. The amendment also limits the amount of plants a dispensary may cultivate to 50 mature plants, however the rules now allow for 50 mature plants and 150 immature plants. What is the Commission's stance on whether this is in opposition to Amendment 98?

The language of the Arkansas Medical Marijuana Amendment limits the number of "mature" plants that a dispensary may cultivate. By that very language, there is consideration that the dispensary will have immature plants that are not subject to the 50 plant limitations. The ABC Board took two related steps in this regard – the 50 mature plant limitation is also the limitation on how many plants may be harvested for Usable Marijuana per month preventing a weekly cycle of 50 "Mature" at each dispensary and also placed a limit on immature plants based on the average growing cycle of the plant. The ABC Board considered the public comment that ranged from suggestions of prohibiting any growing by dispensaries to allowing unregulated growing of plants by dispensaries and crafted this solution.

The Amendment itself authorizes each dispensary to grow up to 50 mature plants which prevents any regulatory action from prohibiting such growth, however unlimited growth by Dispensaries would appear to violate the intent of the Amendment to have the Cultivation Facilities provide the bulk of the Usable Marijuana in Arkansas. Similarly, allowing 50 mature plants to be harvested without a limitation on the frequency of the harvest would have the same effect contrary to the intent of the Amendment. Conversely, limiting a dispensary to only 50 Mature plants to be harvested in a year appeared to be too restrictive on the intent of the Amendment allowing dispensaries a limited cultivation component. Because it takes three to four months for a plant to reach maturity, the proposed rules allow a consistent supply of Usable Marijuana for a Dispensary without creating "mini-cultivation facilities".

A public hearing was held on March 31, 2017 along with the Alcohol Beverage Control Division and MMC received the following comments:

1. **The MMC received several comments requesting a potential waiver or modification of the 3,000-foot (cultivation facilities) and 1,500-foot (dispensary) distance from schools, daycares, and churches requirement.**

RESPONSE: The distance requirement is specifically set out in § 8 (g)(1)(C)(i) and (ii) of the Amendment. Accordingly, the MMC does not have the power to modify this explicit constitutional requirement.

2. **The MMC received several comments requesting that dispensary license selection be conducted by merit, not by the existing qualified lottery framework.**

RESPONSE: The MMC considered these comments and the commissioners elected to adopt public comment and award dispensary licenses based on merit at the April 5, 2017 MMC meeting.

3. **The MMC received several comments regarding the growing capacity of dispensaries. Some commenters requested that the amount of plants dispensaries can legally grow be increased, while others requested the amount of plants be limited further or eliminated entirely.**

RESPONSE: The ability of dispensaries to grow and possess marijuana plants is specifically set out in § 8 (m)(3)(A)(i). Accordingly, the MMC does not have the power to modify this explicit constitutional requirement. Alcoholic Beverage Control Division exercised the authority under the Arkansas Medical Marijuana Amendment to define "mature" plant and the limitations on dispensary cultivation.

4. **The MMC received several comments regarding the inability of the MMC to require that the ownership of entities applying through an individual applicant be composed of at least 60% seven-year residents of the state of Arkansas.**

RESPONSE: The MMC considered this public comment, but declines to adopt the comment into its rules.

5. **The MMC received several comments regarding the prohibition of bankruptcy on the part of any applicant, applying entity, or owner.**

RESPONSE: The MMC considered this comment and elected to only consider bankruptcies filed within the last eight (8) years at the April 5, 2017 MMC meeting.

6. **The MMC received several comments and inquiries regarding what would be necessary to prove the right of use land for a proposed cultivation facility or dispensary.**

RESPONSE: The MMC considered these comments and the commissioners elected to clarify the rules regarding sufficient proof for access to use land for a proposed cultivation facility or dispensary at the April 5, 2017 MMC meeting.

7. **The MMC received several comments regarding the designation and licensing of growing versus non-growing dispensaries.**

RESPONSE: In addition to electing a merit system to license dispensaries, the commissioners eliminated the differentiation between growing and non-growing dispensaries at the April 5, 2017. Accordingly, concerns regarding that differentiation are moot.

8. **The MMC received several comments regarding the seven-consecutive year residency requirement for applicants and a certain percentage of owners.**

RESPONSE: The seven-year consecutive residency requirement is contained in § 8(c) of the Amendment. Accordingly, the MMC does not have the power to modify this explicit constitutional requirement.

9. **The MMC received several comments regarding a drafting error contained in MMC Regulations, Section V(21)(c)(ii).**

RESPONSE: The MMC has corrected the error contained in that Section.

10. **The MMC received several comments regarding the necessity of background checks for all owners, board members, and officers of the entity.**

RESPONSE: The background check requirement of all owners is contained in § 8(g)(2)(A) of the Amendment. Accordingly, the MMC does not have the power to modify this explicit constitutional requirement.

11. **The MMC received several questions regarding when the notice of application would be posted for review.**

RESPONSE: The MMC will post the application for cultivation facilities and dispensaries prior to the opening of application for those licenses. The MMC is mandated to begin accepting applications on July 1, 2017. The MMC does not yet know how far in advance to that period it will release the application and application instructions.

12. **The MMC received several comments regarding the consideration of diversity in awarding licenses**.

RESPONSE: The MMC contemplated the consideration of diversity in its original rules. However, the MMC acknowledged these comments and clarified how diversity would be considered in the application phase.

13. **The MMC received comment regarding clarification of how the geographic diversity should be considered.**

RESPONSE: The MMC considered this public comment and adopted clarification language as well as the Arkansas Economic Development Commission's scaling for economic diversity.

14. **The MMC received comment that it should avoid awarding bonus points for any reason.**

RESPONSE: The MMC considered this public comment, but declines to adopt the comment into its rules.

15. **The MMC received comment requesting that the term "school" be defined for distance purposes.**

RESPONSE: The MMC considered this comment and the commissioners elected to adopt a definition for "school" for inclusion in its rules at the April 5, 2017 MMC meeting.

16. **The MMC received several comments regarding the required assets and/or surety bonds on application and for performance.**

RESPONSE: The MMC considered these comments and clarified the asset and/or bond requirements into its rules at the April 5, 2017 MMC meeting.

17. **The MMC received several comments that the application and/or license costs for cultivation facility and dispensary licenses were too high.**

RESPONSE: The MMC considered this public comment, but declines to adopt the application and license fee cost for the cultivation facilities. In removing the non-growing dispensary option from its rules, the Commission reduced the license fee for the cultivating dispensaries.

18. **The MMC received several comments requesting that the MMC consider granting additional time to applicants who would like to cure issues with their applications.**

RESPONSE: The MMC considered this public comment, but declines to modify its rules. Under the current rules, applications may be submitted in a 90-day timeframe. Applicants may cure issues within that application

timeframe, however, no applicant will be allowed to submit a new or modified application after the application cut-off date and time.

19. **The MMC received several questions inquiring whether applications would be disseminated to the public.**

RESPONSE: The MMC is an entity subject to release of documents under the Freedom of Information Act ("FOIA"). Accordingly, applications may be disseminated after appropriate redactions under § 25-19-101, *et seq*.

20. **The MMC received public comment requesting that licenses for dispensaries be granted after licenses for cultivation facilities.**

RESPONSE: Per § 8 (g)(1) of the Amendment and Act 4 of the 91st General Assembly, the MMC is required to begin accepting applications on July 1, 2017 for both cultivation facilities and dispensaries. Accordingly, the MMC does not have the power to modify this explicit constitutional requirement.

21. **The MMC received public comment requesting that dispensary and cultivation facility licenses be granted for a period longer than one year.**

RESPONSE: Per § 8 (n)(1) of the Amendment, the licenses issued by the MMC expire one (1) year after the date of issuance. Accordingly, the MMC does not have the power to modify this explicit constitutional requirement.

22. **The MMC received several comments requesting additional guidance on the application period, scoring, and timeline.**

RESPONSE: The MMC considered this public comment, but declines to modify its rules. The MMC will release the application, along with the instructions, prior to the application period.

23. **The MMC received several comments requesting that the MMC modify rules regarding alterations of cultivation facilities.**

RESPONSE: The MMC considered this public comment, but declines to modify its rules.

24. **The MMC received several comments requesting that the MMC add in additional merit considerations for certain individuals, including pharmacists and previous dispensary or cultivation facility owners.**

RESPONSE: The MMC considered this public comment, but declines to modify its rules.

25. **The MMC received comment regarding the inclusion of draft reservation references to other chapters**.

RESPONSE: The MMC considered this public comment and modified the rules to remove these reservation references.

26. **The MMC received several comments regarding the existence of a maximum growing capacity for cultivation facilities.**

RESPONSE: Per § 8 (m)(4)(A)(i) of the Amendment, cultivation facilities can cultivate and possess marijuana "in an amount reasonably necessary to meet the demand for and the needs of qualifying patients as determined by the commission with the assistance of the Department of Health." At this juncture, the MMC and Department of Health cannot determine the amount of medical marijuana reasonably necessary to meet the needs of qualifying patients. The MMC declines to set a maximum production capacity limit at this time.

27. **The MMC received comment requesting that biometric locks not be required.**

RESPONSE: The MMC considered this public comment, but declines to modify its rules. The Alcoholic Beverage Control Division exercises regulatory authority over operational requirements for dispensaries and cultivation facilities.

28. **The MMC received comment regarding clarification participation in more than one marijuana business.**

RESPONSE: The MMC considered this public comment, but declines to modify its rules. However, the MMC notes that this is specifically addressed in its rules and in § 8 (l) of the Amendment. Per the Amendment, the MMC cannot expand an individual or entity's ability to have ownership in these businesses.

29. **The MMC received several comments about the cultivation facility and dispensaries ability to obtain initial seeds, seedlings, cuttings, clones, etc.**

RESPONSE: Per the Amendment, the MMC does not have authority to modify these provisions. However, Act 1022 of the 91st General Assembly addresses these concerns.

30. **The MMC received several comments requesting that additional medical ailments be added to the qualifying condition list.**

RESPONSE: Per the Amendment, the MMC does not have authority on this issue. These comments should be directed to the Arkansas Department of Health.

31. **The MMC received comment requesting the 4% privilege tax be removed.**

RESPONSE: Per the Amendment, the MMC does not have authority over the taxation of the sale of medical marijuana.

32. **The MMC received comment requesting the removal of the necessity of a pharmacist in dispensaries.**

RESPONSE: Per the Amendment and Act 1024 of the 91st General Assembly, the MMC does not have authority to modify the requirement of a pharmacy consultant.

33. **The MMC received comment requesting a definition for "applicant."**

RESPONSE: The MMC considered this comment and modified its rules to include a definition for "applicant."

34. **The MMC received comment regarding the addition of language for transporters, processors, and distributors.**

RESPONSE: The MMC will address these new licensure requirements in subsequent rulemaking.

35. **The MMC received public comment requesting information regarding the medical marijuana market and legislative efforts**.

RESPONSE: The MMC has reviewed these comments, however, they are not germane to the promulgation of rules. Accordingly, the MMC declines to modify its rules based on these comments.

36. **The MMC received public comment regarding hemp reform and for individuals convicted of marijuana possession.**

RESPONSE: The MMC has reviewed these comments, however, they are not germane to the promulgation of rules. Accordingly, the MMC declines to modify its rules based on these comments.

37. **The MMC received public comment regarding the Arkansas Department of Health proposed rule public comment.**

RESPONSE: The MMC has reviewed these comments, however, they are not germane to the promulgation of rules. Accordingly, the MMC declines to modify its rules based on these comments.

38. **The MMC received the following comment regarding additional suggested modification to the rules:**

a. **Inclusion of additional language to allow for "co-op" medical marijuana businesses;**

b. **Suggesting the MMC license less dispensaries;**

c. **Requiring all investment monies to go through anti-laundering programs;**

d. **Modification of the definition of "person" in Section IV(1)(b)(i);**

e. **Modification of address requirements in Sections IV(1)(b)(iiI) and V(1)(b)(v);**

f. **Modification of the requirement that statements and information provided in application are condition of language in Sections IV(3)(d) and V(3)(d);**

g. **Providing a definition for "agents";**

h. **Additional language in IV(6)(b) regarding who may gain access to the cultivation facility;**

i. **Removal or modification of Sections IV(8)(a) and V(10)(a);**

j. **Clarification of Section IV(9)(b)(ii)(2);**

k. **Modification of language regarding MMC approval of changes in ownership at a cultivation facility or dispensary;**

l. **Modification of the requirement that applicants be current with the Department of Finance and Administration;**

m. **Deletion of "entities" from proposed rules;**

n. **Addition of transporter, processor, and distributor to defined terms;**

o. **Deletion of Sections IV(2)(b) and V(2)(c);**

p. **Modification of Sections IV(5)(c) and V(5)(c);**

q. **Modification of Sections IV(5)(d) and V(5)(d);**

r. **Deletion of Sections IV(6)(a)(ii) – (iii) and V(6)(a)(ii) – (iii);**

s. **Deletion of Sections IV(10), V(12)(a)(i), V(12)(a)(ii), and V(12)(b);**

t. **Modification of Sections IV(10)(c) and V(12)(a)(iii);**

u. **Modification of Sections IV(9)(b)(ii) and V(7)(a)(ii);**

v. **Modification of Sections IV(9)(b)(iii), V(7)(a)(iii), and V(7)(b)(iii);**

w. **Modification of Sections IV(9)(b)(iv), V(7)(a)(iv), and V(7)(a)(iv);**

x. **Deletion of Sections IV(9)(b)(iv)(5), V(7)(a)(iv)(5), and V(7)(b)(iv)(5);**
y. **Deletion of Sections IV(9)(b)(iv)(6), V(7)(a)(iv)(6), and V(7)(b)(iv)(6);**
z. **Modification of Sections IV(9)(c)(ii) - (iii) and V(8)(a)(ii) - (iii);**
aa. **Deletion of Section IV(12)(a)(vii);**
bb. **Deletion of Section IV(15)(c)(i);**
cc. **Deletion of Section IV(15)(c)(ii);**
dd. **Deletion of Section V(2)(b) and (d);**
ee. **Publication of geographic zone map;**
ff. **Modification of Section V(11)(a);**
gg. **Modification of Section V(11)(e);**
hh. **Modification of Section V(11)(f);**
ii. **Deletion of Section V(11)(i);**
jj. **Deletion of Sections V(19)(a)(iv) and V(19)(b)(iii);**
kk. **Definition for "local"'**
ll. **Modification of Section III(3);**
mm. **Modification of Section IV(1);**
nn. **Modification of Section IV(3);**
oo. **Modification of Section IV(11)(a);**
pp. **Modification of Section IV(12)(a);**
qq. **Modification of Section V(1);**
rr. **Modification of Section V(5);**
ss. **Modification of Section V(13);**
tt. **Modification of Section V(14);**
uu. **Addition of language regarding banking;**
vv. **Addition of definition for "merit";**
ww. **Addition of definition for "proof";**
xx. **Modification of Section V(2)(b);**
yy. **Modification of Section V(2)(d);**
zz. **Modification of Section V(4)(b)(iii)(4);**
aaa. **Modification of rules based upon information submitted regarding environmental and safety concerns;**
bbb. **Addition of rules mandating the state offer cannabis consulting training;**
ccc. **Modification of rules on which certain types of assets may be included for proof of assets;**
ddd. **Addition of language allowing for the provision of free marijuana;** and
eee. **Addition of language to implement price controls.**

RESPONSE: The MMC considered these public comments, but declines to modify its rules.

This rule was approved as an emergency rule on May 3, 2017, in order to comply with the constitutional requirement that rules be in place by May

8, 2017. The proposed effective date is pending legislative review and approval.

FINANCIAL IMPACT: The cost to general revenue for the current fiscal year is estimated at $170,756 and for the next fiscal year at $281,057. However, license fees and taxes will offset the total projected cost, so the estimated cost increase to the state is less than $10,000.

LEGAL AUTHORIZATION: This rule was approved as an emergency rule on May 3, 2017, in order to comply with the constitutional requirement that rules be in place by May 8, 2017.

Amendment 98 § 8(b) of the Arkansas Constitution authorizes the Medical Marijuana Commission ("MMC") to adopt rules necessary to carry out the purposes of the amendment and to perform its duties under the amendment.

Amendment 98 § 8(c)(2) of the Arkansas Constitution states that "[s]ixty percent (60%) of the individuals owning an interest in a dispensary or cultivation facility" shall be current residents of Arkansas who have resided in the state for the previous seven (7) consecutive years. However, the Medical Marijuana Commission's ("MMC") rules state "[s]ixty percent (60%) of the equity ownership interests in the entity are held by individuals who have been residents of the state for at least seven (7) consecutive years prior to the application date." This rule provision appears to conflict with the amendment because it places the residency requirement on an individual owning at least sixty percent (60%) of the entity, thereby basing the residency requirement on ownership interest and not on the number of individuals owning an interest.

E. Rules Filed Pursuant to Ark. Code Ann. § 10-3-309.

1. DEPARTMENT OF EDUCATION (Jennifer Davis)

a. SUBJECT: Education Service Cooperatives

DESCRIPTION: These rules update and clarify the process for the evaluation of education service cooperatives. A summary of the changes follow:

Section 1.2 Regulatory authority updated.

Section 22.2.1 Corrected internal section reference and clarified that the self-study guide is contained in Appendix I.

Section 22.5 Evaluation criteria moved to Appendix 2 with reference added to the appendix.

Section 22.5.1 Section renumbered and evaluation ratings referred to the rubric in Appendix 2.

Appendices 1 and 2

Appendices 1 and 2 were added to provide the cooperatives with a clear set of standards for evaluation from year-to-year. Appendix I contains the self-study guide and Appendix 2 contains the evaluation rubric. This information was removed and included in appendices for clarity and to better comport with the law.

PUBLIC COMMENT: A public hearing was held on April 12, 2017, and the public comment period expired on April 24, 2017. The Department received the following comment:

Phillip Young, Arch Ford Education Service Cooperative: We have noticed a conflict between the Rule and the Self Study Guide Instructions. Rule page 15, 22.2.1 states cooperatives will submit 45 days prior to evaluation team visit a completed self study document. Self Study Guide, page 1, item 3 states that cooperatives will submit the self study document 15 days prior to the evaluation team visit. Of course, we would prefer the 15-day requirement if possible.
RESPONSE: Comment considered. Change made to Section 22.2.1 to reflect 15 days.

The proposed effective date is July 1, 2017.

FINANCIAL IMPACT: There is no financial impact.

LEGAL AUTHORIZATION: Pursuant to Arkansas Code Annotated § 6-13-1013(a), the State Board of Education shall develop such policies, rules, and regulations as may be needed for the proper administration of the Education Service Cooperative Act of 1985, codified at Ark. Code Ann. §§ 6-13-1001 through 6-13-1031, consistent with the need to support and assist education service cooperatives in the delivery of services to school districts and with prudent use of available human and financial resources. Each education service cooperative shall be evaluated during the 2012-13 school year, and at least once within each five-year period, on a schedule established by the Commissioner of Education, all active education service cooperatives must be visited by an evaluation committee of not more than nine (9) persons. *See* Ark. Code Ann. § 6-13-1021(a). The evaluation criteria shall be developed collaboratively between the Department of Education and the director of each education service

cooperative and shall be fully implemented by September 1, 2012. *See* Ark. Code Ann. § 6-13-1021(b)(2). The Department shall promulgate rules necessary for implementing the evaluations required by section 6-13-1021. *See* Ark. Code Ann. § 6-13-1021(e).

2. <u>DEPARTMENT OF ENVIRONMENTAL QUALITY, WATER DIVISION</u>
(Caleb Osborne, ADEQ and Michael Heister, Halliburton)

a. <u>SUBJECT</u>: Regulation No. 2: Water Quality Standards; Third-Party Rulemaking by Halliburton Energy Services, Inc.

<u>DESCRIPTION</u>: Halliburton Energy Services, Inc. ("HESI") proposes to take remedial action to improve conditions at the Dresser Industries Magcobar ("DIM") former mine site (the "DIM Site") in Hot Spring County. The DIM Site was the location of open-pit and underground barite mining from 1939 to 1977. After mining ended, the open pit filled with water that is acidic as a result of precipitation infiltrating through adjacent pyrite-rich spoil piles. Today, the approximately 600-acre site consists of a 90-acre Pit Lake that is 480 feet deep. Pyrite-rich shale in spoil piles border the Pit Lake on the north, east, and west sides.

Water from the Pit Lake above a certain elevation and from the surrounding spoil piles is believed to migrate into several nearby waterbodies: Chamberlain Creek, Cove Creek, Lucinda Creek, Reyburn Creek, Rusher Creek, and Scull Creek/Clearwater Lake. This water from the DIM Site may have an adverse effect on water quality in these waterbodies, but it does not pose any threat to human health.

HESI and the Arkansas Department of Environmental Quality ("ADEQ") have entered into a Consent Administrative Order ("CAO") that authorizes HESI to perform an Environmental Improvement Project ("EIP"), which is a statutory cleanup option in Arkansas available only to former mine sites and the like that require a long-term cleanup. A key component of the EIP is a site-specific, temporary change to water quality standards by third-party rulemaking.

Based on the EIP, HESI seeks a temporary modification of APCEC Regulation No. 2 Water Quality Standards ("WQS") for chloride, sulfate, and total dissolved solids ("TDS") for the following waterbodies: (1) Chamberlain Creek (1,384 mg/L sulfates; 2,261 mg/L TDS; 68 mg/L chlorides; (2) Cove Creek (250 mg/L sulfates; 500 mg/L TDS); (3) Lucinda Creek (250 mg/L sulfates; 500 mg/L TDS); (4) Reyburn Creek (250 mg/L sulfates; 500 mg/L TDS); (5) Rusher Creek (250 mg/L sulfates; 500 mg/L TDS); and (6) Scull Creek/Clearwater Lake (250 mg/L sulfates;

500 mg/L TDS). ADEQ has determined that these limits will be protective of the environment.

HESI's site-specific modifications are supported by the following:

- HESI is not seeking a change from historical water quality conditions in the relevant waterbodies. Rather, HESI seeks temporary WQS that reflect current water quality and allow HESI to implement the EIP in compliance with applicable requirements while protecting the designated uses for these waterbodies;

- There is no current economically feasible treatment for the removal of the minerals. Reverse osmosis treatment technology exists; but, it is not cost effective and generates a concentrated brine that is environmentally difficult to dispose of. It is not required to meet the designated uses and thus would produce no significant additional environmental protection.

- 40 C.F.R. § 131.11(b)(1)(ii) authorizes states to adopt water quality standards that are "modified to reflect site-specific conditions."

- The proposed standards have been found to be not toxic based on approximately 34 whole effluent toxicity tests conducted on the treated water between June 2003 and June 2012.

- According to Arkansas Code Section 8-5-901 *et seq*., the General Assembly has found that mineral extraction sites such as the one at issue would benefit from long-term environmental remediation projects, and ADEQ has concluded the EIP for the DIM Site qualifies.

- ADEQ sent a revised Remedial Action Decision Document ("RADD") proposing the EIP out for public comment in 2014. There were no adverse public comments.

- Halliburton and ADEQ will provide the Commission with annual reports regarding this project. Once the remedy is complete, Halliburton will conduct a Use Attainability Analysis (UAA) on the effected waterbodies that reflect the improvements resulting from the EIP and will request from the Commission a permanent change in WQS in the relevant waterbodies as supported by the results of the UAA.

PUBLIC COMMENT: A public hearing was held on September 27, 2016, in Malvern, Arkansas. The public comment period expired on October 11, 2016. The following public comment summary was provided detailing the public comments received during the public comment period

and the responses by both the Department and the third party proposing the rulemaking, HESI:

Responses to Arkansas Department of Health ("ADH") Comments Received in September 2016

1. *In the long term, reclamation of the former mine site is supportive of maintaining water quality in the Ouachita River which is utilized as a drinking water source for four public water systems. The four public water systems are: the Kimzey Regional Water District, the Malvern Waterworks, the Arkadelphia Waterworks, and the Camden Waterworks. Together these four public water systems provide drinking water to approximately 65,000 Arkansans. Once reclaimed, re-vegetation of the site and other improvements should improve water quality entering the Ouachita River.*
ADEQ's Response: The Department acknowledges this comment.
HESI's Response: ADH's comment is noted. HESI agrees that remediation of the site should result in water quality improvement.

2. *Cove Creek discharges into the Ouachita River in close proximity to the Kimzey Regional Water District intake structure. While the potential for back mixing appears to be minimal, the ADH nevertheless asks that secondary drinking water standards criteria concerning minerals be applied to Cove Creek and this is consistent with the proposed rulemaking.*
ADEQ's Response: According to Regulation No. 2, specifically Reg. 2.511(C), for water quality and designated use attainment, the criteria for Cove Creek are 250, 250, 500 mg/L of chlorides, sulfates, and total dissolved solids, respectively. The criteria in Reg. 2.511(C) are identical to the secondary drinking water standards. Additionally, according to the EIP, "Variations Supported by Environmental Improvement Project" the temporary standards proposed for Cove Creek are "sulfates 250 mg/L; total dissolved solids 500 mg/L."
HESI's Response: ADH's comment is noted.

3. *Chloride concentrations are of particular concern with regards to drinking water systems efforts to control corrosion. Corrosion concerns occur at much lower levels than the secondary drinking water standard of 250 mg/liter for chlorides. While it appears that adequate dilution of chlorides will occur in Cove Creek and then in the Ouachita River, the ADH requests that discharges from the mine site be designed such that lower flow and continuous discharge protocols are favored over higher flow and periodic discharges. This should serve to minimize minerals concentration variations seen by downstream water users and thus facilitate consistency in drinking water treatment.*

ADEQ'S Response: The 2003 Consent Administrative Order (CAO), (LIS 03-061) requires the facility to operate as a hydrograph controlled release (HCR) based on the flow in Cove Creek. This is required to "…enable the reduction of the level of the Pit Lake by up to several feet a year.... discharge of the annual volumes of water necessary to achieve these objectives and protect downstream water quality may require a hydrograph based discharge ..."

According to the June 18, 2003 Revised HCR Discharge Plan "The allowable monthly continuous discharges (Table I) were derived by first determining the critical monthly low flows for both Cove Creek and the Ouachita River. Next, WTS discharges were developed that could be continuously released during each month while protecting existing WQS in the Ouachita River and meeting interim dissolved mineral criteria in Cove Creek (860 mg/L sulfate, 1,600 mg/L Total Dissolved Solids [TDS] and 60 mg/L chloride)." Note: WTS is "Water Treatment System."

Although it may be beneficial to the downstream drinking water treatment facility, the use of a lower flow and continuous discharge may not be protective of all designated uses, especially during periods of low flow in Cove Creek.

HESI's Response: Discharge from the site water treatment system (WTS) from 2003 through 2012 was by a Hydrographically Controlled Release (HCR). This approach will continue in order to meet the criteria set forth in Consent Administrative Order (CAO) LIS 16-043. The HCR allows greater WTS discharge to Cove Creek when its flows are high and lower discharge when its flows are low. This approach is necessary in order to remove the amount of water from the mine pit lake necessary to draw down the pit lake surface and maintain a decreased elevation such that overflow does not occur (i.e., the total annual water withdrawal from the pit lake by the WTS must equal or exceed the amount of precipitation falling on the pit lake surface and its contributing drainage basin). In addition, the HCR provides more consistent minerals concentrations to Cove Creek than would occur if a constant WTS discharge were maintained. Under a constant discharge scenario, minerals concentrations in Cove Creek would be low when its flow is high due to dilution, and would be high when its flows are low because less dilution would occur.

Responses to Environmental Protection Agency ("EPA") Comments Received in September 2016

ADEQ Note: The EIP is for temporary site-specific mineral (Cl, SO4, TDS) criteria. Several comments were received regarding metals and metals participate. These comments are relevant to the overall site remediation, yet not directly related to the EIP.

HESI Note: Several comments have page numbers following the comment to indicate where in the document this item was discussed. The page numbers reflect the page counted by Adobe Acrobat, rather than the page number listed in the document, for the site-related documents posted on ADEQ's web site:
https://www.adeq.state.ar.us/regs/drafts/3rdParty/reg02/16-003-R/

As a preliminary matter, HESI notes that many of the EPA's comments pertain to prior investigations and analyses that are not properly before the Commission as part of this third-party rulemaking. HESI is nevertheless responding to ensure that EPA understands the regulatory history of the site and the process that eventually resulted in ADEQ's approval of the EIP.

General Questions/Comments for the Halliburton Energy Services, Inc. Environmental Improvement Project

1. *1a) How will achievement of downstream criteria, particularly in Cove Creek, be ensured? In Cove Creek the 2000-2012 data demonstrates exceedances of several criteria with the maximum values measured in the creek. 1b) Will the discharge be limited to a certain amount of flow to ensure that the criteria will be met? 1c) What fail safes are in place to alter the permit if downstream criteria are being exceeded?*

ADEQ'S Response: 1a) Downstream criteria attainment will be assessed using the data collected as required by the Effectiveness Monitoring Plan (EMP) and data routinely collected by ADEQ.

1b) Although not a requirement of the current permit, the facility currently operates as a hydrograph controlled release (HCR) based on the flow in Cove Creek per a 2003 CAO (LIS 03-061). According to the CAO, allowable monthly continuous WTS discharge shall be as follows:

> January - 800 gpm, February- 1300 gpm, March - 1500 gpm, April - 1100 gpm, May - 500 gpm,
> June -100 gpm, July, August, September, October - 25-50 gpm, November - 200 gpm, December - 500 gpm.

It also states that the allowable monthly discharge will be the maximum baseline mode of operation (although no discharge will occur if Cove Creek flow is zero). Final discharge amounts will be based on the results of the EMP and be determined after remediation activities are in place.

1c) The permit contains a reopener clause in the event that additional permit requirements need to be implemented. Monitoring and/or limits for specific parameter(s) for waterbody(ies) receiving stormwater runoff from the site could be included in the permit, if necessary.

HESI's Response: HESI assumes that EPA is referring to downstream criteria for dissolved minerals, as the proposed action before the Commission is approval of minerals criteria proposed as part of an EIP. Compliance with downstream criteria for other constituents of concern

(COCs) will be addressed through the remediation process detailed in the Remedial Action Decision Document (RADD) approved by ADEQ in May 2016. The water treatment system resumed treatment operations per the new CAO LIS 16-043 as of mid-August 2016. This CAO implements the same minerals criteria on a temporary basis that are proposed through the EIP.

As discussed in the response to ADH Comment 3, the discharge into Chamberlain Creek used a HCR approach between 2003 and 2012; the discharge was subject to the following criteria per the previous CAO LIS 03-061 (effective May 27, 2003): 60 mg/L for chloride, 860 mg/L for sulfate, and 1,600 mg/L for total dissolved solids (TDS). Based on ADEQ's routine monitoring data, there were no exceedances of the CAO-based criteria during that time frame.

Monitoring to ensure compliance with the proposed criteria is occurring and will continue to be performed throughout the EIP in accordance with the effectiveness monitoring plan (EMP) required by the RADD, which will be prepared after Commission approval of the EIP. The new HCR is following the same discharge protocols as were successfully followed with the 2003-2012 HCR except that the critical flows are now based on lower minerals criteria of the EIP and CAO LIS 16-043. If monitoring performed as part of the EMP or separate monitoring by ADEQ indicates that the proposed minerals criteria are not being met in Cove Creek, the HCR will be adjusted accordingly to address any exceedances.

2. *Whole effluent toxicity (WET) tests downstream of the current water treatment facility have demonstrated toxicity in Chamberlain Creek and at times in Cove Creek, even when toxicity isn't seen in the discharge of the plant. Some of this toxicity is likely due to elements of acid rock drainage (ARD) originating from additional seepage that is not currently being treated by the water treatment facility, but may be captured with the new French drain. After remediation work begins, will toxicity still be monitored downstream on Chamberlain and Cove Creek to assure that the remediation plan is addressing this toxicity from seepage? If toxicity is still found, what steps will be taken to determine the source of the toxicity (i.e. metals vs. pH vs. minerals) and address remediation of this source of toxicity?*

ADEQ's Response: ADEQ will request toxicity testing be included in the Effectiveness Monitoring Plan (EMP). Toxicity testing recommendations and the locations will be determined based on the design and remediation activity schedule. If the results of toxicity testing demonstrate that the implementation of the Remedial Action Decision Document (RADD) is not addressing toxicity, according to Section 11 of the RADD, the RADD and related documents may be revised as necessary.

HESI's Response: The French drain system will be designed to capture the surface water runoff, acidic seepage, and shallow groundwater that are believed to be the sources contributing to downstream toxicity. The purpose of the remedial actions detailed in the RADD is to address water quality (including toxicity) downstream of the site. If other toxicity sources are indicated during the EIP, remedial actions to address the newly identified sources will be developed and proposed, per Section 11.0 of the RADD, which states:

"If compliance, or progress toward compliance, to include obtaining the necessary access agreements and/or institutional controls, is not demonstrated, the RADD may be modified so that additional remedial alternatives can be considered, evaluated, and implemented in a reasonable time frame.

The Responsible Party shall investigate, as appropriate, technologies that become commercially available to facilitate the identification and consideration of additional remedial alternatives to affect permanent control, abatement, prevention, treatment or containment of releases and threatened releases at the site."

Chronic WET testing will continue to be performed at Outfall 001 per the requirements of NPDES Permit No. AR0049794. Additionally, chronic toxicity tests are included in the baseline monitoring program planned for 2017, one during low-flow conditions and one during high-flow conditions. The toxicity tests will evaluate toxicity in Chamberlain Creek just upstream of its confluence with Cove Creek and in Cove Creek just downstream from the Chamberlain Creek inflow.

The EMP will specify the types of toxicity testing and other biological sampling events that will be performed throughout the duration of the project. However, as specified in the RADD (Section 11.1.4), the EMP will include, at a minimum, biological sampling at the following locations once every 5 years: Lucinda Creek (upstream of its confluence with Cove Creek), Chamberlain Creek, Cove Creek (downstream of its confluence of Chamberlain Creek), Reyburn Creek (downstream of the confluences of drainages from tailings ponds and Clearwater Lake), and Stone Quarry Creek (downstream of the drainages from the tailings ponds).

3. *Will toxicity tests be performed for Lucinda Creek, Reyburn Creek, Rusher Creek, Scull Creek, and Clearwater Lake once remediation work has begun?*

ADEQ's Response: ADEQ will request toxicity testing be included in the EMP. Toxicity testing recommendations and the locations will be determined based on the design and remediation activity schedule.

HESI's Response: Please see the response to EPA Comment 2**.**

4. *It appears from the Remedial Action Decision Document (RADD), in the Effectiveness Monitoring Program section, that the remediation plan can be altered if progress towards compliance isn't occurring and new remediation activities need to be considered. Is there a schedule for periodic evaluation of the progress of the remediation and for investigation into new technology to treat minerals? Is there a number of years estimated to see effects of some of the non-point source remediation activities such as revegetation?*

ADEQ's Response: Section 11.0 of the RADD allows for modification of the RADD should progress towards the remedial action objectives not be evident. The timeframe for evaluation will be set in the EMP. The sampling required by the EMP will be used to document progress towards the remedial action objectives.

HESI's Response: It is correct that the RADD allows for adapting the approach to address water quality and toxicity (please see Section 11.0 of the RADD and the response to EPA Comment 2). With regard to the EIP and the schedule for evaluating progress toward meeting water quality criteria for dissolved minerals, Section 7.2 of the EIP NOI states the following:

"HESI proposes that ADEQ, EPA, and HESI confer annually by video conference or meeting to evaluate the status of the project. Such conferences/meetings would commence approximately one year from EPA's approval of the EIP and would continue to the end of the EIP. In addition, HESI will provide an annual written update on remediation activities to ADEQ and EPA approximately 2 weeks prior to each annual discussion."

HESI believes that the above-referenced annual meetings will serve as periodic evaluations of the progress towards compliance once remediation activities have been completed.

It is unknown at this time when the effects of nonpoint source remediation activities will be observed. The EMP will provide a framework for documenting that the implemented remedies are achieving progress toward compliance with downstream water quality standards.

Questions/Comments for Dresser Industries-Magcobar Mine Site Investigation Report, Hot Springs, Arkansas, April 19, 2007 (Appendix A)

5. *Is there any concern that the pH of the sludge ponds will drop? Could the pH drop to a level that would potentially make ARD constituents soluble again? (pg. 223)*

ADEQ's Response: Based on the page reference, this comment appears related to the settling ponds and not the sludge ponds. A large portion of the sludge from the settling ponds and the sludge ponds appears to have been removed; however, some sludge still remains in each. The major concern from the Acid Rock Drainage (ARD) is the pH drop. This pH drop is primarily being effected by mine spoils. The ARD constituents in the settling ponds and the sludge ponds are minimal compared to volume of mine spoils.
HESI's Response: HESI infers that this comment, and those below through EPA Comment 15, pertain to Appendix A, Site Investigation (SI) Report. Page 223 references the Settling Ponds, not the Sludge Ponds. This nomenclature is explained in Section 3.5 of the SI Report (p. 75 of the .pdf file). Per the SI Report, the Sludge Impoundments consist of two sets of three impoundments (the Settling Ponds and the Sludge Ponds). The Settling Ponds are located on natural subgrade near the southwest spoil piles. The Settling Ponds perennially contain water and sludge from former treatment operations is present on the pond bottoms. The Sludge Ponds are located on top of the southwest spoil piles and also contain treatment sludge, but are dry.

Given EPA's page reference, HESI infers that this comment refers to the Settling Ponds. While it is possible that the pH of the waters contained in the Settling Ponds could decrease to the point that metals in the alkaline sediment in the bottom of the ponds may become more susceptible to mobilization, this does not comprise a major concern from a site-wide perspective. A reduction in water pH would be due to runoff of ARD from adjacent mine spoil piles. At the time the SI was conducted (2000-2001 time frame), such runoff had been occurring for several decades and the Settling Pond waters were still near-neutral in terms of pH. Since that time, natural recovery of the spoil piles has continued, with further oxidation and revegetation of the spoil pile surfaces which would tend to reduce ARD production. Smaller amounts of ARD from the spoil piles would, in turn, reduce the likelihood of acidifying the Settling Pond water to the point that metals would be mobilized from the pond sediment. Measurement of the pH of the Settling Pond water will be undertaken as part of the EMP to assess the extent to which the water may have been acidified.

If EPA's comment is instead referring to the Sludge Ponds, HESI is developing a design to cover the former ponds with soil, with run-on and runoff controls, to reduce risks to terrestrial receptors. This closure method is not expected to result in a pH reduction that could increase the mobility of metals in the dried sludge.

6. *In determining the risk presented by metals in the aquatic sediments, was the risk of benthic organisms taking up metals and then the metals bioaccumulating in the food chain considered? (pg. 258)*
ADEQ's Response: Bioaccumulation was considered when evaluating the hazard quotient (HQ) for riparian wildlife receptors of belted kingfishers and raccoons. The ecological risk assessment determined there is a potential for adverse effects on raccoons when their diet consisted of aquatic life from Cove Creek.
HESI's Response: In the Baseline Ecological Risk Assessment (BERA; Appendix B of the SI Report), the diet of the mammalian riparian receptor (raccoon) is a generalized diet assumed to include 50% benthic macroinvertebrates and 50% small fish. Risks (hazard quotients [HQs]) to the raccoon were derived relative to no observed adverse effects level (NOAEL) and lowest observed adverse effects level (LOAEL) and are presented in Table 7-7 of the BERA. Thus, in determining the risk presented by metals in the aquatic sediments, the risk of benthic organisms taking up metals and then the metals bioaccumulating in the food chain was considered.

7. *What is the risk of metals becoming soluble again from the sediments? Is there a pH threshold that would allow these metals to enter into solution again? (pg. 258)*
ADEQ's Response: Lower pH increases the solubility and mobility of metals in soil and sediment. This allows for a higher bioavailability of metals in water, which increases the toxicity, especially for aluminum and manganese. The higher bioavailability will pose a greater risk to aquatic receptors in affected waters. Data shows that if the pH is greater than or equal to 6.5, adverse effects are not anticipated for aquatic life.
HESI's Response: HESI infers that this comment refers to sediment in streams proximal to the site. Though the risk of solubilizing metals from sediment exists, it is expected to be small given that the site is undergoing natural recovery and the amount of ARD produced by the site is decreasing. One caveat is that ARD production may temporarily increase during remedial construction activities, potentially increasing the possibility that metals could be mobilized from stream sediment. However, such ARD will be addressed through the use of best management practices during construction, limiting the amount of ARD that could enter the site streams.

8. *For fish sampling associated with future monitoring, it would be useful to quantify the number of fish caught per unit effort so that sampling at the various locations can be compared. For some locations in the past it appeared that much larger areas were sampled at one site location compared to another.*
ADEQ's Response: Catch per unit effort (CPUE) is a commonly used indirect measure of species abundance. The Department will require HESI

to report electrofishing sample time and reach length in order to evaluate individual species abundance and changes among sites and through time.
HESI's Response: Future fish sampling events will include a comparison of the total abundance across sampling locations by calculating fish caught per unit effort (CPUE). The length of the stream reach sampled is 40 times the average width of the stream per standard methodology; therefore the area sampled for each stream will vary according to the size (width) of the stream.

9. *Streams need to be clearly defined as either perennial or intermittent. In particular the site investigation (SI) switches back and forth between calling Lucinda Creek an intermittent and a perennial stream. (pg. 415)*
ADEQ's Response: According to medium resolution NHD, high resolution NHD data, and topography maps, Lucinda Creek upstream of Lucinda Lake is considered intermittent and downstream of the lake it is considered perennial. The Department will request HESI refer to Lucinda Creek as intermittent when referring to the portion upstream of Lucinda Lake and perennial when referring to the portion downstream of the lake. This will be requested for all future documents and future revisions to existing documents.
HESI's Response: EPA's comment is noted. During the SI, Cove Creek and Lucinda Creek below Lucinda Lake were perennial and other site streams (Chamberlain Creek, Rusher Creek, Scull Creek, Reyburn Creek, and Stone Quarry Creek) were intermittent.

10. *Where did the Region 6 screening level value for sulfate come from? Is there a document that specifies this value? Was this screening level set for aquatic life or for human health? (pg. 436)*
ADEQ's Response: Region 6 screening levels referenced in the table are from the 1986 Quality Criteria for Water or the "Goldbook" that provides screening levels for aquatic life. The value of 860 mg/L corresponds to the screening level for chlorides. This value was selected for sulfates during the SI, since sulfates would not be as toxic as chlorides. This value was also used in previous orders with the Office of Water Quality and EPA, since a sulfate screening level is not available.
HESI's Response: The value for sulfate is an old aquatic life protection screening value that was supported by EPA with an earlier use attainability analysis (UAA) that was approved by ADEQ and EPA (Holly Creek – Alcoa). The value is still found in Regulation 2.511. FTN Associates cited it as a Region 6 Screening level value in its May 2002 Proposed Approach for the Interim Management of the Discharge of Treated Pit Lake Water, which was submitted to ADEQ's Permit Division and ultimately approved by ADEQ and implemented in CAO LIS-03-061.

11. *11a) In several instances it appears that discussion about the precipitate that has been created from pulling the metals out of solution is separated from the discussion about the risk posed by the sediments to the aquatic species. In some instances the precipitate exceeds the no effect concentration (NOEC) while the sediment does not. Given this, how does the presence of the precipitate factor into how the health of the streams was evaluated? 11b) Was it assumed that the precipitate was not bioavailable, and if so, why? 11c) Also, at what pH would the metals in the precipitate become bioavailable? (pg. 470)*

ADEQ's Response: 11a) While not discussed in depth, Appendix B, Baseline Ecological Risk Assessment does note negative "stream health" effects due to the precipitate formation and the resulting embeddedness as well as a reduction in reduced interstitial spaces.

Page 2-1 "Aluminum and iron precipitates may form as acidic drainage waters enter streams, causing temporary embedding and cementing of cobbles in stream substrates and corresponding temporary reduction in the aquatic habitat quality until the precipitates are removed during seasonal high flows."

Page 3-7 "Downstream of Scull Creek, the substrate was even more embedded than at the upstream site. A dull gray precipitate appears to cement the substrates firmly in place"

Page 4-28 "Observations at REY-2 suggested heavy precipitate during fall 2000 that acted to cement substrates providing reduced interstitial spaces."

Page 7-27 "Risks due to toxic effects of aluminum in sediments to organisms are not expected, based on the concentrations measured in Cove Creek and Chamberlain Creek sediments. The precipitate may have two levels of effects, including a small degree of toxicity and physical effects. A small level of effects may be occurring in Cove and Chamberlain Creeks due to the quantity of material precipitating out of solution. Aluminum could cause more of a physical effect to benthic invertebrates such as smothering of intergravel spaces"

11b) A discussion of precipitate bioavailability is not included in the Baseline Ecological Risk Assessment or the SI.

11c) A discussion of the pH at which the metals in the precipitate would become bioavailable is not included in the Baseline Ecological Risk Assessment or the SI. Regulating the pH level through the water treatment system is anticipated to decrease the level of precipitate and the bioavailability of metals.

HESI's Response: The precipitate was not always present nor prevalent during the sampling for the BERA. Though some precipitate was observed in the site streams during the 2000-2001 SI, more pronounced precipitate formation was observed in Chamberlain and Cove creeks after the WTS

began discharging treated water to Chamberlain Creek in June 2003 (see p. 469 of the .pdf file). The more pronounced precipitate formation was found to result from mixing of the near-neutral, treated water and acidic, metal-bearing groundwater entering Chamberlain Creek. Follow-up monitoring was conducted soon after the more pronounced precipitate formation was observed. Concentration data from the precipitate were collected to evaluate against effects thresholds. There were no assumptions about bioavailability as the precipitate formation was temporally variable (i.e., precipitate was typically present during quiescent, low-flow conditions but absent during high-flow conditions).

HESI implemented response actions to reduce the precipitate formation, including extension of the WTS discharge line by approximately 1,000 feet downstream on Chamberlain Creek and collection of shallow groundwater in the upper Chamberlain Creek basin, in late 2005. The collected shallow groundwater is pumped to the pit lake for treatment by the WTS.

12. *How were the physical impacts of the precipitate on the benthic organisms considered in the risk assessment? (pg. 470)*
ADEQ's Response: While not discussed in depth, the SI and Appendix B, Baseline Ecological Risk Assessment does note risks to aquatic organisms.

Page 7-14 of the SI "Potential adverse effects (based on the mean PEC-Q) predicted for benthic invertebrates for the more recent sediment and precipitate data, further strengthens the observation that controlling pH and 7-15 dissolved metals in Chamberlain Creek, primarily, but also in Rusher, Reyburn, and Scull Creek headwaters will reduce risks of COPCs in sediments because the precipitation that currently deposits metals to sediments will be significantly reduced."

Page 7-27 of Appendix B "Risks due to toxic effects of aluminum in sediments to organisms are not expected, based on the concentrations measured in Cove Creek and Chamberlain Creek sediments. The precipitate may have two levels of effects, including a small degree of toxicity and physical effects. A small level of effects may be occurring in Cove and Chamberlain Creeks due to the quantity of material precipitating out of solution. Aluminum could cause more of a physical effect to benthic invertebrates such as smothering of intergravel spaces."
HESI's Response: The physical impacts of the precipitate in streams in the site vicinity were not considered in the BERA. Implementation of the RADD is expected to further reduce the presence and quantity of precipitate in the site streams.

13. *EPA is concerned that manganese was not retained as a contaminant of potential concern (COPC) for sediments, as in many creeks its hazard quotient (HQ) was between 1 and 1.5. When this value was rounded, the justification given for not retaining it as a COPC was that the HQ was not greater than 1, even though it was when the value was not rounded. (pg. 507) This occurs with a few other parameters as well.*

ADEQ's Response: A common risk assessment practice is to round calculations to one significant digit; this methodology was exercised in the SI. ADEQ acknowledges, this methodology could potentially result in certain contaminants of potential concern (COPCs) being prematurely removed from the risk assessment. However, adjustment and safety factors are typically included in the toxicity factors, which would compensate for rounded down risk calculations. Furthermore, ADEQ maintains that the remedial action of regulating the pH level should decrease the level of precipitate and the bioavailability of metals, including manganese. The exclusion of manganese and other constituents as a result of rounding should not adversely affect the overall remedial goals.

HESI's Response: Computed HQs for manganese, and some other metals, in several site streams were between 1 and 1.49. Rounding to the nearest integer for HQ calculations is a common practice in risk assessment and it was also stated in the approved BERA that this approach would be taken. While there is no clear guidance on this practice, the questions asked in the risk characterization are relative to a single digit—is the HQ less than or greater than 1—thus it is logical to derive HQs to a similar level of significant figures.

14. *Is there an upper limit of hardness tolerance in aquatic species? (pg. 523)*

ADEQ's Response: There is not any readily available research specifically related to an upper limit of hardness tolerance to aquatic species. However, when hardness values are high, it may be appropriate to investigate how the concentrations of the various ions would affect aquatic life.

HESI's Response: Hardness is a function of calcium and magnesium. We are not aware of any data that suggest hardness presents a toxicity issue at the calcium and magnesium levels encountered at the site.

15. *In Table 7-3, there appears to be many more values that exceed the lower benchmark value than are actually noted in this table. (pg. 559)*

ADEQ's Response: There are instances when exceedances were not properly flagged, and ADEQ can only attribute this to random error. Ultimately, ADEQ maintains these errors should not adversely affect the overall remedial goals.

HESI's Response: As pointed out by this comment, there are some values that exceed the lower benchmark but are not shaded in Table 7-3. These

include two values for arsenic (MFG Max Background and Tigre-1 sed), four values for beryllium (Cove pool 10, Cove pool 10 dup, Covepool4, and Chm 2.5 ppt), one value for copper (Weston Max Background), one value for nickel (Weston Max Background), and two values for zinc (Weston Max Background and Cove pool 10), which is an oversight. These table cells should have been shaded green. In addition, the cobalt value for Covepool 4 should have been shaded green instead of red because only the lower benchmark was exceeded.

Questions/Comments for Draft Feasibility Study Report Dresser Industries-Magcobar Mine Site, Hot Spring County, Arkansas, August 20, 2009 (Appendix B)

16. *The report states that "Recovery of affected streams is anticipated to be nearly immediate when the pH is controlled." EPA believes this is an overstatement of how quickly the streams will recover and the impact the streams will still experience from elevated minerals and metals that will remain partially elevated even after pH control. (pg. 20)*
ADEQ's Response: The Department acknowledges this comment. The Effectiveness Monitoring Plan (EMP) will serve to determine the rate and extent at which the affected streams recover when pH controls and other control/remediation measures are implemented.
HESI's Response: EPA's comment is noted.

17. *It is unclear from the report how the cost estimate for Alternative 2 was calculated as $6,910,000. The report states that Alternative 2 assumes a periodic cost of $1,000,000 every 5 years, beginning in year 15 and that the life span of the water treatment system (WTS) is 100 years. 100 yrs-15 yrs = 85 yrs /5 yrs = 17. At a minimum this cost should be $17,000,000 just for periodic cost. What other factors are in this equation that makes this cost estimate so much less than 17 million dollars? (pg. 133)*
ADEQ's Response: The cost estimate appears to have been based on one million being spent every 15 years. So, 100 yrs/15 yrs = 6.66 which would provide a similar estimate to $6.91 million cost estimate with cost of consultants billing.
HESI's Response: Per EPA guidance[1] the cost estimates presented in the FS Report were calculated as present values. Present value analysis is a method to evaluate expenditures (capital, annual O&M, and periodic) which occur over different time periods. This standard methodology allows for cost comparisons of different remedial alternatives on the basis of a single cost figure for each alternative. This single number, referred to as the present value, is the amount needed to be set aside at the initial point in time to assure that funds will be available in the future as they are needed, assuming certain economic conditions. An interest rate of 7

[1] A Guide to Developing and Documenting Cost Estimates during the Feasibility Study. EPA 540-R-00-002, OSWER9355.0-75. July 2000.

percent was used in the present value analyses. Thus, the present value for Alternative 2 of $6,910,000 is the amount of money that would need to be invested at the beginning of the project, at an interest rate of 7 percent, to complete the initial construction (capital cost) and to implement O&M and periodic costs for 100 years. Since a return of 7 percent is assumed, the total amount invested at the beginning of the project is less than if no return is assumed (0 percent interest). See Appendix B of the FS Report (pp. 174-176 of the .pdf file).

18. *Why wasn't an alternative that considered upgraded source control without pit treatment considered in the alternatives analysis (a combination of alternative 3 and 5 rather than alternative 5 just expanding on alternative 4)? (pg. 150)*

ADEQ's Response: All of the Alternatives that are presented in this EIP are based on the feasibility study (FS) that was acknowledged by ADEQ. These Alternatives were based on certain criteria that addressed the effectiveness, performance, cost, etc. Upon approval of the FS, the EIP did not require any additional studies to be performed.

HESI's Response: This comment appears to ask why wasn't there an alternative that consisted of continued WTS operation (not pit neutralization) coupled with extensive source control. The extensive source control envisioned as part of Alternative 5 was intended to provide a means for eliminating ongoing water treatment. It would consist of physically relocating most of the spoil to a new repository location to the west (downgradient) of the mine pit lake. The spoil would be amended with lime to limit acid generation as the spoil is placed in the repository. Overall, it was estimated that approximately 14 million cubic yards of spoil would require excavation and transport to the repository location (pp. 107 and 108 of the .pdf file). The conceptual footprint and configuration of the repository is shown on p. 215 of the .pdf file. This spoil pile alternative was developed and considered because it would minimize or eliminate further ARD drainage to the mine pit lake. As discussed under Alternative 5, the WTS would continue operation during and after relocation of the spoil to the repository (p. 107 of the .pdf file). The upper layer of the mine pit lake would be neutralized with lime and, since further ARD drainage to it would be minimized or eliminated, WTS operation would cease when treatment was no longer needed and the pit lake water could be discharged without treatment. Thus, continued WTS operation and extensive source control were considered together in the FS.

Questions/Comments for Remedial Action Decision Document, Dresser Industries- Magcobar Mine Site, Magnet Cove, Hot Spring County, Arkansas (Appendix C)

19. *It is not clear that the improvement in the headwaters surface water quality will lead to sediment improvement without any direct*

remediation on the sediments. What processes are occurring in the sediments that would make the metals unavailable to the benthic organisms? Also, how long are the metals that are already present in the sediment expected to persist?

ADEQ's Response: The primary direct remediation option available would be removal of the sediments via dredging. This could potentially pose additional risks to aquatic life in the short term by mobilizing metals in the surface water. ADEQ maintains the selected remedial action of regulating the pH level will be protective of aquatic receptors in the short and long term. As the pH increases in the surface water, the level of precipitate and the bioavailability of metals should decrease. ADEQ could not estimate the amount of time metals will persist in sediments; however, over time metal levels will ultimately be decreased with the natural mixing of clean sediment.

HESI's Response: As explained in the FS Report (e.g., p. 93 of the .pdf file), the site sediments were characterized as exhibiting low levels of risk (HQs <5) to environmental receptors. HESI and ADEQ agreed that removal of the sediment would destroy existing benthic communities, creating greater harm to the environment than leaving the sediment in place. The metals in the sediment will persist in perpetuity as they will not degrade or break down to other substances. However, it is expected that the concentrations of metals in sediment to which environmental receptors will be exposed will decrease through time by mixing with or becoming covered by sediment with lower metals concentrations that will originate from the site following remediation, given the relatively high gradient of the site streams and the corresponding tendency for sediment transport.

20. *SP3 spoil pile alternative (extensive regrading and revegetating) should potentially be thought of as a next step in the remediation process if monitoring demonstrates that initial actions are not sufficient to meet remediation goals. (pg.33)*

ADEQ's Response: The Department acknowledges this comment. The RADD, Section 11.0, includes provisions for a change in remedy should the selected remedy not prove effective. A remedy included in the Feasibility Study or another remedy may be proposed.

HESI's Response: Please see the response to EPA Comment 18. Extensive regrading and revegetation of the site spoil piles, as described in the FS Report, would have consisted of excavation, relocation, and lime amendment of most of the spoil. This spoil pile alternative was not selected by ADEQ as part of the site remedy and therefore is no longer under consideration.

21. *Reference sites should be included in the biological sampling plan (upstream of mine influence and potentially one off site) to act as a control while monitoring the progress of the remediation and so that any outside*

impacts unrelated to the remediation work at the site can be taken into account. (pg. 43)

ADEQ's Response: While not noted in the body of the RADD, reference sites are noted in other related documents.

- The RADD response to comments included on page 52 of 75 states " ... Basin Creek (the background location)..."
- The July 28, 2016 version of the Baseline Sampling and Analysis Plan (SAP) makes reference to reference sampling stations and biological sampling at those stations.
    - COVE-5 Upstream reference conditions for Cove Creek above influence of Lucinda Creek, Chamberlain Creek
    - BAS-0 Non-impacted stream upgradient of Chamberlain Creek and tributary to Cove Creek (serves as reference)
    - REF-1, 2, 3, & 4 Reference stream to be identified during site reconnaissance
    - Reference streams in the area will also be identified and used throughout the baseline sampling. The reference streams will be selected based on comparability of size, watershed size, and flow to Chamberlain Creek, Lucinda Creek, Rusher Creek, Scull Creek, and Reyburn Creek. The purpose of the reference stream characterization will be to provide chemical, biological, and habitat information to describe attainable aquatic life uses expected for similar local streams.
- The Department concurs that biological sampling of reference sites should occur as part of the baseline monitoring, during remediation monitoring, and as part of the effectiveness monitoring included in the EMP.

HESI's Response: HESI anticipates the use of reference sites being a component of future sampling activities. The baseline sampling plan scheduled to be underway before the end of this year provides for water quality and biological sampling in up to four reference streams (to be selected in cooperation with ADEQ personnel) as well as in Basin Creek, a non-impacted stream upgradient of Chamberlain Creek that is also a tributary to Cove Creek, and in Cove Creek upstream of the site.

22. *What sort of monitoring will be performed to assure that no metals are leaching from sludge ponds and that contact by terrestrial receptors is prevented? Is there a monitoring plan to test the soil cover that will be placed over the sludge piles to make sure that no metals are leaching?*

ADEQ's Response: Monitoring will be established through the Effectiveness Monitoring Plan (EMP). Additionally, Halliburton will utilize a soil cover for the sludge ponds, which will diminish the direct contact pathway for terrestrial receptors and reduce water infiltration.

HESI's Response: Soil cover is the selected remedy in the ADEQ-approved RADD to prevent contact by terrestrial receptors with the sludge ponds and "will isolate the sludge from contact by terrestrial receptors,

thus effectively eliminating the risk posed by the sludge to the environment in both the short-term and the long-term" (Section 7.1.5 of the RADD). The EMP (Section 11.0 of the RADD) will direct the monitoring and document the progress at the site and will include a section for each area of concern listed in Section 4 of the RADD (which includes the sludge ponds).

23. *The current plan is designed for 100 years and involves active management, including active water treatment, to assure that the level of water in the pit is kept at a non-dangerous depth and that the water released from the pit is not toxic to wildlife. The plan does not seem to address a longer term solution, so what actions are anticipated after the hundred years that will assure that the pit lake and its water are not a risk to the environment?*

ADEQ's Response: The time frame of 100 years was used to allow continuing evaluation at the Magcobar site. The site owners will be performing additional periodic reviews that will be outlined in the Effectiveness Monitoring Plan. These periodic reviews include assessing new technologies as they become available.

HESI's Response: It is anticipated that the WTS will be operated in perpetuity, unless the pit lake water quality improves to the point that the WTS is no longer needed. The 100-year period was adopted in the FS report for the purposes of calculating present value costs for each of the remedial alternatives and exceeds the 30-year evaluation period that is often assumed for FS purposes.

24. *If Halliburton Energy Services, Inc. (HESI) isn't going to pay for new residents to be connected to the municipal water source, how is it assured that new residents will not drill into the ground water for a drinking water supply that may potentially be impacted by the mine site?*

- *What expense is the company responsible for in terms of adding new municipal water source connections? In the comments on the RADD HESI seems to imply they are not responsible for this cost, but the cost estimate is included in the feasibility study.*

ADEQ's Response: The RADD requires Halliburton to submit a report documenting that persons within the area noted on Figure 3 of the RADD have access to municipal water. The remedy for shallow and deep groundwater is designed to prevent groundwater use as a domestic water supply. Halliburton is responsible for any cost associated with implementing this remedy, and therefore, the cost of connecting these persons to a municipal water supply.

HESI's Response: HESI will pay the connection costs for future residents within the Municipal Supply Connection Area to be connected. For new residents, HESI intends to work with the Magnet Butterfield Water Association to (1) periodically monitor new development or changes in ownership of existing property in the affected area, (2) notify new

residents of site conditions and potential risks, and (3) offer to connect such residents to a municipal water supply at no charge to the resident(s).

- HESI will pay the connection costs for future residents within the Municipal Supply Connection Area to be connected to a municipal water supply.

25. *25a) Is there any enforcement power for the metals that do not have state criteria? 25b) Is there any enforcement power to assure that the remediation work is completed, aside from the NPDES permit for the water treatment facility?*

ADEQ's Response: 25a) ADEQ has the authority to implement federal criteria in permits when there is not an adopted state standard. Additionally, federal criteria can be utilized for state enforcement actions. ADEQ will use the federal criteria noted in, but not limited to, the EPA National Water Quality Criteria – Aquatic Life Criteria Table and the 1986 Gold Book criteria. https ://**Error! Hyperlink reference not valid.**

25b) CAO LIS16-043, Order and Agreement, paragraph 18 addresses the consequences of a failure to comply with any provisions of the Order. The RADD is incorporated into the Order, CAO LIS 16-043, Order and Agreement, paragraph 3.

HESI's Response: Enforcement power for attainment of water quality standards and completion of remediation work are embodied not only in NPDES Permit No. AR0049794 for the WTS, but also in Consent Administrative Order LIS 16-043 as well as the RADD, which were both executed in May 2016.

26. *Please include a description of how the physical presence of precipitates will be evaluated and how their impacts on benthic organisms will be minimized.*

ADEQ's Response: Chemical, biological, and sediment sampling will be established through the EMP that has not been submitted or approved to date. Additionally, ADEQ maintains the selected remedial action of regulating the pH level should decrease the level of precipitate and the bioavailability of metals to ecological receptors.

HESI's Response: HESI assumes that this comment refers to the formation of precipitate in Cove Creek downstream of the site. The presence of precipitate will be evaluated through field documentation during chemistry and biological community sampling performed as part of the EMP (see Section 11.0 of the RADD). It is expected that remediation activities implemented per the RADD will improve water quality such that the formation of precipitate will be significantly reduced or eliminated.

Questions/Comments for Seasonal Monitoring in Chamberlain and Cove Creeks, Per CAO LIS 03-061 Section B.3. December 9, 2005 (Appendix D)

27. *Please make sure that monitoring data is appropriately described. For instance, one sentence states "The percent of total individuals as EPT was relatively constant across Cove Creek stations and decreased slightly during the monitoring period across all stations." This statement appears to be misleading as the percent of total individuals as EPT was about 65% in October 2003 and was about 18% in April 2005. A loss of approximately 45% is more than a slight decrease. (pg. 26, 28)*
ADEQ's Response: The Department will request HESl make scientifically valid descriptions and conclusions when describing and interpreting data collected during the baseline monitoring, during remediation monitoring, and as part of the effectiveness monitoring.
HESI's Response: EPA's comment is noted.

28. *28a) Please also make sure that all information is accurately represented. In Table 4.3, two metals, aluminum and manganese, are listed as having 0 permit violations. However, both of these metals are listed as report in the 2008 permit and do not have a limit, so listing them as having 0 violations is misleading. This is operating under the assumption that the 2008 permit contains the same limits as the previous permit. This should have an n/a since there was no limit in place that could be violated. 28b) In addition, both of these metals are still being discharged at concentrations that are quite high, even though the treatment has resulted in a large reduction in their concentrations. (pg. 29)*
ADEQ's Response: 28a) The Department will request that in future reports and related documentation that HESI use the terminology " violation" only for those parameters that have permit limits. For those parameters that are "report," the terminology "exceedance of state or federal criteria" should be used.
28b) The Department acknowledges this comment.
HESI's Response: EPA's comment is noted.

29. *In Table 4.3, why is there no average pH or median pH values? (pg. 29)*
ADEQ's Response: The Department will request HESI report descriptive statistics for all parameters for data collected during the baseline monitoring, during remediation monitoring, and as part of the effectiveness monitoring. This will include but is not limited to, min, max, average, median, and lower quartile.
HESI's Response: HESI has reviewed this 2005 summary report and cannot determine why these statistics for pH were omitted from Table 4.3. Future reports containing summary statistics will include average or median values as appropriate or will contain an explanation for potentially incomplete data sets.

30. *For Table 4.3, it appears that according to the 2008 permit TDS and sulfate both actually had permit violations. A previous version of the permit could not be located online, but according to the 2008 permit, sulfate values and TDS values are both in violation. The listed TDS limit is 212 mg/L for monthly average and for sulfate is 31 mg/L. Was another standard or permit value in place that made these values not in violation for the time period reported in this report?*
ADEQ's Response: The facility had a permit effective February l, 2003, which expired January 31, 2008. This permit was superseded by CAO LIS 03-061. The amended Exhibit A of the 2003 CAO states "Report only for Minerals," therefore no permit limit violations for sulfate or TDS would have been noted.
HESI's Response: Please see the response to EPA Comment 1 regarding CAO LIS 03-061. CAO LIS 03-061 contained interim limits for chloride, sulfate, and TDS.

31. *For the biological monitoring results, please specify why particular taxa were excluded from the total taxa count. It appears that the highlighted taxa could potentially fit into another counted taxa, which is why they were excluded, but this is not clear from the footnote. (pg. 40)*
ADEQ's Response: The Department will request HESI give details regarding taxa groupings and/or exclusions for data collected during the baseline monitoring, during remediation monitoring, and as part of the effectiveness monitoring.
HESI's Response: It is correct that the highlighted taxa were excluded because they could potentially fit into another counted taxon. Future documents will include a more detailed explanation for this convention in the methods section.

Questions/Comments for Appendix E: Historical Database

32. *Even when the WTS was operating, aluminum concentrations, although reduced, were still very high and at times the pH was still below 6. What elements of the remediation plan will work to bring the aluminum and pH into ranges that are not harmful to aquatic life? What sort of fail safes are in place if the initial remediation plan is not sufficient?*
ADEQ's Response: A Sampling and Analysis Plan (SAP) being performed in accordance with Remedial Action Decision Document (RADD) will monitor the performance of the remedy. If the aluminum and pH fall out of specifications, then Magcobar site owners will have to stop discharging until they return to the allowed discharge concentrations. The RADD, section 11.0, requires HESI to demonstrate progress towards compliance and allow for modification of the RADD, if necessary, to effect progress.
HESI's Response: The remediation plan has control elements that were not in place when the WTS was operating earlier. All elements of the

remediation plan are designed to reduce acidity entering the site streams, thereby resulting in pH increases and reduction of metal levels in the streams. These elements include continued operation of the WTS, consolidation of spoils within the Chamberlain Creek syncline where ARD in runoff and infiltration will flow to the pit lake for treatment, and capture of ARD outside of the syncline and directing the captured ARD to the WTS. Further, as discussed in the response to EPA Comment 2, the RADD includes provisions to evaluate additional remedial alternatives, as necessary. Finally, as discussed in the response to EPA Comment 4, annual meetings of EPA, ADEQ, and HESI will be held to discuss progress toward achieving the RADD water quality standards.

33. *Several concentrations are listed as less than concentrations rather than exact measurements, while exact measurements were attained during another monitoring season for concentrations below that less than threshold (ex: Lead at Scull Creek was measured at a maximum of 0.6 µg/L during the SI monitoring, but was measured at <40 µg/L during 2006 monitoring). Going forward, please make sure that the assessment methods utilized for the monitoring can detect the parameter in the range that is necessary to determine whether it is causing impairments to aquatic life.*

ADEQ's Response: The Department will request HESI use analytical methods that can detect parameters in the range that is necessary to determine whether it is causing impairments to aquatic life.

HESI's Response: Only laboratory analytical methods that were developed and/or approved by EPA and ADEQ will be used on any future analyses of site environmental media. Use of these methods sometimes results in variable reporting limits due to the intermittent need to dilute samples because of high concentrations that, without dilution, would be beyond the measurement range of laboratory instruments.

Questions/Comments for Halliburton Energy Services, Inc. Dresser Industries-Magcobar Former Mine Site Notice of Intent of an Environmental Improvement Project, October 29, 2014

34. *Currently the notice of intent (NOI) states that no direct remediation will be conducted to treat the elevated concentrations of minerals that are a result of the ARD from the Magcobar mine. It also implies that no work will be done to investigate new remediation techniques in the future that may assist in lowering minerals levels and may be more practical than reverse osmosis techniques. EPA would like to encourage the inclusion of consideration of new minerals treatment techniques over the course of the EIP so that minerals can potentially undergo remediation in the future.*

ADEQ's Response: According to Section 11 of the RADD, the RADD and related documents may be revised as necessary in the event that new treatment techniques and technologies become available.
HESI's Response: EPA's comment is noted. HESI will continue to evaluate new mineral reduction techniques throughout the EIP. Per Section 11.0 of the RADD:
"The Responsible Party shall investigate, as appropriate, technologies that become commercially available to facilitate the identification and consideration of additional remedial alternatives to affect permanent control, abatement, prevention, treatment or containment of releases and threatened releases at the Site."

35. *35a) In several locations the temporary minerals criteria that are being proposed are much higher than the maximum concentration of that parameter that had been measured in that creek over the past 12 years. EPA would recommend dividing some of these creeks into upstream and downstream sections to designate different criteria for those area more impacted by the mine versus those less impacted by the mine. This seems to be appropriate for Scull Creek upstream and downstream of Clearwater Lake, Cove Creek upstream and downstream of Chamberlain Creek, and Reyburn Creek upstream and downstream of Scull Creek. 35b) Also for some creeks, such as Rusher and Lucinda, a lower criteria than 500 mg/L TDS and 250 mg/L sulfate seems more appropriate as these creeks are not demonstrating concentrations this high. If the higher minerals criteria are anticipated due to the construction effort associated with the remediation project than perhaps the higher standard can be applied just during the construction period and then reduced to a lower value after the regrading/revegetating is complete.*

Creek Sampling Site	Proposed TDS Criteria (mg/L)	Max TDS from 2000-2012 (mg/L)	Proposed Sulfate Criteria (mg/L)	Max Sulfate from 2000-2012 (mg/L)
RUS-1W	500	220	250	140
RUS-1E	500	280	250	190
RUS-0	500	230	250	160
LUC-0	500	82	250	72
COV-5	500	72	250	16
COV-4	500	84	250	21
COV-3	500	640	250	440
COV-2	500	1500	250	1050
COV-1	500	793	250	538
SCL-1	500	570	250	430
SCL-0	500	94	250	63
CRL-4S (mean)	500	100	250	62
CRL-4B (mean)	500	120	250	67
CRL-1S (mean)	500	110	250	63
CRL-1B (mean)	500	110	250	66
REY-3	500	400	250	230
REY-2	500	240	250	150

ADEQ's Response: 35a) ADEQ concurs that the stream segments not impacted by the mine and the associated remediation activities do not need to be included in the ElP. ADEQ will request HESI clarify that the EIP does not include those stream segments that are definitively outside the influence of the mine and remediation activities. ADEQ will request HESI provide further specification for where EIP reaches began. This will include but is not limited to Lucinda, Cove, and Scull creeks.

35b) At this time there are portions of the waterbodies surrounding the mine that do not appear to be influenced by the current drainage patterns. However, the facility cannot certify that certain waterbody reaches may not be temporally influenced by remediation activities. These stream reaches are included in EIP due to the potential for impact during remediation activities.

HESI's Response: HESI agrees that in some cases the proposed temporary minerals criteria are higher than maximum concentrations documented in that creek. HESI anticipates that minerals concentrations will increase significantly during remediation, particularly during earthwork activities, due to exposure of pyritic materials, and that these anticipated increases will persist for years; this was the basis for the EIP schedule continuing 6 to 7 years following active remediation activities (see Section 7.0 of the EIP NOI). However, the EIP NOI schedule is necessarily an estimate. HESI anticipates, based on experience at similar sites and similar remediation activities, that this proposed period for stabilization of disturbed/amended spoils will be sufficient. If this time frame is not sufficient to allow stabilization of downstream minerals levels, based on EMP data, HESI may propose an extension of the EIP to properly develop attainable downstream minerals concentrations.

The historical data do not necessarily predict where remediation (i.e., earth disturbing activities) will occur. HESI cannot predict the exact location or to what magnitude increases in minerals concentrations will be observed in response to remediation activities. Therefore, HESI respectfully does not propose to potentially limit or restrict remediation activities by dividing creeks into upstream and downstream sections with lower criteria for some sections.

However, as an ancillary issue resulting from EPA's comment, HESI agrees it would be helpful to identify in more detail the stream reaches to which the proposed criteria will apply. The specific stream reaches to which the proposed criteria apply are as follows:

- Chamberlain Creek from its headwaters to its confluence with Cove Creek;
- Cove Creek from its confluence with Chamberlain Creek to its confluence with the Ouachita River;
- Lucinda Creek from its confluence with Rusher Creek to its confluence with Cove Creek;
- Rusher Creek from the confluence of the east and west forks to its confluence with Lucinda Creek;
- Scull Creek beginning approximately 350 feet upstream of Clearwater Lake to Clearwater Lake (including Clearwater Lake) and from Clearwater Lake dam to the confluence with Reyburn Creek; and
- Reyburn Creek from its headwaters to its confluence with Francois Creek.

These specific reaches have been included in the proposed changes to Regulation No. 2 to narrow and refine where the proposed temporary criteria will apply.

For EPA's additional information, per CAO LIS 16-043, the following monitoring stations apply for each of these stream segments to document compliance with the proposed criteria for these reaches:

- Chamberlain Creek at CHM-0,
- Cove Creek at COV-3,
- Lucinda Creek at LUC-0,
- Reyburn Creek at REY-2, and
- Rusher Creek at RUS-0.

36. *In several instances there are places where a maximum value is listed as less than a number and then an exact number is provided for the mean. This seems to imply that two different techniques were used to measure the concentration of this parameter over the years. Moving forward, as these streams continue to be monitored, a measurement technique that can provide an exact value rather than a less than value*

should be selected. Without an exact value, the effectiveness of the remediation cannot be appropriately assessed.
ADEQ's Response: ADEQ will coordinate with Halliburton to ensure that all analytical methods are conducted with low enough detection limits to provide adequate values for analysis. Additionally, there should be a concise method on the use of non-detect values when determining maximum values and means.
HESI's Response: Please see the response to EPA Comment 33. For the purpose of computing summary statistics, censored data (i.e., results that are below detection limits and therefore reported as "less than" values) are typically given a value according to a rule described in the text. Typical rules for assigning values to censored data include using the detection limit or one-half of the detection limit. Provided that detection limits are appropriate (i.e., less than the applicable water quality criterion or target level), censored data do not prevent assessment of the effectiveness of remediation. For all COCs tested under the EMP, detection limits will be at or below the level necessary to determine if RADD goals are being met.

37. *Is there any data for pH in Scull Creek? (pg. 39)*
ADEQ's Response: Appendix E. page 41 of 46, page 43 of 46 have pH data for site SCL0. Additionally, ADEQ measures pH in Scull Creek quarterly and the data is available upon request.
HESI's Response: pH data for Scull Creek are provided on page 433 of Appendix E, Historical Database.

38. *Please explain why metals weren't assessed in Clearwater Lake? (pg. 40)*
ADEQ's Response: Data from previous investigations are provided in Appendix E, including Clearwater Lake (page 33 and 34 of 46). Additionally, metals were not discussed in the EIP NOI since limits on metal discharge are not being altered in this rulemaking.
HESI's Response: Metals data for Clearwater Lake are provided on pages 425 and 426 of Appendix E, Historical Database. These data were reviewed during the Site Investigation (see Appendix A of the EIP NOI, Section 5.4.1) and were determined to indicate ARD impacts to the lake (see the first paragraph on page 5-19 of the SI Report).

39. *Is there any pH data for Reyburn Creek? (pg. 41)*
ADEQ's Response: Appendix E. page 35 of 46, page 37 of 46 have pH data for sites REY1 and REY2. ADEQ measures pH in Reyburn Creek quarterly and the data is available upon request.
HESI's Response: pH data for Reyburn Creek are provided on p. 427 of Appendix E, Historical Database.

40. *Are the bench sheets available for the WET testing that was performed? (pg. 42)*

ADEQ's Response: The WET tests were conducted as part of an ADEQ and EPA cooperative project. EPA Houston lab did not provide ADEQ with bench sheets for these tests. ADEQ was provided with brief final reports which were forwarded to Karen Kesler on July 25, 2016.
HESI's Response: The WET testing referenced in Tables 3.8 and 3.9 was performed on samples collected by ADEQ and submitted to EPA's Houston laboratory. Reports provided by EPA's Houston laboratory do not include bench sheets.

41. *In Table 3.8, on November 3, 2008 there is no value for percent mortality, but it is still marked as significantly different. How is it known that the results were significantly different if the data values are unknown? (pg. 43)*
ADEQ's Response: The * in Table 3.8 is reflective of how EPA Region 6 Houston lab reported the data to ADEQ on page 4 of a 12/5/08 report. Additionally, page 1 of the 12/5/08 report states:
Report Narrative
Ceriodaphnia dubia and Pimephales promelas:
After 24 hours, the test showed total mortality for both species of test organisms exposed to the Chamberlin Creek water sample tested (0811002-01).
HESI's Response: The data tables of the original laboratory report only contained the asterisks indicating statistically significant differences. A review of the narrative text from the laboratory report showed that the mortality for both species was 100%.

42. *The language indicating significance is inappropriate for the toxicity data tables. It states "*Significantly different ($p \geq 0.95$) from control." If the p value was greater than or equal to 0.95, than these values would not be significantly different; the p value should be less than 0.05 to indicate a statistically significant difference. After speaking to the EPA Houston Lab it appears that they are determining significance by seeing if the data falls outside of the 95% confidence interval. This footnote should be corrected to appropriately indicate how significance was determined. (pg. 43)*
ADEQ's Response: The footnote for Tables 3.8 and 3.9 are reflective of how EPA Region 6 Houston lab reported toxicity data to ADEQ. The Department will request EPA Houston Lab clarify "*Significantly different ($p \geq 0.95$) from control," when/if ADEQ receives 96 hour acute toxicity test data as part of future cooperative sampling projects.
HESI's Response: EPA's comment is noted. Statistical significance is based on a statistical test that is appropriate for the characteristics of the data. It is not possible to capture in a single footnote how statistical significance is determined for all data because different data sets often require different statistical procedures. The original laboratory report must be consulted to determine the actual test used to determine statistical

significance for any given test. HESI reproduced these data from a joint effort by EPA and ADEQ and is not, therefore, qualified or authorized to change the results. HESI agrees with the commenter that the reference to statistical significance should read, "Significantly different ($p<0.05$) from the control."

43. *In Table 3.9, please provide the bench sheets for the 3/23/2009 toxicity test. It is surprising that 47.5% mortality was not significantly different from the control. EPA would like to see the bench sheets to review the amount of variation between the samples and review the amount of mortality present in the controls. (pg. 43)*
ADEQ's Response: The WET tests were conducted as part of an ADEQ and EPA cooperative project. EPA Houston lab did not provide ADEQ with bench sheets for these tests. ADEQ was provided with brief final reports which were forwarded to EPA Region 6 on July 25, 2016.
HESI's Response: Reports provided by EPA's Houston laboratory do not include bench sheets, nor do they include information that allows a review of variability among test replicates. Since the tests only involve a single sample, there is no variability among samples to review. However, the data table and narrative text in the laboratory report received from EPA for that sampling event do state that the value of 47.5% mortality was not statistically significant as compared to the control. The report provided a result for a t-test that showed the t-statistic as less than the critical t-value, which indicates that the result was not statistically significant. However, since the control had no mortality (and therefore its variance was equal to zero), it is unclear how a t-test could have been performed. FTN was unable to contact EPA staff to clarify the results at the time the results were received.

44. *In section 3.3.1, please state when this fish sampling was conducted.*
ADEQ's Response: Section 3.3 states that biological sampling of waterbodies occurred in April 2012. Specifically, fish sampling occurred April 25-26, 2012.
HESI's Response: The first paragraph of Section 3.3 of the EIP NOI states that biological sampling was conducted in April 2012. Fish were sampled on April 25 and 26, 2012.

45. *Please provide the lab sheets for the WET testing results presented in Table 5.1. The discharge monitoring reports (DMR) data appendix only provides the lab sheets for the water chemistry data and not for the WET testing. (pg. 50)*
ADEQ's Response: The Department will request HESI submit the requested data if available.
HESI's Response: Reports prior to April 2008 were not scanned by the laboratory that performed the tests, but reports for tests from April 2008

through June 2012 were obtained. Many of the laboratory reports for tests performed from 2003 through 2008 were located on-site. The available laboratory reports are attached.

46. *During what years was the water treatment system operational? DMR values from Outfall 001 seem to indicate that it was operational from 2003 to 2012, but with various points of nonoperation within that time frame. Please indicate when the plant was and was not operational and why operation was suspended during this time.*

ADEQ's Response: The facility was in operation from June 2003 until September 2012. The facility ceased operation in August 2013 and did not discharge again until August 2016. The Department has monthly DMR data for the June 2003 until September 2012 discharge period and notes the following periods of no discharge: August – October 2006, June – October 2008, August – November 2010, and August – October 2011. These periods are during the discharge period where "An extremely low flow rate of approximately 25-50 gpm of treated water may be discharged during the July-October period to improve water quality of Chamberlain and Cove Creek."

HESI's Response: The water treatment system was operational between July 2003 and June 2012 and has been operational since mid-August 2016. As discussed in the response to EPA Comment 1, Outfall 001 discharges using an HCR according to the flow rate in Cove Creek. In order to meet the water quality criteria in Cove Creek, discharge is adjusted (or discontinued) at times of lower flows in Cove Creek. Regarding months for which DMR data were not included in Table 5.1, Outfall 001 was not discharging due to low flow in Cove Creek for 10 months from July 2003 through June 2012. However, during the process of addressing this comment, two clarifications/corrections were identified and are shown in the table attached to these responses: (1) additional data from tests conducted during that period were discovered from DMR and laboratory records that were not included when originally developing Table 5.1 of the EIP NOI; and (2) the March 2005 result was one of three consecutive results resulting in toxicity to both organisms (due to a suspected pathogen; see Section 5.1 of the EIP NOI) and should not have been included in the original table. A revised table is attached and includes the lethal and sub-lethal no-observed-effect concentrations (NOECs) for each organism and the associated dissolved minerals values. Note that the additional WET testing results showed both lethal and sub-lethal NOECs of 100% effluent. When the minerals data associated with the additional tests are included in the proposed criteria calculations, using the same approach as was used in the EIP NOI, the new 95th percentile values are slightly higher (<10 mg/L) for both TDS and sulfate. HESI does not wish to amend the proposed criteria to reflect the less-stringent values.

47. *Was any chronic WET testing performed? If so, what were these results? The 2008 permit indicates that WET testing for growth for fathead minnows and reproduction for* Ceriodaphnia dubia *were supposed to be conducted. Please provide the results from that testing. (pg. 50)*
ADEQ's Response: As part of the permit requirements, chronic WET testing was conducted using Fathead minnow and *C. dubia*. The Department has records for chronic (lethal and sub-lethal endpoints) WET tests conducted by the facility from June 2003 until August 2013. The facility ceased operation in August 2013 and did not discharge again until August 2016. A summary of the WET test data is available upon request.
HESI's Response: Table 5.1 showed the results of chronic WET testing performed according to the NPDES permit for the facility. The attached table and laboratory reports provide the results of chronic WET testing from July 2003 to June 2012, including the dates that were not included in Table 5.1 (see the response to EPA Comment 46).

48. *Please also provide the minerals, pH, and metals DMR data for all of the WET tests performed while the plant was operational. Please include this data for tests where toxicity was and was not present. (pg. 50)*
ADEQ's Response: The Department will request HESI submit the requested data if available.
HESI's Response: The minerals values listed in Table 5.1 were measured from samples collected concurrently (or nearly so) with samples for WET testing. The DMR data reported for minerals, pH, and metals reflect averages and maximums from samples collected during each month. Table 5.1 in the EIP NOI and the attached table provide the measured minerals concentrations associated with the WET testing samples. DMR data for pH, metals, and minerals are available through EPA's ECHO database.

49. *Please justify why the secondary drinking water standards for TDS and sulfate are used as the criteria for Lucinda Creek, Rusher Creek, Scull Creek, Clearwater Lake, and Reyburn Creek when the most sensitive use is aquatic life. How are these criteria protective of aquatic life? (pg. 55)*
ADEQ's Response: The secondary drinking water standards are identical to the criteria in Reg. 2.511(C); 250, 250, 500 mg/L for chlorides, sulfates, and total dissolved solids, respectively. Waterbodies without site specific criteria listed in Reg. 2.511(A) are assessed against Reg. 2.511(C). The effectiveness of the criteria to protect aquatic life was evaluated in the SI and will be evaluated again in the EMP.
HESI's Response: Biological data collected during the site investigation (see Appendix A of the EIP NOI) were the basis for the statement on page 55 referring to aquatic life protection. The proposed criteria for minerals were determined to be protective of aquatic life during the SI. Use of secondary drinking water standards for minerals is also consistent with ADEQ's 303(d) assessment methodology for streams without site specific minerals standards when evaluating for aquatic life impairment. Aquatic

life protection will continue to be evaluated through the EMP in accordance with the RADD.

50. *Please discuss what the anticipated time frame is for meeting metals and pH criteria.*
ADEQ's Response: Metals criteria are not expected to be met site-wide until the remedial construction activities are complete. With the proposed schedule, that should be the year 2020. The EMP will be used to track progress towards the remedial action objectives and keep the project moving forward.
HESI's Response: The RADD provides the anticipated time frame for meeting metals and pH criteria. The EIP process, and the associated proposed temporary water quality criteria for dissolved minerals, is anticipated to last between 12 and 13 years (see Section 7.0 of the EIP NOI).

The proposed effective date is pending legislative review and approval.

FINANCIAL IMPACT: There is no financial impact.

LEGAL AUTHORIZATION: Pursuant to Arkansas Code Annotated § 8-4-201(b)(1)(A), the Arkansas Pollution Control and Ecology Commission is given and charged with the power and duty of promulgating rules and regulations, including water quality standards and the classification of the waters of the state and moratoriums or suspensions of the processing of types or categories of permits, implementing the substantive statutes charged to the Department for administration. *See also* Ark. Code Ann. § 8-4-202(b)(3) (providing that the Commission's rules and regulations may, among other things, prescribe water quality standards, performance standards, and pretreatment standards). The instant proposed rule changes were initiated by a third-party, Halliburton Energy Services, Inc. Any person shall have the right to petition the Commission for the issuance, amendment, or repeal of any rule or regulation. *See* Ark. Code Ann. § 8-4-202(c)(1).

3. DEPARTMENT OF FINANCE AND ADMINISTRATION, REVENUE DIVISION (Michelle Baker)

a. SUBJECT: Rule 2016-3: Standard Mileage Rates for Income Tax Purposes

DESCRIPTION: The following sets the standard mileage rates effective January 1, 2017 through December 31, 2017 for income tax purposes as follows:

1. For employees or self-employed individuals, the rate will decrease by .5¢ from 54¢ to 53.5¢ per mile.

2. For transportation expenses deductible as medical or moving expense, the rate will decrease by 2¢ per mile from 19¢ to 17¢ per mile.

3. For charitable organizations, the rate will remain the same at 14¢ per mile.

This will coordinate with changes to the change in the allowable federal rate.

PUBLIC COMMENT: A public hearing was held on February 7, 2017. The public comment period expired on March 9, 2017. The department received no public comments.

Michael Harry, attorney with the Bureau of Legislative Research, asked the following:

In reviewing the rule that was filed with our office last week, I noticed a typo. The rule states that the mileage rate will be **increased** by .5 rather than **decreased**. I wasn't sure if that had been brought up previously or not.

Response: That typo was located in the rule summary statement; an amended summary statement will be filed with the correct changes.

The proposed effective date is pending legislative review and approval.

FINANCIAL IMPACT: It will cost less than $10,000 for the current fiscal year and less than $10,000 for the next fiscal year in state general revenue.

LEGAL AUTHORIZATION: Arkansas Code Annotated § 26-18-301 states the Director shall "administer and enforce the provisions of every state tax law and when necessary shall promulgate and enforce the rules and regulations."

Specifically, Ark. Code Ann. § 26-51-423(a)(3) states that the Director of the Department of Finance and Administration has the authority to determine the deduction for vehicle miles.

4. DEPARTMENT OF HUMAN SERVICES, BEHAVIORAL HEALTH (Robert Nix)

a. SUBJECT: DHS Behavioral Health Provider Certification Manuals and Forms

DESCRIPTION: These Behavioral Health Provider Certification Manuals are required to implement the previously approved Behavioral Health Transformation package that was filed with the Secretary of State's Office on December 27, 2016 and given rule number 016.06.16-024. These manuals set out the requirements for certification to provide services as allowed under the transformation package.

These certification manuals and accompanying forms are necessary to implement the previously approved Behavioral Health Transformation package which accomplishes the goals within the Behavioral Health System. The rules are necessary t ensure that behavioral health care reimbursed by Medicaid is:

1, Family/consumer-driven and person-centered, to support and promote evidence-based, recovery-oriented practices that guide service delivery and payment efficiency;

2. Provides customized, culturally and linguistically competent, community-based services;

3. Offers the least restrictive care;

4. Utilizes a team-based approach to treatment decisions to address service needs; and

5. Ensures services are high quality based on data from outcomes and evaluation tools.

PUBLIC COMMENT: No public hearing was held. The public comment period expired on May 11, 2017. The department received the following comments:

Jamie Frank

Comment: In Independently Licensed Practitioner Manual, Page 10, item D, requirement to provide individual and family therapy, as well as pharmacologic management services were not previously a requirement made of Licensed Psychologists who provided only assessment/testing services.

Will this exclusion remain true moving forward?

Response: The intent of the Behavioral Health transformation within Arkansas is to ensure that Psychological Testing is a component of determining treatment needs as part of a continuum of treatment. As psychologists can provide multiple other services within Tier 1 of the Outpatient Behavioral Health Services program, DHS does not want psychological testing to occur outside of a treatment regimen. There is nothing that would limit a psychologist from conducting psychological testing for Behavioral Health Agency clients or based upon referrals from treating practitioners. If the psychologist cannot provide the required individual and family therapy for clients being tested, as well as have pharmacologic management service provisions for clients, then they will not be allowed to be certified as an independently licensed practitioner.

Comment: Why is there not a separate manual for Licensed Psychologists and no mention is made of services provided by Neuropsychologists or Neuropsychological Technicians which are licensed in this state?

Response: Due to changes within the Medicaid program, Licensed Psychologists are considered Independently Licensed Practitioners which can provide services independently of working for a Behavioral Health Agency. The allowable services to be billed by Independently Licensed Practitioners are contained within the Outpatient Behavioral Health Services (OBHS) Medicaid manual and do not include anything outside of those allowable services.

Lynley Christian

Comment: Until a few months ago I had been a LMHP and had a private practice Medicaid number. Since I rarely had requests for services from Medicaid recipients and the price structure was so low, I determined to let that go. While globally I agree with the new regulations, as it is bringing competition to RSPMI companies, by bringing each practice site and practitioner up to Joint Commission standards, the reality is that it will reduce good individual providers. I've been providing Mental Health services as a licensed professional for 25 years. As a private practitioner, a 1 man band so to speak, the manpower in me will not be able to invest or maintain this new design. I at least believe I have a great track record in providing excellent services and this is just going to close me out.

Which brings me to the paragraph defining Sites and a question: It clearly states that accepted sites include MD's, psychologist offices and clearly excludes schools, long term care facilities and childcare centers. My question is how are home based practices rated? Certain criteria such as separate entrance, security of records, etcetera or are they also not

accepted at all?

Response: The definition of site means a distinct place of business dedicated to the delivery of Outpatient Behavioral Health Services. Each site where an Independently Licensed Practitioner performs services at must be certified by the Division of Behavioral Health Services. There is no restriction on home based practices and it is not implied within the policy. A new requirement for Independently Licensed Clinicians is that their site will be inspected in person prior to being issued a certification by DHS. The site requirements are explained in Section X. of the proposed rules and include the criteria necessary for certification. These requirements are for certification by DHS to become enrolled as a Medicaid provider.

Roland Irwin, Mid-South Health Systems

Therapeutic Communities Certification Manual

Comment: 113.000 (b): We believe a staff-to-client ration of 1 staff to every 4 clients (8:00 a.m. – 5:00 p.m.) is adequate to provide necessary services and ensure client and staff safety. This ration also works nicely with a 16-bed unit.

Response: DHS is in agreement with this recommendation and has amended the certification manual to read:
(a) A Level 1 Therapeutic Community shall have no less than the following staff-to-client ratios to ensure safety of clients receiving services:

a. 1 staff member for every 4 clients during daytime (8:00 A.M. – 5:00 P.M.)

b. 1 staff member for every 8 clients during evening and overnight (5:00 P.M to 8:00 A.M.)

Comment: 115.000 (b): This section stipulates minimum hours per week of mental health professional services to be provided to each client. Based on our assessment these services can generally be covered in a 16-bed program with 3 full time therapists. However, in order to ensure that these requirements are met every single week over an extended period, we will have to employ an additional therapist. For example, in the event that a therapist is a scheduled for a week's vacation, and another therapist unexpectedly becomes ill that same week, it would not be possible to provide the full 10 hours of mental health professional services during that

particular week. We recommend your consideration of the following options:

a. Require that 10 or more mental health professional hours be provided during xx percent of all weeks during each quarter of treatment (or during the client's episode of care). During weeks when the 10 hours of mental health professional services are not provided, each client must still receive a minimum of 42 hours of mental health treatment, OR

b. Require that each client receive an average of xx hours of mental health professional treatment each week. The average would need to be lower than 10 hours, because it would be nearly impossible to exceed 10 hours per client in any week with a mental health professional staffing pattern that is financially feasible.

Response: DHS is in agreement with Option 1 and have added the following sentence to Section 115.000 of the certification manual "The Therapeutic Community must ensure that 10 hours of Professional Services are provided during 90% of all weeks during each quarter of treatment of the client."

Partial Hospitalization Certification Manual

Comment: 111.000: This section states the Registered Nurse is one of the five types of allowable staff that can be used to meet the ratio of 1 staff to every 5 clients. Please clarify if a Registered Nurse with psychiatric experience is allowed to provide a portion of the required 90 minutes of "documented service provided by a Mental Health Professional." I was unable to find where the term 'Mental Health Professional' excludes Registered Nurse, in either the Partial Hospitalization Certification Manual or the Outpatient Behavioral Health Services Manual.

Response: An RN is allowable meet the staff ratio of 1 to every 5 clients, but cannot provide Mental Health Professional services as they are not allowed to provide those services within the OBHS manual.

Behavioral Health Acute Crisis Unit Certification Manual

Comment: 111.000: While most admissions will be resolved within 4 days, our experience with crisis units indicates that some admissions will require considerably longer to reach stability. We understand that the expectation is that those requiring longer stays will be transferred to inpatient psychiatric hospitals. However, in some cases there will be no beds immediately available. Because of this, we ask that you consider implementing an option for extension of the 4-day limit.

Response: Yes, extension of benefits will be available based upon medical necessity.

Comment: 114.000 (E)(3): This section states that medical detoxification is a required service in Crisis Units. While we understand the importance of medical detox, we believe this requirement will make the successful development of Crisis Units across the state more difficult at best. Obtaining sufficient psychiatric coverage will be difficult due to this requirement.

Response: DHS does not intend for medical detoxification to be a required service within an Acute Crisis Unit. The sentence in 114.000 (E)(3) has been moved from under (e) Services shall minimally include, to a separate section in (f) which now states "Medically-supervised and co-occurring disorder capable detoxification may be provided in an Acute Crisis Unit if appropriately staffed and in compliance with procedures outlined in the Arkansas DHS Regional Alcohol and Drug Detoxification Manual.

Julie Meyer, PFH

Therapeutic Communities Certification

Comment: Will providers be required to be certified as a Behavioral Health Agency under the Behavioral Health Agency Certification policy to become certified as a provider of Therapeutic Community services?

Response: All existing certified RSPMI sites as of July 1, 2017 will be grandfathered in as Behavioral Health Agencies. DHS will allow sites to who are certified as a Therapeutic Community to provide the Therapeutic Communities service even if the entire agency has not switched from providing Rehabilitative Services for Persons with Mental Illness (RSPMI) services to Outpatient Behavioral Health Services (OBHS).

Comment: "Mental Health Paraprofessional" language is still located within the definition of "Qualified Behavioral Health Provider" on page 3.

Response: The sentence under #4 for the "Qualified Behavioral Health Provider" definition has been amended to read "Acknowledges in writing that all qualified behavioral health provider services are controlled by client care plans and provided under the direct supervision of a mental health professional." This sentence previously read "Acknowledges in writing that all mental health paraprofessional services are controlled by client care plans and provided under the direct supervision of a mental health professional.

Comment: How will the State determine if an individual qualifies for Level 1 or Level 2 Therapeutic Communities?

Response: The determination between Level 1 and Level 2 Therapeutic Communities will be based upon results from the independent assessment and the placement that the client needs.

Comment: What is the definition of "secure facility" in regards to the requirements of Level 1?

Response: A "secure facility" means a locked facility.

Comment: Can Level 1 and Level 2 clients reside in the same setting?

Response: No. A Level 1 Therapeutic Community client must reside in a locked facility. A Level 2 Therapeutic Community client cannot reside in a locked facility.

Comment: What is the staffing ratio expectations for both levels of Therapeutic Communities in the evening and overnight?

Response: The staffing ratio is spelled out in Section 113.000 for Level 1 Therapeutic Communities and Section 118.000 for Level 2 Therapeutic Communities. For Level 1 Therapeutic Communities, 1 staff member for every 4 clients during daytime (8:00 A.M. – 5:00 P.M.) and 1 staff member for every 8 clients during evening and overnight (5:00 P.M to 8:00 A.M.). For Level 2 Therapeutic Communities, 1 staff member for every 8 clients during daytime (8:00 A.M. – 5:00 P.M.) and appropriate staff supervision shall be documented in policies and procedures of the Therapeutic Community for clients during evening and overnight (5:00 P.M to 8:00 A.M.). Level 2 Therapeutic Communities must have the ability for residents to be seen by appropriate caregivers when necessary 24 hours a day. Appropriate supervision must be documented and maintained at Level 2 Therapeutic Communities.

Comment: Will 911 clients be presumptively eligible for Therapeutic Communities?

Response: During the initial phases of the Behavioral Health transformation, 911 clients will be presumptively eligible in Tier 3 for Therapeutic Communities.

Comment: Will 911 clients be subject to an Independent Assessment?

Response: Yes, 911 clients will still receive an Independent Assessment.

Comment: Will 911 clients be presumptively eligible for a specific level of Therapeutic Communities?

Response: Depending on the level of care necessary for a 911 client, presumptive eligibility will be based upon the level of acuity of the client. If a 911 client needs services in a locked facility, then that client would be presumptively eligible for Level 1 Therapeutic Communities.

Comment: Since rates for Therapeutic Communities are being promulgated within this policy, will rates for Acute Crisis Units, Partial Hospitalization, and Outpatient Behavioral Health Services be available for public comment and then promulgated?

Response: Rates are not being promulgated for Therapeutic Communities in this promulgation. Rates aren't promulgated but are posted for notice only--the notice includes a link to the site showing proposed rate sheets, then once the related underlying rule or methodology is promulgated and effective the rates are also effective and posted to the "fee schedules" section on the Medicaid site.

Comment: How were the rates for Therapeutic Communities determined?

Response: The rates for Therapeutic Communities were determined by the following methodology as outlined within the Arkansas State Plan, "Based on the information gained from the peer state analysis and the consideration of adjustment factors such as Bureau of Labor Statistics (BLS) along with Geographic Pricing Cost Index (GPCI) to account for economic differences, the state was able to select appropriate rates from fee schedules published by peer states. Once this rate information was filtered according to Arkansas requirements a "state average rate" was developed. This "state average rate" consisting of the mean from every peer state's published rate for a given procedure served as the base rate for the service, which could then be adjusted by previous mentioned factors (BLS), (GPCI) etc."

Behavioral Health Acute Crisis Unit Certification

Comment: Will providers be required to be certified as a Behavioral Health Agency under the Behavioral Health Agency Certification policy to become certified as a Behavioral Health Acute Crisis Unit provider?

Response: All existing certified RSPMI sites as of July 1, 2017 will be grandfathered in as Behavioral Health Agencies. DHS will allow sites to who are certified as an Acute Crisis Unit to provide the Acute Crisis Unit service even if the entire agency has not switched from providing

Rehabilitative Services for Persons with Mental Illness (RSPMI) services to Outpatient Behavioral Health Services (OBHS).

Comment: Will Acute Crisis Units have to be licensed as a substance abuse provider through the Division of Behavioral Health Services?

Response: The Acute Crisis Unit must be certified by DHS as an acute crisis unit. If the acute crisis unit will provided detoxification services, they will be required to be licensed by DHS as defined in the Regional Alcohol and Drug Detoxification Manual.

Comment: Does the Division of Behavioral Health Services plan to update the Arkansas DHS Regional Alcohol and Drug Detoxification Manual?

Response: No

Comment: Will staff within an Acute Crisis Unity have to be trained and certified as a Regional Detoxification Specialist?

Response: If the Acute Crisis Unit will be providing detoxification services, yes, the staff would have to be trained and certified.

Comment: "Mental Health Paraprofessional" language is still located within the definition of "Qualified Behavioral Health Provider" on page 5.

Response: The sentence under #4 for the "Qualified Behavioral Health Provider" definition has been amended to read "Acknowledges in writing that all qualified behavioral health provider services are controlled by client care plans and provided under the direct supervision of a mental health professional." This sentence previously read "Acknowledges in writing that all mental health paraprofessional services are controlled by client care plans and provided under the direct supervision of a mental health professional.

Comment: What licensure requirements/qualifications are necessary for nurses in the Acute Crisis Unit setting?

Response: A nurse in an Acute Crisis Unit must be an Arkansas licensed nurse in good standing.

Comment: Is a nurse required to be on-site 24 hours a day?

Response: Yes

Partial Hospitalization Certification

Comment: Will providers be required to be certified as a Behavioral Health Agency under the Behavioral Health Agency Certification policy to become certified as a provider of Partial Hospitalization?

Response: All existing certified RSPMI sites as of July 1, 2017 will be grandfathered in as Behavioral Health Agencies. DHS will allow sites to who are certified as a Partial Hospitalization program to provide Partial Hospitalization services even if the entire agency has not switched from providing Rehabilitative Services for Persons with Mental Illness (RSPMI) services to Outpatient Behavioral Health Services (OBHS).

Comment: The certification policy outlines the requirement for 1:5 staffing ratio. Why aren't QBHPs included in the staff-to-patient ratio? See page 6.

Response: The staff required to meet the 1:5 staffing ratio are those listed on Page 6 in Section 111.000.

Behavioral Health Agency Certification

Comment: How will rates be determined for Outpatient Behavioral Health Services?

Response: The rates for Outpatient Behavioral Health Services were determined by the following methodology as outlined within the Arkansas State Plan, "Based on the information gained from the peer state analysis and the consideration of adjustment factors such as Bureau of Labor Statistics (BLS) along with Geographic Pricing Cost Index (GPCI) to account for economic differences, the state was able to select appropriate rates from fee schedules published by peer states. Once this rate information was filtered according to Arkansas requirements a "state average rate" was developed. This "state average rate" consisting of the mean from every peer state's published rate for a given procedure served as the base rate for the service, which could then be adjusted by previous mentioned factors (BLS), (GPCI) etc."

Comment: Where can rates for Behavioral Health Agency services be located?

Response: Rates are posted for notice only--the notice includes a link to the site showing proposed rate sheets, then once the related underlying rule or methodology is promulgated and effective the rates are also effective and posted to the "fee schedules" section on the Medicaid site.

The rates have been shared multiple times with a variety of stakeholders anytime that they were requested and are included in response to this question.

Comment: What are the staffing requirements for Intensive Outpatient Substance Abuse treatment?

Response: The requirements for Intensive Outpatient Substance Abuse Treatment are located in the Outpatient Behavioral Health Services Medicaid manual.

Comment: Can an agency list more than one Clinical Director for their organization?

Response: Yes.

Comment: Will there be a separate certification process promulgated for Planned Respite?

Response: Yes.

Comment: Will the certification policies for Peer Support Specialists, Family Support Partner, and Youth Support Partner be promulgated?

Response: Certification requirements for these specialties are currently being developed by DHS. Those requirements will be shared when finalized.

Comment: To provide co-occurring or substance abuse services, will providers have to be licensed as a substance abuse provider by the Division of Behavioral Health Services?

Response: A Behavioral Health Agency will have to be licensed as a substance abuse provider by the Division of Behavioral Health Services.

Comment: What is considered "standardized mapping application"?

Response: A standardized mapping application could include Google Maps, MapQuest, etc.

Comment: What is the purpose of the 50 mile radius policy in the Outpatient Behavioral Health Services program?

Response: This ensures that if services are necessary for individuals, particularly in a crisis situation, that the provider would be able to make a reasonable accommodation to seek out and assist the client within a reasonable time frame.

Comment: The language within Section V.I.2. does not align with current CARF Accreditation standards and language.

Response: National Accreditation is required to be certified as a Behavioral Health Agency. DHS recognizes CARF as a national accreditation entity using this existing language within the RSPMI program.

Comment: Please provide details on how and when providers will transition from RSPMI to the BHA certification.

Response: All existing certified RSPMI sites as of July 1, 2017 will be grandfathered in as Behavioral Health Agencies. The agency must then inform DHS and its contractors when they intend to switch to providing OBH services. Agencies can continue to provide RSPMI services under existing RSPMI rules until June 30, 2018. The presumption will be that a provider will provide RSPMI services unless they specifically notify DHS and its contractors that they will now provide OBH services.

Jared Sparks, Ozark Guidance

Partial Hospitalization

Comment: Section 111.000, Service Definition – Partial Hospitalization – "This service shall include at a minimum, individual therapy, group therapy, and psychoeducation. Partial Hospitalization shall be at a minimum (5) hours a day of which 90 minutes must be a documented service by a Mental Health Professional. If a beneficiary receives other services during the week but also receives Partial Hospitalization, the beneficiary must receive, at a minimum, 20 documented hours of services on no less than 4 (four) days in that week.

Does the individual therapy, group therapy, and psychoeducation have to occur each day or do those services only have to be part of the service array that must be provided during the week or course of treatment?

Response: Individual therapy, group therapy, and psychoeducation do not have to occur each day. These services are included as part of the service array that must be provided during the week and course of treatment.

Comment: Does the 90 minutes of MHP service have to be provided each day or can it average to 90 minutes a day? For example, if group and family therapy occurred one day, resulting in 120 minutes of services, can another day only have 60 minutes of service provided by an MHP?

Response: 90 minutes of MHP services MUST occur each day with documentation of circumstances arise required. The Partial Hospitalization program must adhere to the OBHS manual requirements. Documentation of rationale for not meeting the minimum requirements is required.

Comment: Does the "5 hours a day" only consist of services identified in the OBHS manual or are there other acceptable structured activities, such as education… or what we currently provide as rehabilitative day service for children? For example, would it be acceptable to provide three hours of education by a certified teach and two hours of MHP services per day?

Response: No, the 5 hours a day of services must be from the services identified within the OBHS manual.

Comment: Are there OBHS services or other activities that QBHPs can provide in Partial Hospitalization that contributed to the minimum five hours of services a day?

Response: Yes, QBHPs can provide allowable QBHP services in Partial Hospitalization that contribute to the minimum five hours of services a day.

Comment: Do all services provided to clients receiving Partial Hospitalization fall under Partial Hospital Certification policies? For example, can medical services be provided and billed separately from Partial Hospitalization if a client is receiving Partial Hospitalization?

Response: If billing under the Outpatient Behavioral Health Services (OBH) program, a beneficiary cannot receive any other OBH services on that same date as the Partial Hospitalization rate is a per diem which would include all OBH services. This does not restrict the beneficiary from receiving medical services outside of the OBH program.

Comment: If the per diem is not used because a client does not participate in the full 5 hour day, can they provide bill for individual services as delivered?

Response: The only way that a provider can be reimbursed for services provided in the Partial Hospitalization service is if they meet the requirements of the service definition. Providers are required to document any instances in which the minimum amount of hours are not met.

Comment: What is the minimum hourly required participation to receive per diem reimbursement for a week of services? For example, if an adult client leaves one hour early on two days of the week, resulting in the client receiving 18 of the 20 hours of available services, is that client still eligible for the per diem? If not, how is that reimbursed?

Response: In order to be reimbursed, the provider must meet the requirements of the service definition. If the beneficiary receives other

OBH services during the week but also receives Partial Hospitalization, the beneficiary must receive, at a minimum, 20 documented hours of service on no less than 4 (four) days in that week. Documentation of not meeting the minimum requirement is necessary.

Comment: 113.000 – Organization Structure and 117.000 Facility Environment

(a) The partial hospitalization unit shall be a separate, identifiable organizational unit with its own director, or supervisor, and staffing pattern…
(b) A partial hospitalization program is defined by its staff and organizational structure rather than by a specific building or facility.

Do the clients receiving partial hospitalization treatment have to receive services separately from other levels of care? For example, can partial hospitalization clients be in the same psychotherapy group with clients of a therapeutic day treatment? (In the proposed model, PH clients would routinely transition to and from TDT) If clients are not allowed to share age and treatment appropriate services, specific services such as the required group may not be available or effective. For example, there may be 10 partial hospitalization clients sharing a building with 60 therapeutic day treatment clients. If PH and TDT clients are not able to share the same group, there may not be enough age appropriate PH only clients to have a safe and effective group. You could conceivable be required to have 7 and 17 year olds in the same group therapy to meet the service definition requirement of PH.

Response: The two statements from the manual mean that a Partial Hospitalization program shall be a separate unit, with separate staffing patterns, than other programs offered by providers. This does not mean that PH clients may only receive services with other PH clients. Age appropriate group therapy requirements still exist and programs shall make accommodations for that within their existing clientele.

Comment: If clients are able to receive services outside of those identified in OBHS as part of the 5 hour day, may those services be provided with clients from another level of care. For example, could PH clients share the same classroom with age related Therapeutic Day Treatment clients?

Response: Allowable services for meet the 5 hour day are those included within the OBHS manual, which also specified age requirements and restrictions for those services.

David Kuchinski, Birch Tree

Comment: If you total the available reimbursement for the service array for Tier 2 averaged over a year that amount comes out to $35-$45 per day. As a result, there is a significant drop off in service availability from Level 2 Therapeutic Communities at $175 a day to Tier 2 at $35-45 per day as individual's transition to more autonomous living arrangements.
Could an Extension of Benefits be offered for Tier 2 Services based on medical necessity for transition from Therapeutic Communities?

Response: Yes, authorizations for all OBH services are allowed to have extensions of benefits if medically necessary.

Therapeutic Communities Certification Manual

Comment: The progress note log presents potential EHR security rights challenges. Having to allow different roles (MHPP, MHP, MD, etc.) to share a progress note, we'd have to allow each to share security rights, which would be inappropriate for several reasons.
Could it be possible to break out the "log" into a few service groups, in order to maintain security rights by role, all of which would tie together by date of service and all of which would still be reviewed and be "signed off on" by the MHP?

Response: The log is required for purposes of ensuring that clients are receiving services while in a Therapeutic Community. This is particularly necessary for auditing purposes. The way your entity handles the daily service log is completely up to you as long as it is made available to auditing entities when asked.

Comment: Section 114.000, Level 1/2, Physician Services - Psychiatric Nurse Practitioners are not listed in this section and/or other section in this Manual and the other Certification Manuals. Could Psychiatric Nurse Practitioners be added to the pertinent sections or have a definition that defines a "prescriber"?

Response: The following sentence has been added to both Level 1 and Level 2 Physician Services requirements “This service can also be provided by an Advanced Practice Nurse (Adult Psychiatric Mental Health Clinical Nurse Specialist; Child Psychiatric Mental Health Clinical Nurse Specialist; Adult Psychiatric Mental Health APN; Family Psychiatric Mental Health APN) as allowable within the Outpatient Behavioral Health Services Medicaid Manual.“

Comment: Based on the definition of Critical Incidents and the requirements in the standard, "requiring medical care by a physician or nurse or follow-up attention and incidents requiring hospitalization or immediate off-site medical attention", would require a substantially increased volume of reporting.
A suggestion could be that Critical Incidents that meet (1) are documented and monitored internally, with a quality assurance and improvement process that would be made available for review and/or audit by appropriate agency.

Response: This suggestion has resulted in removing (1) from the incidents requiring reporting to DHS. It now states, in a new section, "The Therapeutic Community shall document and monitor internally, with a quality assurance and improvement process that will be made available for review and/or audit by an appropriate agency the following:

(1) Critical incidents requiring medical care by a physician or nurse or follow-up attention and incidents requiring hospitalization or immediate off-site medical attention shall be delivered via fax or mail to DHS Provider Certification within twenty-four (24) hours of the incident being documented."

Comment: Section 168.000 (c) - The requirement that clinical staff be trained in non-violent intervention within 30 and shall occur prior direct patient contact presents challenges to practical application. For example, new hires have contact with patients in new hire training before they receive this training by the end of the week. MHP's could not provide services until training is offered, which may be 1 time per month.
Could the standard be edited to read that until staff received the non-violent training that staff shall only work in proximity of staff with the non-violent training?

Response: No, this is a required training that is necessary prior to client contact.

Comment: Section 172.000 (b) (1) - At our Therapeutic Community sites, we do not "administer medications" because MHPP's are not authorized/licensed to do so. We only administer at our Crisis Unit by RN's.
Could this standard be edited to read "Written procedures for medication administration or monitoring…"?

Response: The sentence has been amended to read "Written procedures for medication administration or monitoring shall be available and accessible in all medication storage areas, and available to all staff authorized to administer medications."

Comment: The Level 2 Services within Therapeutic Communities will work exceptionally well for the majority of Birch members and allowing Birch to operationalize an effective Recovery-oriented treatment milieu. These standards were well thought out and allows the provider to apply best practices for effective ROI. As a result the members will benefit greatly!

Response: Thank you.

Acute Crisis Unit Certification

Comment: It will be an ongoing challenge to resolve all Acute Crisis Unit stays within the 4 day limit due to the following issues;

1. Many of the referrals we accept from ASH and/or private hospitals are not completely stable upon discharge. We at times step an individual down directly to our Crisis Unit because they are not stable to be admitted outside of a locked unit. Further, we have a sizeable group of individuals that at any one time meet criteria to be in a private hospital or ASH, and we manage them between the home branch and the Crisis Unit several times to save the state money and to keep them out of the hospital.

2. Private hospitals only average a length of stay of 5 days due to AMFC limits. Often, we receive our member back from the private hospital just as acute and we'll keep the member at HH until they stabilize further or re-hospitalize.

3. Private hospitals won't accept individuals when their Medicaid days (24) are used up or if they are highly aggressive.

4. ASH is over full! It takes us 2-3 weeks to get individuals accepted to ASH, but only if we swap one of theirs for one of ours. A recent referral remained on the ASH waiting list for 46 days before they were admitted.

Could an Extension of Benefits be offered to extend the 4 day limit for this service based on medical necessity and attempts to hospitalize?

Response: Yes, extension of benefits will be available based upon medical necessity.

Comment: The wording here indicates that medically monitored detoxification would be prescribed as needed and suggests that this would be a mandatory service if the patient needed it. If this is a mandatory service based on need, this would be way out of Birch's level of expertise and would not be able to meet this standard.

If this is interpretation is not correct, could the standard be edited to reflect that the provider has the option of providing this service and/or referring out to an appropriate facility if needed?

Response: DHS does not intend for medical detoxification to be a required service within an Acute Crisis Unit. The sentence in 114.000 (E)(3) has been moved from under (e) Services shall minimally include, to a separate section in (f) which now states "Medically-supervised and co-occurring disorder capable detoxification may be provided in an Acute Crisis Unit if appropriately staffed and in compliance with procedures outlined in the Arkansas DHS Regional Alcohol and Drug Detoxification Manual.

Comment: We also ask for consideration that the medically fragile be eligible for Acute Crisis Units. We provide integrated care for acute, high-risk medical stepdown with our population at the Hope House. We do this because hospitals discharge after significant medical procedures to their home without adequate rehab or trained staff. Due to inability to self-care, immediate medical regression and potential for crisis, we place individuals at Hope House with skilled nursing to rehab and monitor. In our opinion it would be unethical to wait for crisis or regression to occur before we act.

Response: The Acute Crisis Unit is for a behavioral health crisis which is related to acute symptomology. The Acute Crisis Unit is not for a physical health crisis.

Comment: Section 157.000 (c)(1) - Same comment and request for this standard as mentioned above for Therapeutic Communities.

Response: This suggestion has resulted in removing (1) from the incidents requiring reporting to DHS. It now states, in a new section, "The Therapeutic Community shall document and monitor internally, with a quality assurance and improvement process that will be made available for review and/or audit by an appropriate agency the following:

(1) Critical incidents requiring medical care by a physician or nurse or follow-up attention and incidents requiring hospitalization or immediate off-site medical attention shall be delivered via fax or mail to DHS Provider Certification within twenty-four (24) hours of the incident being documented."

Comment: Section 168.000 (c) - Same comment and request for this standard as mentioned above for Therapeutic Communities.

Response: No, this is a required training that is necessary prior to client contact.

Mental Health Council

Comment: Please date each document when it is issued so that providers or potential providers can be sure they are working from the most current document. Please post page numbers on documents. Mission statement was omitted in most recent document.

Response: Effective Date will be added to front page of each manual. Page numbers will be posted on each manual. Mission statement will be not included in certification manuals.

Comment: "Contemporaneous" means by the end of the performing provider's first work period following the provision of care of services to be documented, or as provided in the Outpatient Behavioral Health Services manual, whichever is longer. Can this requirement be more clearly defined? There is no statement in the OBHS Medicaid manual Documentation section referencing when documentation is due.

Response: The definition means that documentation must be completed by the performing provider during the first work period following the provision of care. If documentation timeline changes are added to the OBHS manual, that statement would allow the OBHS manual to determine appropriate documentation timelines.

Comment: Compliance Timeline: DHS may authorize temporary compliance exceptions for new accreditation standards that require independent site surveys and specific subset accreditation. Such compliance exceptions expire at the end of the provider's accreditation cycle and may not be renewed or reauthorized.
Can this sentence be revised for clarity?

Response: This sentence has been in the DBHS RSPMI Certification manual since 2010. The intent is that if a national accreditation body changes their accreditation standards that would, in turn, require an onsite site survey for accreditation, DHS would have the ability to make an exception requiring accreditation for that specific program.

Therapeutic Communities Certification

Comment: The progress note log presents potential EHR security rights challenges. Having to allow different roles (MHPP, MHP, MD, etc.) to share a progress note, we'd have to allow each to share security rights, which would be inappropriate for several reasons.

Could it be possible to break out the "log" into a few service groups, in order to maintain security rights by role, all of which would tie together by date of service and all of which would still be reviewed and be "signed off on" by the MHP?

Response: The log is required for purposes of ensuring that clients are receiving services while in a Therapeutic Community. This is particularly necessary for auditing purposes. The way your entity handles the daily service log is completely up to you as long as it is made available to auditing entities when asked.

Comment: 113.000 (b): We believe a staff-to-client ration of 1 staff to every 4 clients (8:00 a.m. – 5:00 p.m.) is adequate to provide necessary services and ensure client and staff safety. This ration also works nicely with a 16-bed unit.

Response: DHS is in agreement with this recommendation and have amended the certification manual.

Comment: Section 114.000, Level 1/2, Physician Services - Psychiatric Nurse Practitioners are not listed in this section and/or other section in this Manual and the other Certification Manuals. Could Psychiatric Nurse Practitioners be added to the pertinent sections or have a definition that defines a "prescriber"?

Response: The following sentence has been added to both Level 1 and Level 2 Physician Services requirements "This service can also be provided by an Advanced Practice Nurse (Adult Psychiatric Mental Health Clinical Nurse Specialist; Child Psychiatric Mental Health Clinical Nurse Specialist; Adult Psychiatric Mental Health APN; Family Psychiatric Mental Health APN) as allowable within the Outpatient Behavioral Health Services Medicaid Manual."

Comment: 115.000 (b): This section stipulates minimum hours per week of mental health professional services to be provided to each client. Based on our assessment these services can generally be covered in a 16-bed program with 3 full time therapists. However, in order to ensure that these requirements are met every single week over an extended period, we will have to employ an additional therapist. For example, in the event that a therapist is a scheduled for a week's vacation, and another therapist unexpectedly becomes ill that same week, it would not be possible to provide the full 10 hours of mental health professional services during that particular week. We recommend your consideration of the following options:

a. Require that 10 or more mental health professional hours be provided during xx percent of all weeks during each quarter of treatment (or during the client's episode of care). During weeks when the 10 hours of mental health professional services are not provided, each client must still receive a minimum of 42 hours of mental health treatment, OR
b. Require that each client receive an average of xx hours of mental health professional treatment each week. The average would need to be lower than 10 hours, because it would be nearly impossible to exceed 10 hours per client in any week with a mental health professional staffing pattern that is financially feasible.

Response: DHS is in agreement with Option 1 and have added the following sentence to Section 115.000 of the certification manual "The Therapeutic Community must ensure that 10 hours of Professional Services are provided during 90% of all weeks during each quarter of treatment of the client."

Comment: Based on the definition of Critical Incidents and the requirements in the standard, "requiring medical care by a physician or nurse or follow-up attention and incidents requiring hospitalization or immediate off-site medical attention", would require a substantially increased volume of reporting.
A suggestion could be that Critical Incidents that meet (1) are documented and monitored internally, with a quality assurance and improvement process that would be made available for review and/or audit by appropriate agency.

Response: This suggestion has resulted in removing (1) from the incidents requiring reporting to DHS. It now states, in a new section, "The Therapeutic Community shall document and monitor internally, with a quality assurance and improvement process that will be made available for review and/or audit by an appropriate agency the following:

(1) Critical incidents requiring medical care by a physician or nurse or follow-up attention and incidents requiring hospitalization or immediate off-site medical attention shall be delivered via fax or mail to DHS Provider Certification within twenty-four (24) hours of the incident being documented."

Comment: Section 168.000 (c) - The requirement that clinical staff be trained in non-violent intervention within 30 and shall occur prior direct patient contact presents challenges to practical application. For example, new hires have contact with patients in new hire training before they

receive this training by the end of the week. MHP's could not provide services until training is offered, which may be 1 time per month. Could the standard be edited to read that until staff received the non-violent training that staff shall only work in proximity of staff with the non-violent training?

Response: No, this is a required training that is necessary prior to client contact.

Comment: Section 172.000 (b) (1) - At our Therapeutic Community sites, we do not "administer medications" because MHPP's are not authorized/licensed to do so. We only administer at our Crisis Unit by RN's.
Could this standard be edited to read "Written procedures for medication administration or monitoring…"?

Response: The sentence has been amended to read "Written procedures for medication administration or monitoring shall be available and accessible in all medication storage areas, and available to all staff authorized to administer medications."

Partial Hospitalization Certification

Comment: Definition of restraint, "Restraint" refers to manual, mechanical, and chemical methods that are intended to restrict the movement or normal functioning of a portion of the individual's body. For clients: mechanical restraints shall not be used.

We recommend that the word "mechanical" be removed from the restraint list. But leave the sentence – For clients: "restraints shall not be used."

Response: The use of mechanical restraints is not allowed per the certification requirements.

Comment: 111.000 – Service Definition – Partial Hospitalization – First paragraph, last sentence – "If a beneficiary receives other services during the week but also receives Partial Hospitalization, the beneficiary must receive, at a minimum, 20 documented hours of services on no less than 4 (four) days a week." Please clarify in the PH service definition that if the beneficiary is offered services, at least, 4 days a week and does not attend, the services that were provided are to be documented and billed. Note that the beneficiary was scheduled for additional days and did not attend. Document what attempts were made to engage the beneficiary.

Response: If the amount of services required to meet the service are not met, then Partial Hospitalization cannot be billed. Services can be billed

as provided outside of Partial Hospitalization, but in order to be paid the per diem for Partial Hospitalization, the service definition requirements must be met. A provider is required to document if a client does not or cannot participate in treatment and why that level of care continues to be necessary if the beneficiary cannot participate regularly in the program.

Comment: 111.000: This section states the Registered Nurse is one of the five types of allowable staff that can be used to meet the ratio of 1 staff to every 5 clients. Please clarify if a Registered Nurse with psychiatric experience is allowed to provide a portion of the required 90 minutes of "documented service provided by a Mental Health Professional." I was unable to find where the term 'Mental Health Professional' excludes Registered Nurse, in either the Partial Hospitalization Certification Manual or the Outpatient Behavioral Health Services Manual.

Response: An RN is allowable meet the staff ratio of 1 to every 5 clients, but cannot provide Mental Health Professional services as they are not allowed to provide those services within the OBHS manual.

Acute Crisis Unit Certification

Comment: It will be an ongoing challenge to resolve all Acute Crisis Unit stays within the 4 day limit due to the following issues;

1. Many of the referrals we accept from ASH and/or private hospitals are not completely stable upon discharge. We at times step an individual down directly to our Crisis Unit because they are not stable to be admitted outside of a locked unit. Further, we have a sizeable group of individuals that at any one time meet criteria to be in a private hospital or ASH, and we manage them between the home branch and the Crisis Unit several times to save the state money and to keep them out of the hospital.

2. Private hospitals only average a length of stay of 5 days due to AMFC limits. Often, we receive our member back from the private hospital just as acute and we'll keep the member at HH until they stabilize further or re-hospitalize.

3. Private hospitals won't accept individuals when their Medicaid days (24) are used up or if they are highly aggressive.

4. ASH is over full! It takes us 2-3 weeks to get individuals accepted to ASH, but only if we swap one of theirs for one of ours. A recent referral remained on the ASH waiting list for 46 days before they were admitted.

Could an Extension of Benefits be offered to extend the 4 day limit for this service based on medical necessity and attempts to hospitalize?

Response: Yes, extension of benefits will be available based upon medical necessity.

Comment: The wording here indicates that medically monitored detoxification would be prescribed as needed and suggests that this would be a mandatory service if the patient needed it. If this is a mandatory service based on need, this would be way out of Birch's level of expertise and would not be able to meet this standard.
If this is interpretation is not correct, could the standard be edited to reflect that the provider has the option of providing this service and/or referring out to an appropriate facility if needed?

Response: DHS does not intend for medical detoxification to be a required service within an Acute Crisis Unit. The sentence in 114.000 (E)(3) has been moved from under (e) Services shall minimally include, to a separate section in (f) which now states "Medically-supervised and co-occurring disorder capable detoxification may be provided in an Acute Crisis Unit if appropriately staffed and in compliance with procedures outlined in the Arkansas DHS Regional Alcohol and Drug Detoxification Manual.

Comment: We also ask for consideration that the medically fragile be eligible for Acute Crisis Units. We provide integrated care for acute, high-risk medical stepdown with our population at the Hope House. We do this because hospitals discharge after significant medical procedures to their home without adequate rehab or trained staff. Due to inability to self-care, immediate medical regression and potential for crisis, we place individuals at Hope House with skilled nursing to rehab and monitor. In our opinion it would be unethical to wait for crisis or regression to occur before we act.

Response: The Acute Crisis Unit is for a behavioral health crisis which is related to acute symptomology. The Acute Crisis Unit is not for a physical health crisis.

Comment: 114.000 (E)(3): This section states that medical detoxification is a required service in Crisis Units. While we understand the importance of medical detox, we believe this requirement will make the successful development of Crisis Units across the state more difficult at best. Obtaining sufficient psychiatric coverage will be difficult due to this requirement.

Response: DHS does not intend for medical detoxification to be a required service within an Acute Crisis Unit. The sentence in 114.000 (E)(3) has been moved from under (e) Services shall minimally include, to

a separate section in (f) which now states “Medically-supervised and co-occurring disorder capable detoxification may be provided in an Acute Crisis Unit if appropriately staffed and in compliance with procedures outlined in the Arkansas DHS Regional Alcohol and Drug Detoxification Manual.

Comment: Based on the definition of Critical Incidents and the requirements in the standard, "requiring medical care by a physician or nurse or follow-up attention and incidents requiring hospitalization or immediate off-site medical attention", would require a substantially increased volume of reporting.
A suggestion could be that Critical Incidents that meet (1) are documented and monitored internally, with a quality assurance and improvement process that would be made available for review and/or audit by appropriate agency.

Response: This suggestion has resulted in removing (1) from the incidents requiring reporting to DHS. It now states, in a new section, “The Therapeutic Community shall document and monitor internally, with a quality assurance and improvement process that will be made available for review and/or audit by an appropriate agency the following:

(1) Critical incidents requiring medical care by a physician or nurse or follow-up attention and incidents requiring hospitalization or immediate off-site medical attention shall be delivered via fax or mail to DHS Provider Certification within twenty-four (24) hours of the incident being documented.”

Comment: Section 168.000 (c) - The requirement that clinical staff be trained in non-violent intervention within 30 and shall occur prior direct patient contact presents challenges to practical application. For example, new hires have contact with patients in new hire training before they receive this training by the end of the week. MHP's could not provide services until training is offered, which may be 1 time per month. Could the standard be edited to read that until staff received the non-violent training that staff shall only work in proximity of staff with the non-violent training?

Response: No, this is a required training that is necessary prior to client contact.

Cookie Higgins, Centers for Youth and Families

Comment: Please date each document when it is issued so that providers or potential providers can be sure they are working from the most current document. Please post page numbers on documents. Mission statement was omitted in most recent document.

Response: Effective Date will be added to front page of each manual. Page numbers will be posted on each manual. Mission statement will be not included in certification manuals.

Behavioral Health Agency Certification

Comment: "Contemporaneous" means by the end of the performing provider's first work period following the provision of care of services to be documented, or as provided in the Outpatient Behavioral Health Services manual, whichever is longer. Can this requirement be more clearly defined? There is no statement in the OBHS Medicaid manual Documentation section referencing when documentation is due.

Response: The definition means that documentation must be completed by the performing provider during the first work period following the provision of care. If documentation timeline changes are added to the OBHS manual, that statement would allow the OBHS manual to determine appropriate documentation timelines.

Comment: Compliance Timeline: DHS may authorize temporary compliance exceptions for new accreditation standards that require independent site surveys and specific subset accreditation. Such compliance exceptions expire at the end of the provider's accreditation cycle and may not be renewed or reauthorized.
Can this sentence be revised for clarity?

Response: This sentence has been in the DBHS RSPMI Certification manual since 2010. The intent is that if a national accreditation body changes their accreditation standards that would, in turn, require an onsite site survey for accreditation, DHS would have the ability to make an exception requiring accreditation for that specific program.

Partial Hospitalization Certification

Comment: Definition of restraint, "Restraint" refers to manual, mechanical, and chemical methods that are intended to restrict the movement or normal functioning of a portion of the individual's body. For clients: mechanical restraints shall not be used.

We recommend that the word "mechanical" be removed from the restraint list. But leave the sentence – For clients: "restraints shall not be used."

Response: The use of mechanical restraints is not allowed per the certification requirements.

Comment: 111.000 – Service Definition – Partial Hospitalization – First paragraph, last sentence – "If a beneficiary receives other services during the week but also receives Partial Hospitalization, the beneficiary must receive, at a minimum, 20 documented hours of services on no less than 4 (four) days a week." Please clarify in the PH service definition that if the beneficiary is offered services, at least, 4 days a week and does not attend, the services that were provided are to be documented and billed. Note that the beneficiary was scheduled for additional days and did not attend. Document what attempts were made to engage the beneficiary.

Response: If the amount of services required to meet the service are not met, then Partial Hospitalization cannot be billed. Services can be billed as provided outside of Partial Hospitalization, but in order to be paid the per diem for Partial Hospitalization, the service definition requirements must be met. A provider is required to document if a client does not or cannot participate in treatment and why that level of care continues to be necessary if the beneficiary cannot participate regularly in the program.

The proposed effective date is July 1, 2017.

FINANCIAL IMPACT: There is no financial impact.

LEGAL AUTHORIZATION: The Department of Human Services is authorized to "make rules and regulations and take actions as are necessary or desirable to carry out the provisions of this chapter [Public Assistance] and that are not inconsistent therewith." Ark. Code Ann. § 20-76-201 (12). Arkansas Code § 20-77-107 specifically authorizes the department to "establish and maintain an indigent medical care program."

5. DEPARTMENT OF HUMAN SERVICES, CHILDREN AND FAMILY SERVICES (Christin Harper)

a. SUBJECT: Policy Regarding Child Involved in a Protective Services Case Who is Missing

DESCRIPTION: This establishes a new division policy regarding when a child involved in a protective services (in home) case is missing from his/her parents' home. This new rule will ensure that the state is in compliance with federal PL 113-183 regarding the requirement to report any child under the supervision of the state child welfare agency to the National Center for Missing and Exploited Children as well as to report to local law enforcement any youth involved with DCFS who is identified as a sex trafficking victim.

PUBLIC COMMENT: No public hearing was held. The public comment period expired on February 7, 2017. The department received no comments.

The proposed effective date is pending legislative review and approval.

FINANCIAL IMPACT: There is no financial impact.

LEGAL AUTHORIZATION: This rule is promulgated in order to comply with federal regulation Fed. Pub. L 113-183, § 104.

According to Arkansas Code Annotated § 9-28-103 (b), the Department of Human Services, Division of Children and Family Services, is authorized to promulgate rules and regulations necessary to administer this subchapter [Children and Family Services].

b. SUBJECT: Internal Review of Assessment Decisions

DESCRIPTION: This establishes a new policy to allow certain DHS staff to have assessment decisions reviewed if a staff member believes a child in the custody of the Department of Human Services can be safely returned to his/her home or that a child needs to be taken into the custody of the department due to unsafe conditions in his/her home.

PUBLIC COMMENT: No public hearing was held. The public comment period expired on February 7, 2017. The department received no comments.

The proposed effective date is pending legislative review and approval.

FINANCIAL IMPACT: There is no financial impact.

LEGAL AUTHORIZATION: According to Arkansas Code Annotated § 9-28-103 (b), the Department of Human Services, Division of Children and Family Services, is authorized to promulgate rules and regulations necessary to administer this subchapter [Children and Family Services].

c. SUBJECT: Procedure Regarding Family Assessments

DESCRIPTION: This revises division procedure regarding family case assessments (FAST and CANS) to ensure that any identified sex trafficking victims are reported to local law enforcement within 24 hours. This revised rule will ensure that the state is in compliance with federal PL 113-183.

PUBLIC COMMENT: No public hearing was held. The public comment period expired on February 7, 2017. The department received no comments.

The proposed effective date is pending legislative review and approval.

FINANCIAL IMPACT: There is no financial impact.

LEGAL AUTHORIZATION: This rule is promulgated in order to comply with federal regulation Fed. Pub. L 113-183, § 104.

According to Arkansas Code Annotated § 9-28-103 (b), the Department of Human Services, Division of Children and Family Services, is authorized to promulgate rules and regulations necessary to administer this subchapter [Children and Family Services].

6. DEPARTMENT OF HUMAN SERVICES. DEVELOPMENTAL DISABILITIES SERVICES (Melissa Stone)

a. SUBJECT: DDS Community and Employment Services Waiver Certification Standards

DESCRIPTION: The Department of Human Services Division of Develop-mental Disability Services is proposing changes to the DDS Community and Employment Supports (CES) Waiver Certification Standards. The CES Waiver Certification Standards are being updated and amended to simplify and clarify the standards applicable to CES Waiver provider. The amendment includes, but is not limited to, the following changes:

1. Changes name from Alternative Community Services to reflect the emphasis on integrating participants into the community and providing supported employment opportunities.

2. Adds more detailed requirements for conflict free case management, including a stipulation that prohibits an organization from providing case management and any direct service to the same beneficiary and detailing the independent assessment tool that will be used to evaluate all waiver participant's level of need to develop their individualized person centered service plan, along with the functional assessments and application packet by a third party vendor.

3. Adds the home and community based setting rule requirements.

4. Adds solicitation prohibition.

5. Removes and simplifies numerous provisions that place burdens on providers that are unrelated to providing necessary home and community based services to beneficiaries.

PUBLIC COMMENT: A public hearing was held on March 29, 2017. The public comment period expired on April 1, 2017. The department received no comments.

The proposed effective date is July 1, 2017.

FINANCIAL IMPACT: There is no financial impact.

LEGAL AUTHORIZATION: The Department of Human Services is authorized to "make rules and regulations and take actions as are necessary or desirable to carry out the provisions of this chapter [Public Assistance] and that are not inconsistent therewith." Ark. Code Ann. § 20-76-201 (12). Arkansas Code § 20-77-107 specifically authorizes the department to "establish and maintain an indigent medical care program."

b. SUBJECT: DDS Community and Employment Supports (CES) Waiver and Medicaid Provider Manual #2-17

DESCRIPTION: The Department of Human Services Division of Medical Services (DMS) is proposing changes to the Medicaid Provider Manual, Division of Developmental Disabilities Services (DDS) Community and Employment Supports (CES) Waiver (formerly the Alternative Community Services Waiver) and the DDS CES Waiver AR 0188. The changes in the Waiver and the Manual are consistent.

The following is the summary of changes:

1. Changes name from Alternative Community Services to reflect the emphasis on integrating participants into the community and providing supported employment opportunities.

2. Adds 500 slots pursuant to Act 50 of 2017.

3. Details the independent assessment tool that will be used to evaluate all waiver participant's level of need and to develop their individualized person centered service plan, along with the functional assessments and application packet, by a third party vendor.

4. Modifies service definitions for Supportive Living and Respite to reflect the new two tier system used by the independent assessment.

5. Clarifies other portions of the waiver, including service definitions, so that the manual and the waiver mirror each other.

PUBLIC COMMENT: A public hearing was held on March 29, 2017. The public comment period expired on April 1, 2017. The department received the following comments:

Written comments received by Disability Rights Arkansas (DRA):

Regarding Waiver expansion, DDS continues to work to eliminate the waitlist for Waiver services. As you may be aware, under the new Provider Led Organized Care Act, Act 775 of the 2017 Regular Session, half of the revenue generated from the premium tax will be used to fund waiver slots for clients on the waitlist.

Regarding the suggestion that we conduct more stakeholder education for waiver participants and their families, you will be happy to hear that we have already begun that process. We have scheduled meetings specifically for participants' families during the next few months to answer any questions they may have about the upcoming changes to the Waiver and to explain to them the changes that will be coming with the Provider Led Entity model being implemented. On March 29, 2017, Director Stone met with families at ICM; on April 5, 2017, she conducted a web conference with families from ASN; and on April 11, 2017, she met with families at Easter Seals. We are also encouraging all families to attend the provider meetings on Monday afternoons during the month of April. These meetings will be held at St. Vincent's Main Auditorium from 1:30 to 3:00 p.m. The meeting on April 10, 2017, was specifically geared toward DDS providers and clients.

Regarding access to Third Party Contractor Performance Assessments, Vendor Performance Reports are performed and available for all state contract vendors. Also, the RFP for the Independent Assessments requires the Vendor to perform a minimum of quarterly evaluations to ensure Beneficiaries are being properly assessed and assigned to the correct tier, that the IT platform is accurately capturing scores, and that the algorithms used are accurately measuring tiers. These evaluations must be submitted to DHS with the monthly reports. The RFP also requires that the Vendor have a system in place for participants to provide feedback and complaints and for complaints to be investigated.

Regarding implementation of conflict free case management, we assure everyone that we are continuing to address this issue and to bring the CES Waiver into alignment with CMS regulations. The Independent Assessment is a first step to meeting the conflict free case management rule. In the next amendment to the Waiver, we will specifically add

requirements that the PASSE must provide conflict free case management. For example, there will be a requirement that the PASSE cannot use a direct service provider to provide case management services to the same clients.

Regarding the suggestion that case managers be required to make monthly face-to-face contacts with their clients, we agree. This change will be made.

Regarding shared direct care, the comment does not accurately reflect the Waiver language that was put out for public comment. In response to several comments from clients and their families, we deleted any requirements for shared staffing before putting the Waiver out for public comment. Instead, the CES Waiver requires the following:

The PCSP development team must utilize the results of the Independent Assessment in creating the PCSP. When developing the PCSP the development team must consider cost-efficient options that foster independence, such as shared staffing and other adaptations. When such options are not utilized in the PCSP for a Tier 3 participant, it must be documented that the participant's health and safety require one on one staffing, twenty-four hours a day. Appendix D-1(d).

Regarding the appeals process, we agree that the beneficiary should have more than ten (10) days from receipt of the notice to respond. Therefore, we are extending this timeframe out to *fifteen business days*. The Waiver appeal process was amended to reflect the appeal process used for all Medicaid programs and found in the Medicaid Provider Manual, Section 191.000. Any changes from the previous appeal process will be explained and due process of beneficiaries and providers will be protected.

Regarding the Independent Assessment tool, DDS assures everyone that it has provided as much information as it currently able to regarding the tool that will be used to assess Waiver participants. As soon as more information is available, this information will be shared with the providers, clients, and their families so that public input can be obtained.

Written comments received by David Ivers with David Ivers with Mitchell, Blackstock, Ivers & Sneddon, PLLC:

Regarding case management under the PASSE, we will be making amendments to the CES Waiver and writing a concurrent 1915(b) waiver

that will address case management under the PASSE. Case management will no longer be a service under the Waiver, but will be coordinated by the PASSE and paid for as part of the overall global payment. Children receiving targeted case management through EPSDT and on the Waiver will begin receiving case management through the PASSE once that model is implemented and will still need to undergo a prior authorization process for services until the PASSE takes full risk in January 2019.

Regarding the new rates, DDS will use an existing contract with an actuarial company to begin a rate study in May-June 2017. The results of this rate study will be used to implement a new rate methodology in the next waiver amendment.

The Tier 2 daily rate did not increase. In the September 1, 2016 Waiver, the daily rate for limited services was $176.00 and the daily rate for extensive services was $184.80. In the CES Waiver, DDS combined limited and extensive and made them Tier 2, or less than 24/7 level of care. Because we have no basis to change the rates, the daily maximum for Tier 2 was left at the daily maximum for extensive services, $184.80.

The timeframes regarding enrolling individuals into the PASSE are all estimates based on timelines established by the Transformation efforts and the Provider Led Organized Care Act. These timeframes will be adjusted as we get more information on how these changes will be implemented.

Regarding changes to the Medicaid Provider Manual and Licensure standards, we agree that significant changes will have to be made to these documents to implement the PASSE model. However, if we do not change the manuals to reflect the current waiver changes, we cannot implement the Waiver amendments effectively. Therefore, we must change the documents along with the Waiver amendments.

Written comments received from Syard Evans, Ph.D., Deputy CEO, Arkansas Support Network:

Regarding the comment that we 24/7 requirement forcing individuals to utilize 24/7 services when they are not needed. We appreciate this comment and understand your concerns. We hope that the new cost methodology will address these concerns by more accurately reflecting a rate for less than 24/7 care. Until such time, clients who have a medically necessary need for more than Tier 2 level of services ($184.80 per day), may have their Person Centered Service Plan amended to utilize more services with appropriate documentation.

We agree that clients should have an option for self-directed services. We are looking at ways to implement this in future waiver amendments.

In regards to adaptive equipment, DDS expanded the definition to include "enabling technology," which is technology that:
empowers participants to gain independence through customizable technologies that allow them to safely perform activities of daily living without assistance while still providing monitoring and response for those participants, as needed. Enabling technology allows participants to be proactive about their daily schedule and integrates participant choice. Before any enabling technology may be approved, it must be shown to meet a goal of the PCSP, ensures the participant's health and safety, and provides for adequate monitoring and response. Each participant who receives enabling technology must have an assessment conducted and a plan created for how that technology will be used to meet a PCSP goal, ensure the participant's health and safety, and provide adequate monitoring and response.

Written comments received from Mark George:

In regards to the reserved waiver capacity, this was a scrivener's error. The 200 slots are still reserved for children in the custody of DCFS. The CES Waiver will be changed to reflect this.

The Waiver priority language was revised, as suggested, so that the sentence makes sense.

Regarding the Level of Care criteria, the CFR referenced, 42 CFR § 440.150, defines an ICF/IID. But, we agree that this is not necessary to reference and the reference will be removed. We also agree that the near future language should be removed. This section will be changed to reflect that the individual would be at risk for institutionalization absent waiver services.

Comments on the renewal application were addressed during that public comment period.

Regarding administrative review and appeal, all beneficiaries and providers may still ask for reconsideration or appeal of an adverse decision or a denial of eligibility pursuant to the Medicaid Provider Manual § 191.000 and the Arkansas Administrative Procedures Act, as well as the Arkansas Medicaid Fairness Act. The Waiver language was amended to reflect this process, not to remove the right to administrative review of decisions. However, the state does not offer an alternative process, only the reconsideration and appeal process outlined in Appendix F-1.

Case Managers should discuss all approvals and denials with their client and as such, do have a responsibility to ensure the client receives those. However, you are correct that DDS has the legal responsibility to ensure notice is received by the client. This language does not negate that legal responsibility.

We agree that the language in the definition of adaptive equipment regarding the minimum purchase is confusing and will change it.

We agree that "vehicle modifications" should be added to conditions to make it clear that care and maintenance of vehicle modifications are the responsibility of the individual. This change will be made.

We agree that the language in Appendix F-1 regarding notice of appeal rights was confusing. We have reworded it to make it clearer. Regarding the responsibilities of the case manager, this language explains the case manager's role in providing choice counseling and assisting the beneficiary with appeals. Regarding reconsideration, it is a standard part of the due process rights provided to Medicaid beneficiaries and is not an alternative dispute resolution process.

Regarding continuation of service during an appeal, it is the provider who assumes liability for non-payment of services. We have added this language back in to clear up any confusion.

The appeal section was re-written to conform to the Arkansas Provider Manual regarding administrative appeals.

The Medicaid finance team assists with compiling Appendix J and we believe that the numbers contained in Appendix J are accurate. However, we will review these tables for accuracy before finalizing the Waiver application.

Mark George also made oral comments at the public hearing on March 29, 2017, that were similar to his written ones and have already been addressed.

Mike McCreight with Pathfinder made several oral comments at the public hearing on March 29, 2017. Most of his comments were addressed in the responses to the written comments above. However, he did comment that group homes should not be eliminated as an option for respite. We agree. This was an oversight and group homes will be added back in as a setting for respite.

The proposed effective date is July 1, 2017.

FINANCIAL IMPACT: The cost to implement the rule is $27 million for the current fiscal year ($7,943,400 in general revenue and $19,056,600 in federal funds); and $27 million for the next fiscal year ($7,865,100 in general revenue and $19,134,900 in federal funds). The $7,943,400 represents the amount of money being redirected to the DDS Waiver from the Tobacco Settlement Funds. The total is the state share based on an estimated cost of $54,000 per recipient and the addition of 500 new recipients.

Since the new or increased cost or obligation is at least one hundred thousand dollars ($100,000) per year to a private individual, private entity, private business, state government, county government, municipal government, or to two (2) or more of those entities combined, the agency submitted the following information:

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

The waiver is being amended to add 700 slots pursuant to Act 50 of 2017, which redirected $8.7 million of tobacco settlement funds to DHS to reduce the number of people on the waiting list for Waiver services. The waiver is also being amended to require all participants undergo an independent assessment which will be used to assist in determining the appropriate level of services for the client and develop the person centered case plan.

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

There is currently a waitlist for waiver services that has approximately 3000 people on it. Some of these individuals have been waiting for ten years to receive services. The additional funding will help to reduce the number of people on the waitlist by approximately 500 people.

(3) a description of the factual evidence that:
(a) justifies the agency's need for the proposed rule; and
(b) describes how the benefits of the rule meet the relevant statutory objectives and justify the rule's costs;

The new rule will help to reduce the waitlist by 3000 people; also by incorporating the independent assessment, DDS is hoping to ensure that all services provided to Waiver participants are appropriate for the level of need the person has. The purpose of the independent assessment is to have a third party assess the needs of the individual and to require that assessment be used to develop the Person Centered Case Plan, along with other testing.

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

N/A

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

Unknown at this time.

(6) a statement of whether existing rules have created or contributed to the problem the agency seeks to address with the proposed rule and, if existing rules have created or contributed to the problem, an explanation of why amendment or repeal of the rule creating or contributing to the problem is not a sufficient response; and

N/A

(7) an agency plan for review of the rule no less than every ten (10) years to determine whether, based upon the evidence, there remains a need for the rule including, without limitation, whether:
(a) the rule is achieving the statutory objectives;
(b) the benefits of the rule continue to justify its costs; and
(c) the rule can be amended or repealed to reduce costs while continuing to achieve the statutory objectives.

The waiver must be renewed every five years, so DDS and DMS reviews the waiver and Provider Manual during that time to ensure that services are being provided to participants in the most cost efficient manner available while still ensuring participant's health and safety.

LEGAL AUTHORIZATION: The Department of Human Services is authorized to "make rules and regulations and take actions as are necessary or desirable to carry out the provisions of this chapter [Public Assistance] and that are not inconsistent therewith." Ark. Code Ann. § 20-76-201 (12). Arkansas Code § 20-77-107 specifically authorizes the department to "establish and maintain an indigent medical care program."

c. **SUBJECT: DDS Alternative Community Services Waiver (DDS ACS) Update #1-17 and Developmental Disabilities Services ACS Waiver**

DESCRIPTION: The Department of Human Services, Division of Medical Services is proposing changes to the Medicaid Provider Manual, Division of Developmental Disability Services (DDS) Home and Community Based Services (HCBS) Waiver (formerly the Alternative Community Services Waiver).

The following is a summary of the changes:

1. Changes the title of the services, to reflect that they are Home and Community Based Services under the federal regulations.

2. Incorporates changes from the September 1, 2016 Waiver renewal, specifically, as follows:

a. Adds supportive living retainer payments to providers for the lesser of 14 consecutive days or the number of days during which an individual is in an ineligible setting.

b. Adds requirements for conflict free case management, including a stipulation that prohibits an organization from providing case management and any direct service to the same person.

c. Removes restrictions on paying overtime and family members hired as staff working more than 40 hours per week.

d. Adds the Home and Community Based Settings Transition Plan.

e. Changes the effective term of Interim Plan of Care (IPOC) from 90 days to 60 days.

PUBLIC COMMENT: A public hearing was held on March 29, 2017. The public comment period expired on April 1, 2017. The department received no comments.

The proposed effective date is pending legislative review and approval.

FINANCIAL IMPACT: The financial impact is $1,652,800 for the current fiscal year ($499,641 in general revenue and $1,153,159 in federal funds) and $2,605,050 for the next fiscal year ($789,591 in general revenue and $1,815,459 in federal funds). In the increased cost to the state, the fiscal impact is comprised of increased general revenue

requirements due to the addition of 40 waiver slots in SFY 2017, beginning September 1, 2017, and five slots per quarter the following year.

Since there a new or increased cost or obligation of at least one hundred thousand dollars ($100,000) per year to a private individual, private entity, private business, state government, county government, municipal government, or to two (2) or more of those entities combined, the agency submitted the following additional information:

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

The Medicaid Provider Manual for DDS ACS Waiver is being updated to reflect the Medicaid ACS Waiver, AR 0188, which provides an alternative to institutional care for individuals with ID/DD. The waiver provides services and supports to allow individuals that meet II/ID level of care to work, live and be fully integrated into the community.

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

The agency seeks to continue implementation of the waiver program to provide services and supports to individuals who are eligible for the waiver so that they may remain in their community. The waiver operates under 1915(c) of the Social Security Act and 42 CFR 441. The proposed rule incorporates the September 1, 2016 amendments into the Provider Manual.

(3) a description of the factual evidence that:
(a) justifies the agency's need for the proposed rule; and
(b) describes how the benefits of the rule meet the relevant statutory objectives and justify the rule's costs;

The HCBS waiver provides an alternative to facility based care. The annual average cost for Waiver services in the community is $49,610.51; as compared with the ICF residential facility annualized average cost of care, which is $149,576.27.

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

N/A

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

N/A

(6) a statement of whether existing rules have created or contributed to the problem the agency seeks to address with the proposed rule and, if existing rules have created or contributed to the problem, an explanation of why amendment or repeal of the rule creating or contributing to the problem is not a sufficient response; and

N/A

(7) an agency plan for review of the rule no less than every ten (10) years to determine whether, based upon the evidence, there remains a need for the rule including, without limitation, whether:
(a) the rule is achieving the statutory objectives;
(b) the benefits of the rule continue to justify its costs; and
(c) the rule can be amended or repealed to reduce costs while continuing to achieve the statutory objectives.

The renewal was submitted to CMS in accordance with 42 CFR 441, which requires a HCBS waiver to be submitted or renewal every five years. Accordingly, DDS must assure that providers are in compliance with standards and in compliance with the State of Arkansas to participate in the Medicaid Waiver Program. Therefore, DDS, in cooperation with the Division of Medical Services, updates the Medicaid Provider Manual to reflect the new ACS Waiver requirements.

LEGAL AUTHORIZATION: The proposed rule is necessary to update the Medicaid Provider Manual so that is consistent with the waiver approved by CMS. The Department of Human Services is authorized to "make rules and regulations and take actions as are necessary or desirable to carry out the provisions of this chapter [Public Assistance] and that are not inconsistent therewith." Ark. Code Ann. § 20-76-201 (12). Arkansas Code § 20-77-107 specifically authorizes the department to "establish and maintain an indigent medical care program."

7. DEPARTMENT OF HUMAN SERVICES, MEDICAL SERVICES
(Items b, c, d, e, and f, Tami Harlin; Items a and g, Tami Harlan and Jason Derden)

a. SUBJECT: Pharmacy Manual #1-17 and Section 1 1-17

DESCRIPTION: CMS published the Covered Outpatient Drug final rule (CMS-2345-FC) on February 1, 2016 pertaining to reimbursement for covered outpatient drugs in the Medicaid program. It outlines key changes that states need to address when determining their reimbursement methodology for ingredient costs based on actual acquisition cost (AAC) plus a professional dispensing fee among other things.

PUBLIC COMMENT: No public hearing was held. The public comment period expired on May 15, 2017. The department received no comments.

This rule was filed and approved as an emergency rule on April 1, 2017. The proposed effective date for the permanent rule is July 1, 2017.

FINANCIAL IMPACT: There is no financial impact.

LEGAL AUTHORIZATION: This rule is required in order to ensure compliance with CMS-2345-FC and 81 FR 5170. The Department of Human Services is authorized to "make rules and regulations and take actions as are necessary or desirable to carry out the provisions of this chapter [Public Assistance] and that are not inconsistent therewith." Ark. Code Ann. § 20-76-201 (12). Arkansas Code § 20-77-107 specifically authorizes the department to "establish and maintain an indigent medical care program."

b. SUBJECT: Visual 2-16

DESCRIPTION: This proposed rule is to prior authorize an initial 16 treatments in a 12-month period with no more than one treatment per seven calendar days of orthoptic and/or pleoptic training performed in a licensed optometrist or ophthalmologist office for Medicaid eligible children ages 20 and under and for CHIP eligible children ages 18 and under; to prior authorize one sensorimotor examination in 12-month period performed in a licensed optometrist or ophthalmologist office for Medicaid eligible children ages 20 and under and for CHIP eligible children ages 18 and under who have received a covered diagnosis based on specific observed and documented symptoms; and to prior authorize one developmental testing in a 12-month period performed in a licensed optometrist or ophthalmologist office for Medicaid eligible children ages 20 and under and for CHIP eligible children ages 18 and under who have received a covered diagnosis based on specific observed and documented systems. The proposed rule is also to update with information regarding the risks of non-payment for services performed before acquiring prior authorization and pertaining to contact lens services procedure code S0592.

PUBLIC COMMENT: No public hearing was held. The public comment period expired on May 11, 2017. The department received no comments.

The proposed effective date is July 1, 2017.

FINANCIAL IMPACT: There will be a savings of $973,273 for each of the current fiscal year and the next fiscal year ($686,936 in federal funds and $286,337 in general revenue). Savings/cost avoidance was generated by setting limits on procedures that previously had no limit.

LEGAL AUTHORIZATION: The Department of Human Services is authorized to "make rules and regulations and take actions as are necessary or desirable to carry out the provisions of this chapter [Public Assistance] and that are not inconsistent therewith." Ark. Code Ann. § 20-76-201 (12). Arkansas Code § 20-77-107 specifically authorizes the department to "establish and maintain an indigent medical care program."

c. SUBJECT: Home Health 2-16; Prosthet 3-16; CNM 1-16; Nursprea 3-16

DESCRIPTION: CMS published the Medicaid program; Face-to-Face Requirements for Home Health Services; Policy Changes and Clarifications Related to Home Health final rule (CMS-2348-F)(42 CFR Part 440), with an effective date of 7/1/2016. It outlines key changes that stated need to address the settings in which home health services are provided. CMS has required states to revise their documentation to come into compliance by July 1, 2017.

PUBLIC COMMENT: No public hearing was held. The public comment period expired on May 5, 2017. The department received no comments.

The proposed effective date is July 1, 2017.

FINANCIAL IMPACT: There is no financial impact.

LEGAL AUTHORIZATION: This rule is required in order to ensure compliance with CMS-2348-F and 42 CFR Part 440. The Department of Human Services is authorized to "make rules and regulations and take actions as are necessary or desirable to carry out the provisions of this chapter [Public Assistance] and that are not inconsistent therewith." Ark. Code Ann. § 20-76-201 (12). Arkansas Code § 20-77-107 specifically authorizes the department to "establish and maintain an indigent medical care program."

d. SUBJECT: Patient Centered Medical Home (PCMH 1-17)

DESCRIPTION: The Patient Centered Medical Home (PCMH) Manual is being updated to reflect that practice support will now continue until June 30, 2018. The current manual specifies that the practice support would end on June 30, 2017. This rule is essential to orientate new practices into the PCMH program.

PUBLIC COMMENT: No public hearing was held. The public comment period expired on May 13, 2017. The department received the following comment:

David Wroten, Arkansas Medical Society

Comment: The language below is from the Proposed revisions to the PCMH manual. Something does not look right and I would appreciate your review. In the first paragraph it defines "practice support" as both care coordination payments AND practice transformation support. It is our understanding that the intent is that practice transformation payments might be limited to a certain period of time and the 3rd paragraph alludes to that (24 months).

However, in the 4th paragraph is states that "practice support" payments may not extend past June 30, 2018. Going back to the definition in paragraph 1, it would appear that pmpm payments for care coordination (not just practice transformation) may also cease on June 30, 2018. IS THIS CORRECT?

Without pmpm care coordination payments, PCMP will cease to exists. I am hoping that this is an error in drafting.

PLEASE LET ME KNOW.

Second issue: In the Provider Relations contract renewal for AFMC, there is no mention of AFMC's work with AMS for physician outreach services. Last year, the modest amount spent was transferred to AFMC and I thought it was done through a contract addendum. Could you please check on this and advise whether or not our physicians will have the benefit of a support person for payment improvement efforts?

Response: You are correct, it should say Practice Transformation instead of practice support. I'll work with our policy department to correct the error.

Let me do further research on your second issue but please note the provider rep contact is currently out for bid for next year https://www.medicaid.state.ar.us/General/rfp/rfp.aspx

FINANCIAL IMPACT: The financial impact for the current fiscal year is $620,000 ($310,000 in general revenue and $310,000 in federal funds). The $310,000 is matched at the 50/50 administrative match rate.

Since there a new or increased cost or obligation of at least one hundred thousand dollars ($100,000) per year to a private individual, private entity, private business, state government, county government, municipal government, or to two (2) or more of those entities combined, the agency submitted the following information:

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

The purpose of the rule change is to allow newly enrolled PCMHs to receive practice transformation coaching. This coaching has been deemed essential to the success of practices participating in PCMH. This service is a temporary and practice may utilize it for 24 months to assist in the transition into a patient centered medical home.

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

The agency is seeking additional funds to aid newly enrolled providers with transitioning into a patient centered medical home. PCMHs have historically proven that they are more efficient and yield cost avoidance of Medicaid funds.

(3) a description of the factual evidence that:
(a) justifies the agency's need for the proposed rule; and

This service is required for newly enrolled practices to succeed in the patient centered medical home program.

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

Practices enrolled in PCMH have historically spent less Medicaid funds and their beneficiaries tend to use the ER less often than those practices not enrolled in the program.

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

Similar vendors that provide similar support charge anywhere from $5 - $9 per member per month.

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

Research has shown that alternative vendors are charging higher rates.

(6) a statement of whether existing rules have created or contributed to the problem the agency seeks to address with the proposed rule and, if existing rules have created or contributed to the problem, an explanation of why amendment or repeal of the rule creating or contributing to the problem is not a sufficient response; and

Existing rules have not contributed or created problems.

(7) an agency plan for review of the rule no less than every ten (10) years to determine whether, based upon the evidence, there remains a need for the rule including, without limitation, whether:
(a) the rule is achieving the statutory objectives;
(b) the benefits of the rule continue to justify its costs; and
(c) the rule can be amended or repealed to reduce costs while continuing to achieve the statutory objectives.

This contract will end within a few years. Practice transformation services are provided by DMS for the first 24 months of enrollment in the PCMH program. Currently nearly 90% of eligible providers are enrolled in PCMH. Within a few years, there would be no new practices enrolling thus no need for practice transformation.

LEGAL AUTHORIZATION: The Department of Human Services is authorized to "make rules and regulations and take actions as are necessary or desirable to carry out the provisions of this chapter [Public Assistance] and that are not inconsistent therewith." Ark. Code Ann. § 20-76-201 (12). Arkansas Code § 20-77-107 specifically authorizes the department to "establish and maintain an indigent medical care program."

e. SUBJECT: Hospice 1-16

DESCRIPTION: Effective January 1, 2016, Medicaid Hospice Payment Rates were adjusted by the Centers for Medicaid and Medicaid Services (CMS). Arkansas Medicaid is updating the Hospice Policy to be in compliance with federal guidance. This rule changes the payment methodology for Routine Home Care (RHC) to implement two rates that

will result in a higher base payment for the first 60 days of hospice care and a reduced base payment rate for days thereafter. This also establishes an add-on payment for services provided by a registered nurse or social worker during the last seven days of a beneficiary's life.

This implements a 2 Tier Hospice rate and adds procedure codes (G0155, G0299) for Service Intensity Add-on Payment.

PUBLIC COMMENT: No public hearing was held. The public comment period expired on December 30, 2016. The department received no comments.

The proposed effective date is pending legislative review and approval.

FINANCIAL IMPACT: The cost to implement this rule is $512,092 for the current fiscal year ($154,288 in general revenue and $363,804 in federal funds; and $1,036,183 for the next fiscal year ($313,238 in general revenue and $722,945 in federal funds).

The agency provided the following information with respect to whether there is a new or increased cost or obligation of at least $100,000 per year to a private individual, private entity, private business, state government, county government, municipal government, or two or more of those entities combined:

(1) a statement of the rule's basis and purpose; **To incorporate mandatory Medicaid fee schedule rates and requirements published by CMS as is required by our State Plan.**

(2) the problem the agency seeks to address with the proposed rule, including a statement of whether a rule is required by statute; **To incorporate mandatory Medicaid fee schedule rates and requirements published by CMS as is required by our State Plan.**

(3) a description of the factual evidence that:
(a) justifies the agency's need for the proposed rule; and
(b) describes how the benefits of the rule meet the relevant statutory objectives and justify the rule's costs; **To incorporate mandatory Medicaid fee schedule rates and requirements published by CMS as is required by our State Plan.**

(4) a list of less costly alternatives to the proposed rule and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule; **N/A, The State must follow these requirements issued by CMS.**

(5) a list of alternatives to the proposed rule that were suggested as a result of public comment and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule; **N/A, The State must follow these requirements issued by CMS.**

(6) a statement of whether existing rules have created or contributed to the problem the agency seeks to address with the proposed rule and, if existing rules have created or contributed to the problem, an explanation of why amendment or repeal of the rule creating or contributing to the problem is not a sufficient response; and **N/A, The State must follow these requirements issued by CMS.**

(7) an agency plan for review of the rule no less than every ten (10) years to determine whether, based upon the evidence, there remains a need for the rule including, without limitation, whether:
(a) the rule is achieving the statutory objectives;
(b) the benefits of the rule continue to justify its costs; and
(c) the rule can be amended or repealed to reduce costs while continuing to achieve the statutory objectives.
The State must follow these requirements issued by CMS. These rates are reviewed each year.

LEGAL AUTHORIZATION: Pursuant to Arkansas Code Annotated § 20-76-201, the Department of Human Services ("the Department") shall administer assigned forms of public assistance, supervise agencies and institutions caring for dependent or aged adults or adults with mental or physical disabilities, and administer other welfare activities or services that may be vested in it. *See* Ark. Code Ann. § 20-76-201(1). The Department shall also make rules and regulations and take actions as are necessary or desirable to carry out the provisions of Title 20, Subtitle 5, Chapter 76, Public Assistance Generally, of the Arkansas Code. *See* Ark. Code Ann. § 20-76-201(12).

f. SUBJECT: Prosthetics 2-16 and Section V 7-16

DESCRIPTION: Effective May 1, 2017, Arkansas Medicaid Prosthetics Manual has been updated to clarify the process (or procedure) of submitting prior authorization requests for wheelchairs and wheelchair seating systems for individuals two through adult by Durable Medical Equipment (DME) providers.

PUBLIC COMMENT: No public hearing was held. The public comment period expired on December 30, 2016. The department received no comments from the public.

Michael Harry, attorney with the Bureau of Legislative Research, asked the following question: are the procedures described for prior authorization requests for wheelchairs new or are they just a clarification or re-statement of current procedures?

Tami Harlan, Department of Human Services/ Division of Medical Services, responded that this rule was merely clarification of existing procedures.

The proposed effective date is pending legislative review and approval.

FINANCIAL IMPACT: There is no financial impact.

LEGAL AUTHORIZATION: Pursuant to Arkansas Code Annotated § 20-76-201, the Department of Human Services ("the Department") shall administer assigned forms of public assistance, supervise agencies and institutions caring for dependent or aged adults or adults with mental or physical disabilities, and administer other welfare activities or services that may be vested in it. *See* Ark. Code Ann. § 20-76-201(1). The Department shall also make rules and regulations and take actions as are necessary or desirable to carry out the provisions of Title 20, Subtitle 5, Chapter 76, Public Assistance Generally, of the Arkansas Code. *See* Ark. Code Ann. § 20-76-201(12).

g. SUBJECT: State Plan Amendment #2016-003 – Pharmacy Pricing Methodology

DESCRIPTION: CMS published the Covered Outpatient Drug final rule (CMS-2345-FC) (81 FR 5170) on 2/1/2016 pertaining to reimbursement for covered outpatient drugs in the Medicaid program. It outlines key changes that states need to address when determining their reimbursement methodology for ingredient costs based on actual acquisition cost (AAC) plus a professional dispensing fee among other things. CMS has required states to revise their state plans and submit a SPA to comply with these provisions.

PUBLIC COMMENT: No public hearing was held. The public comment period expired on December 30, 2016. The department received no comments.

The proposed effective date is pending legislative review and approval.

FINANCIAL IMPACT: There will be a savings of $5,185,753 for the current fiscal year ($1,567,653 in general revenue and $3,618,100 in federal funds); and $20,800,000 for the next fiscal year ($6,119,360 in general revenue and $14,680,640 in federal funds).

LEGAL AUTHORIZATION: This rule is promulgated in order to comply with federal regulations CMS-2345-FC and 81 FR 5170.

Pursuant to Arkansas Code Annotated § 20-76-201, the Department of Human Services ("the Department") shall administer assigned forms of public assistance, supervise agencies and institutions caring for dependent or aged adults or adults with mental or physical disabilities, and administer other welfare activities or services that may be vested in it. *See* Ark. Code Ann. § 20-76-201(1). The Department shall also make rules and regulations and take actions as are necessary or desirable to carry out the provisions of Title 20, Subtitle 5, Chapter 76, Public Assistance Generally, of the Arkansas Code. *See* Ark. Code Ann. § 20-76-201(12).

8. OIL AND GAS COMMISSION (Lawrence Bengal and Shane Khoury)

a. SUBJECT: General Rule B-19 Requirements for Well Completion Utilizing Fracture Stimulation

DESCRIPTION: This amendment reduces the regulatory burden for smaller oil and gas operators by exempting relatively small frac jobs (10,000 barrels of fluid or less) on vertical wells from General Rule B-19. This proposed amendment does not increase any environmental risks associated with the exempted process, and it primarily impacts smaller oil producers in south Arkansas.

PUBLIC COMMENT: Public hearings were held on April 24, 2017, in El Dorado, and on May 2, 2017, in Fort Smith. The public comment period expired on May 15, 2017. The Commission received no public comments.

The proposed effective date is pending legislative review and approval.

FINANCIAL IMPACT: There is no financial impact.

LEGAL AUTHORIZATION: The Oil and Gas Commission shall have jurisdiction of and authority over all persons and property necessary to administer and enforce effectively its statutory authority relating to the exploration, production, and conservation of oil and gas, and after hearing and notice, "may make such reasonable rules, regulations, and orders as are necessary from time to time in the proper administration and enforcement of this act." Ark. Code Ann. § 15-71-110(a)(1), (d).

b. SUBJECT: General Rule B-27 Salt Water

DESCRIPTION: This repeals a rule requiring a Commission-mandated production practice concerning the reporting requirements for produced salt water that is no longer applicable in Arkansas mature oil fields.

PUBLIC COMMENT: Public hearings were held on April 24, 2017, in El Dorado, and on May 2, 2017, in Fort Smith. The public comment period expired on May 15, 2017. The Commission received no public comments.

The proposed effective date is pending legislative review and approval.

FINANCIAL IMPACT: There is no financial impact.

LEGAL AUTHORIZATION: The Oil and Gas Commission shall have jurisdiction of and authority over all persons and property necessary to administer and enforce effectively its statutory authority relating to the exploration, production, and conservation of oil and gas, and after hearing and notice, "may make such reasonable rules, regulations, and orders as are necessary from time to time in the proper administration and enforcement of this act." Ark. Code Ann. § 15-71-110(a)(1), (d).

c. SUBJECT: General Rule B-33 Production Practice

DESCRIPTION: This repeals a rule requiring a Commission-mandated production practice concerning the production of naturally flowing wells that is no longer applicable in Arkansas mature oil fields.

PUBLIC COMMENT: Public hearings were held on April 24, 2017, in El Dorado, and on May 2, 2017, in Fort Smith. The public comment period expired on May 15, 2017. The Commission received no public comments.

The proposed effective date is pending legislative review and approval.

FINANCIAL IMPACT: There is no financial impact.

LEGAL AUTHORIZATION: The Oil and Gas Commission shall have jurisdiction of and authority over all persons and property necessary to administer and enforce effectively its statutory authority relating to the exploration, production, and conservation of oil and gas, and after hearing and notice, "may make such reasonable rules, regulations, and orders as are necessary from time to time in the proper administration and enforcement of this act." Ark. Code Ann. § 15-71-110(a)(1), (d).

d. SUBJECT: General Rule C-6: Monthly Reports Costs

DESCRIPTION: This repeals a rule that is no longer applicable or necessary given all Commission notices and reports are published on the AOGC webpage. Additionally, accessibility and applicable fees are governed by the Arkansas Freedom of Information Act.

PUBLIC COMMENT: Public hearings were held on April 24, 2017, in El Dorado, and on May 2, 2017, in Fort Smith. The public comment period expired on May 15, 2017. The Commission received no public comments.

The proposed effective date is pending legislative review and approval.

FINANCIAL IMPACT: There is no financial impact.

LEGAL AUTHORIZATION: The Oil and Gas Commission shall have jurisdiction of and authority over all persons and property necessary to administer and enforce effectively its statutory authority relating to the exploration, production, and conservation of oil and gas, and after hearing and notice, "may make such reasonable rules, regulations, and orders as are necessary from time to time in the proper administration and enforcement of this act." Ark. Code Ann. § 15-71-110(a)(1), (d). This authority permits the Commission discretion to make rules or regulations for the purpose of prescribing a reasonable and necessary charge or fee per copy and per subscription for notices and reports prepared and published by the Commission deemed necessary to reimburse the Commission for the cost of those notices and reports. *See* Ark. Code Ann. § 15-71-110(d)(17)(A)(ii).

e. SUBJECT: General Rule D-9 Gas Oil Ratio

DESCRIPTION: This repeals a rule requiring a Commission-mandated production practice limiting the amount of gas produced that is no longer applicable in Arkansas mature oil fields.

PUBLIC COMMENT: Public hearings were held on April 24, 2017, in El Dorado, and on May 2, 2017, in Fort Smith. The public comment period expired on May 15, 2017. The Commission received no public comments.

The proposed effective date is pending legislative review and approval.

FINANCIAL IMPACT: There is no financial impact.

LEGAL AUTHORIZATION: The Oil and Gas Commission shall have jurisdiction of and authority over all persons and property necessary to administer and enforce effectively its statutory authority relating to the exploration, production, and conservation of oil and gas, and after hearing and notice, "may make such reasonable rules, regulations, and orders as are necessary from time to time in the proper administration and enforcement of this act." Ark. Code Ann. § 15-71-110(a)(1), (d).

f. SUBJECT: General Rule D-11 Pipeline Maps

DESCRIPTION: This repeals language in General Rule D-11 requiring that pipeline maps indicating the location, size, extensions and any portions abandoned or not used shall be filed at the request of the Commission. Requirements for maps of pipelines have been updated, and current requirements are set forth in General Rule D-17. This rule is no longer necessary.

PUBLIC COMMENT: Public hearings were held on April 24, 2017, in El Dorado, and on May 2, 2017, in Fort Smith. The public comment period expired on May 15, 2017. The Commission received no public comments.

The proposed effective date is pending legislative review and approval.

FINANCIAL IMPACT: There is no financial impact.

LEGAL AUTHORIZATION: The Oil and Gas Commission shall have jurisdiction of and authority over all persons and property necessary to administer and enforce effectively its statutory authority relating to the exploration, production, and conservation of oil and gas, and after hearing and notice, "may make such reasonable rules, regulations, and orders as are necessary from time to time in the proper administration and enforcement of this act." Ark. Code Ann. § 15-71-110(a)(1), (d).

g. SUBJECT: General Rule D-13 Use of Gas for Other Than Light or Fuel

DESCRIPTION: This repeals an obsolete rule on the use of gas for purposes other than light or fuel. This rule is no longer a necessary regulatory function of the Commission due to modern industry practice.

PUBLIC COMMENT: Public hearings were held on April 24, 2017, in El Dorado, and on May 2, 2017, in Fort Smith. The public comment period expired on May 15, 2017. The Commission received no public comments.

The proposed effective date is pending legislative review and approval.

FINANCIAL IMPACT: There is no financial impact.

LEGAL AUTHORIZATION: The Oil and Gas Commission shall have jurisdiction of and authority over all persons and property necessary to administer and enforce effectively its statutory authority relating to the exploration, production, and conservation of oil and gas, and after hearing and notice, "may make such reasonable rules, regulations, and orders as are necessary from time to time in the proper administration and enforcement of this act." Ark. Code Ann. § 15-71-110(a)(1), (d).

G. Adjournment.