ADMINISTRATIVE RULES SUBCOMMITTEE
OF THE
ARKANSAS LEGISLATIVE COUNCIL

Thursday, September 14, 2023
1:30 p.m. or Tentative
Room A, MAC
Little Rock, Arkansas

A. Call to Order

B. Reports from the Executive Subcommittee Concerning Emergency Rules

C. Reports from ALC Subcommittees Concerning the Review of Rules

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

1. DEPARTMENT OF AGRICULTURE, STATE PLANT BOARD

a. SUBJECT: Arkansas Industrial Hemp Production Rule

DESCRIPTION: The Department of Agriculture's State Plant Board proposes the repeal of its Arkansas Industrial Hemp Research Program Rules and the promulgation of its Arkansas Industrial Hemp Production Rule. The Board provided the following summary of the rule:

Act 565 of 2021, also known as the Arkansas Industrial Hemp Production Act ("Act"), was passed in response to the 2018 Farm Bill, which transitioned state hemp programs from research-only to a closely regulated industry. The Act requires the Department to obtain an approved state plan from the USDA under the 2018 Farm Bill for primary regulatory authority over hemp. The Department obtained an approved state plan from the USDA on December 10, 2021. The proposed Rule was reviewed by the Plant Board Industrial Hemp Committee on January 28, 2022, followed by approval of the proposed Rule at the full Plant Board's meeting March 3, 2022. Since the Act repealed previous industrial hemp law, existing Board rules regarding industrial hemp will need to be repealed. The proposed Rule will implement the provisions of the new Act.

The Act provides that the Plant Board shall promulgate rules regarding sampling, testing, inspections, specific requirements for applications, and licensing fees. The Act also provides that the Board may adopt other rules necessary for the implementation of the Act. The Rule covers the areas

necessary for oversight of industrial hemp production in Arkansas, including but not limited to the growing, processing, handling, storage, sale, transfer, importation, and distribution of industrial hemp. Other specific matters covered by the Rule include acquisition of hemp seeds and seedlings, the importation of hemp into Arkansas, and the submission of planting reports to the Farm Service Agency as required by the Act. The Rule also continues to prohibit the retail sale of hemp floral material or the manufacture and distribution of controlled substances.

Additional changes were made after the expiration of the public comment period. Act 629 of 2023 contains a definition of hemp that does not exactly track the definition of hemp in federal law. Ark. Code Ann. § 2-15-506 (The Arkansas Hemp Production Act) states that in any place where there is a conflict between Arkansas and federal law, federal law controls. While the 2018 federal Farm Bill does say we can regulate more restrictively, we cannot change federal law. The Federal definition is also recognized in Section 7 of Act 629, further evidencing that the intent is to be consistent with federal law. While the Department does not view the definition of hemp found in Act 629 to conflict in any way with federal law, we believe that it is appropriate to clarify the definition of hemp in the proposed rule. Accordingly, an amended definition of hemp has been incorporated into the proposed rule. Since it is only a clarification, it is not a substantial change and does not require approval of the Plant Board or additional public comment.

Section 8 of the proposed rule has been clarified to make it more consistent with statutory language. Ark. Code Ann. § 2-15-509(b) provides that growers shall pay the costs of inspections, and 2-15-505 provides that the board ***shall*** establish fees, therefore the fees are mandatory. Section 507 provides that any fees assessed are to administer the program. Therefore, we believe the proposed language in Section 8 of the proposed rule referencing cost recovery instead of fees will more clearly indicate that amount charged applicants and licensees are to recover the costs of administering the program. No new fees have been added so this is not a change that would require any additional public comment or Plant Board approval.

PUBLIC COMMENT: A public hearing was held on April 14, 2022. The public comment period expired that same day. The Board provided the following summary of the comments that it received and its responses thereto:

FOR

William Morgan, BioGen, LLC

The rules appear to be in line with current guidelines but would like to see more assistance offered to growers/researchers and less fees. Hemp

industry in Arkansas faces two main obstacles: 1) "Lack of education of the market," and 2) burdensome fees. Commenter states he had to shut down a genetics research program because a $100 compliance fee "is ridiculous," and locally produced genetics need to be supported. Would like to see the Department of Agriculture offer more assistance and less rules.

RESPONSE:
The Board appreciates your comments and also believes the rules reflect current USDA and Arkansas legislative requirements. The Department of Agriculture receives no funding for the program or for assistance to hemp growers or researchers.

UNDECIDED
Brian Madan, Tree of Life Seeds
The Department is doing a great job administering the program but there should be additional funding to the Department so the program would not have to be supported by fees. Commenter states that he will not apply for a license this year due to the "cost of entry and poor commodity prices."

RESPONSE:
The Board appreciates your comments. The Department receives no funding for the program other than that authorized by Ark. Code Ann. §§ 2-25-505(d) and 507(h), which specifically state that the Plant Board may establish and collect fees to administer the program.

Ray Benton
"I'm out of the hemp business. Not growing this year or any other. I'm done with having to deal with all of it."

RESPONSE:
The Board appreciates your comments.

Rebecca Miller-Rice, an attorney with the Bureau of Legislative Research, asked the following questions:

(1) Section 4(k): This section appears to be premised on Ark. Code Ann. § 2-15-513(a), as amended by Act 565 of 2021, § 2, which appears to render an individual convicted of a felony offense related to a controlled substance under federal or state law ineligible to participate in the program for the ten-year period *following* the date of the conviction. *See also* 7 USC § 1639p(e)(3)(B)(i). The rule as written, however, seems to suggest it is a ten-year period previous from the date of conviction. Is there a reason the language appears to differ? **AGENCY RESPONSE:** We do not read the rule as somehow allowing us to prohibit someone from holding a license prior to a conviction. That would in fact, be an

impossibility, because *we would not know* prior to a conviction that the individual was going to be convicted. Accordingly, it would be impossible to implement the rule as you suggest.

(2) Section 5(7): Is there a reason the terminology of "with or without cause" was used in this section, when Section 15(a) uses "for any lawful purpose"? **AGENCY RESPONSE:** The two are interchangeable.

(3) Section 6(f): This section appears to be premised on Ark. Code Ann. § 2-15-513(c)(2), as amended by Act 565, § 2. Should the reference to "department" be to the Department of Public Safety in accord with the statute? **AGENCY RESPONSE:** The department in this context is the Department of Agriculture. The actual criminal background checks and their contents are not disclosed to the Plant Board unless it is used as evidence in an administrative hearing. This is to make sure the licensees understand this information will become public record should such a hearing occur.

(4) The rules appear to contemplate the licensing of processors of hemp. Ark. Code Ann. § 2-15-507(a) provides that the board may establish a procedure for the annual licensure of persons to grow industrial hemp, and "grower" is defined in Ark. Code Ann. § 2-15-503(3) as "a person licensed to grow and produce industrial hemp" by the board. Ark. Code Ann. § 2-15-508(a) requires that a person shall obtain a grower license under the Arkansas Industrial Hemp Act before planting or growing industrial hemp in the state. Additionally, while Ark. Code Ann. § 2-15-502(a)(2) provides that one of the purposes of the Act is to recognize the cultivation, processing, and transportation of industrial hemp as an agricultural activity in the state, the statute also provides that the Act shall not be construed to grant the Department of Agriculture the authority to regulate hemp processing practices or methodologies. *See* Ark. Code Ann. § 2-15-502(b). Under what authority will the board be licensing processors? **AGENCY RESPONSE:** Ark. Code Ann. 2-15-516(a)(1) & (2) provides in pertinent part that it shall be unlawful for a grower to: ". . . process . . . living industrial hemp plants, viable hemp seed, leaf, or floral material . . . in a manner inconsistent with this subchapter or Plant Board rule." (and) ". . . provide false, misleading, or incorrect information to the department pertaining to **the licensee's** cultivation, **processing**, or transportation of industrial hemp, **including without limitation information provided in any application**, report, record, **or inspection** required or maintained in accordance with this subchapter and board rule;" (emphasis supplied).

As noted, the Act declares that it is prohibited to *process* hemp in a manner inconsistent with the law *or Plant Board rules*, and further indicates that it is prohibited to provide false information regarding

processing, *including information submitted with an application or inspection*. This indicates that there is legislative intent for the Department and Plant Board to have jurisdiction over processing, and since the law specifically states that it is prohibited to provide false information regarding a *licensee's processing* or in an *application or inspection,* it also appears to indicate authority to license processors. The Plant Board just does not have authority to regulate the techniques that make up a licensee's hemp processing methods and practices, which would be the practices or methodologies referenced in 2-15-502(b).

(5) Section 3(14) – I see that you have redefined "'hemp' or 'industrial hemp'" in a manner that differs from the definition set forth in Ark. Code Ann. § 2-15-503(5), as amended by Act 629 of 2023, § 2. Can you explain the reasoning for this? **AGENCY RESPONSE:** Act 629 of 2023 contains a definition of hemp that does not exactly track the definition of hemp in federal law. Ark. Code Ann. § 2-15-506 (The Arkansas Hemp Production Act) states that in any place where there is a conflict between Arkansas and federal law, federal law controls. While the 2018 federal Farm Bill does say we can regulate more restrictively, we cannot change federal law. The Federal definition is recognized in Section 7 of Act 629, further evidencing that the intent is to be consistent with federal law. We believe that it is appropriate to clarify that the Department does not view the definition of hemp found in Act 629 to conflict in any way with federal law. Accordingly, an amended definition of hemp has been incorporated into the proposed rule to provide that clarification.

(6) Section 8 – It appears that the term "fee" has been changed to "cost." Arkansas Code Annotated §§ 2-15-505(d) and 2-15-507(h-i) authorize the establishment and collection of fees by the board to administer the provisions of the Arkansas Industrial Hemp Production Act. What is the reasoning behind the change in terms? **AGENCY RESPONSE:** Section 8 of the proposed rule has been clarified to make it more consistent with statutory language. Ark. Code Ann. § 2-15-509(b) provides that growers shall pay the ***costs*** of inspections, and 2-15-505 provides that the board ***shall*** establish fees, therefore the fees are mandatory. Section 507 provides that any fees assessed are to administer the program. Therefore, we believe the proposed language in Section 8 of the proposed rule referencing cost recovery instead of fees will more clearly indicate that amount charged applicants and licensees are not only mandatory but are to recover the costs of administering the program.

The proposed effective date is pending legislative review and approval.

FINANCIAL IMPACT: The Board states that the repeal of its former rule and the promulgation of its new rule do not have a financial impact.

LEGAL AUTHORIZATION: The proposed rules implement Act 565 of 2021, which was sponsored by Representative David Hillman, amended the law regarding industrial hemp production, repealed the Arkansas Industrial Hemp Act, and established the Arkansas Industrial Hemp Production Act.

Pursuant to Arkansas Code Annotated § 2-15-505(a), as amended by Act 565, § 2, the State Plant Board shall adopt rules to implement and administer the Arkansas Industrial Hemp Production Act ("Act"), Ark. Code Ann. §§ 2-15-501 to -516. Rules adopted by the Board shall prescribe the sampling, inspection, and testing procedures to ensure that the tetrahydrocannabinol concentration of industrial hemp planted, grown, or harvested in this state is not more than the acceptable hemp tetrahydrocannabinol level as defined by federal law; and provide due process for growers, including an appeals process. *See* Ark. Code Ann. § 2-15-505(b), as amended by Act 565, § 2. The Board is further permitted to establish and collect fees to administer the program. *See* Ark. Code Ann. § 2-15-505(d), as amended by Act 565, § 2; Ark. Code Ann. § 2-15-507(h), as amended by Act 565, § 2. *See also* Ark. Code Ann. § 2-15-507(e), as amended by Act 565, § 2 (providing that the Board shall establish a fee for an initial license and annual renewal license). Fees collected by the Board under the Act are not refundable and may be used by the Department of Agriculture to administer the Act. *See* Ark. Code Ann. § 2-15-507(i), as amended by Act 565, § 2.

2. DEPARTMENT OF CORRECTIONS

a. SUBJECT: Payment of a Death Benefit

DESCRIPTION: Section 47 of Act 203 of 2022, Fiscal Session, now codified as Ark. Code Ann. § 12-27-150, requires the Board of Corrections to promulgate rules to establish criteria for the payment of a death benefit from special revenues held by the Department of Corrections or its various divisions for any Department employee killed in the line of duty. The Act establishes guidelines for the directors to follow in requesting payment of a death benefit for a Department employee who is killed in the line of duty. That payment shall not exceed five thousand dollars ($5,000).

PUBLIC COMMENT: A public hearing was not held in this matter. The public comment period expired on December 7, 2022. The agency received no comments.

The proposed effective date is pending legislative review and approval.

FINANCIAL IMPACT: The agency indicated that the proposed rules have a financial impact and that the rule authorizes expenditure of up to $5,000 per eligible case; however, the agency did not provide an estimated amount because it did not have an identified number of deceased employees for whom this payment might be requested. In response to a staff question, the agency stated that it would be dependent upon the number of employees passing away in the line of duty, then requests being received, contingent upon the board approval amount, etc. as set out in the rule. Payment of funds will be contingent upon availability of money as well.

LEGAL AUTHORIZATION: Subject to the approval of the Board of Corrections, the Secretary of the Department of Corrections may authorize the payment of a death benefit not exceeding $5,000, from special revenues held by the Department of Corrections or its various divisions to any department employee killed in the line of duty. The Secretary of the Department shall promulgate any rules necessary to implement the death benefit. *See* Ark. Code Ann. § 12-27-150, *as amended by Act 203 of 2022*.

3. DEPARTMENT OF HEALTH, STATE BOARD OF HEALTH

a. SUBJECT: Rules for Declaratory Orders

DESCRIPTION:

Background

The Department of Health is tasked with adopting rules for declaratory orders under Ark. Code Ann. § 25-15-206. A petition for declaratory order may be used only to resolve questions or doubts as to how the statutes, rules, or orders may apply to the petitioner's particular circumstances. A declaratory order is not the appropriate means for determining the conduct of another person or for obtaining a policy statement of general applicability from an agency. A petition or declaratory order must describe the potential impact of statutes, rules, or orders upon the petitioner's interests.

Proposed Rules

The proposed rules implement the required rules regarding declaratory orders, pursuant to Ark. Code Ann. § 25-15-206, and implement the model rules outlined in Ark. Code Ann. § 25-15-215.

PUBLIC COMMENT: No public hearing was held on this rule. The public comment period expired on July 29, 2023. The agency indicated that it received no public comments.

The proposed effective date is January 1, 2024.

FINANCIAL IMPACT: The agency indicated that this rule has no financial impact.

LEGAL AUTHORIZATION: "Each agency shall provide by rule for the filing and prompt disposition of petitions for declaratory orders as to the applicability of any rule, statute, or order enforced by it." Ark. Code Ann. § 25-15-206. The proposed rules implement model rules published by the Arkansas Attorney General. *See* Ark. Code Ann. § 25-15-215(b)(1) ("Each agency created after August 13, 2001, shall adopt, in accordance with the provisions of this subchapter, those model rules that are practicable.").

4. DEPARTMENT OF HUMAN SERVICES, DIVISION OF MEDICAL SERVICES

a. SUBJECT: Clinical Trials Attestation SPA and Provider Manual Updates & REPEALS: Crippled Children's State Plan; PUB 407 – Notice of Privacy Practices

DESCRIPTION:

Statement of Necessity

The Center for Medicaid and CHIP Services (CMCS) issued a State Medicaid Director Letter outlining new Medicaid state plan requirements for assuring coverage of routine patient costs associated with participation in qualifying clinical trials. This guidance applies to states and territories and with respect to items and services furnished to Medicaid beneficiaries, including beneficiaries enrolled in Alternative Benefit Plans (ABPs), who are participating in a qualifying clinical trial on or after January 1, 2022.

Rule Summary

Added new State Plan pages to comply with new requirements.

Revised Sections 210.100, 212.200, and 215.300 by deleting the word, "experimental" from non-covered services.

Added Section 215.301 to the Hospital Manual to clarify the Indications and Limitations of Coverage for Medicaid. Effective July 1, 2023, for

items and services furnished on or after January 1, 2022, Medicaid shall cover the routine costs of qualifying clinical trials, as such costs are defined below, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. Providers must submit a Medicaid attestation form to Medicaid for each beneficiary participating in a clinical trial. Instructions for submitting the form and a link to it is provided. All other Medicaid rules apply.

- Routine costs of a clinical trial include all items and services that are otherwise generally available to Medicaid beneficiaries (for example, there exists a benefit category, it is not statutorily excluded, and there is not a national non-coverage decision) that are provided in either the experimental or the control arms of a clinical trial except:
    - The investigational item or service itself, unless otherwise covered outside of the clinical trial;
    - Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (for example, monthly CT scans for a condition usually requiring only a single scan); and
    - Items and services customarily provided by the research sponsors free-of-charge for any enrollee in the trial.
- Routine costs in clinical trials include:
    - Items or services that are typically provided absent a clinical trial (for example, conventional care);
    - Items or services required solely for the provision of the investigational item or service (for example, administration of a noncovered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
    - Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service, for the diagnosis or treatment of complications.

Updated Section IV of the Arkansas Medicaid Provider Manuals is revised to add the definition of Routine Standard of Care Associated with qualifying Clinical Trials, and to revise the definition of "Investigational Product" acknowledging coverage of routine standard of care associated with qualifying clinical trials. The definition of "Medical Necessity" is revised to delete the word "experimental" and correct a typo.

Repeals pursuant to the Governor's Executive Order 23-02:

(1) Crippled Children's State Plan; and
(2) PUB 407 - Notice of Privacy Practices.

PUBLIC COMMENT: A public hearing was held on this rule on July 12, 2023. The public comment period expired on July 17, 2023. The agency indicated that it received no public comments.

The proposed effective date is October 1, 2023.

FINANCIAL IMPACT: The agency indicated that this rule has no financial impact.

LEGAL AUTHORIZATION: The Department of Human Services has the responsibility to administer assigned forms of public assistance and is specifically authorized to maintain an indigent medical care program (Arkansas Medicaid). *See* Ark. Code Ann. §§ 20-76-201(1), 20-77-107(a)(1). The Department has the authority to make rules that are necessary or desirable to carry out its public assistance duties. Ark. Code Ann. § 20-76-201(12). The Department and its divisions also have the authority to promulgate rules as necessary to conform their programs to federal law and receive federal funding. Ark. Code Ann. § 25-10-129(b).

With respect to items and services furnished on or after January 1, 2022, the Social Security Act requires states to provide coverage for "routine patient costs" associated with a "qualifying clinical trial." 42 U.S.C. § 1396d(gg); *see also* P.L. 116-260, div. CC, tit. II, § 210(e) (Dec. 27, 2020) (establishing effective date of January 1, 2022). The Centers for Medicare and Medicaid Services (CMS) issued a State Medicaid Director Letter on April 13, 2022 outlining new Medicaid state plan requirements for assuring coverage of routine patient costs associated with participation in qualifying clinical trials. *See* Ctrs. for Medicare & Medicaid Servs., State Medicaid Director Letter (Apr. 13, 2022), https://www.medicaid.gov/sites/default/files/2022-04/smd21005.pdf.

E. Agency Updates on the Status of Outstanding Rulemaking Pursuant to Act 595 of 2021[1]

1. Department of Agriculture*

2. Department of Corrections*

3. Department of Education

4. Office of Arkansas Lottery

F. Adjournment

[1] For those items designated by an asterisk ("*"), no update may be required depending on the action taken by the Subcommittee with respect to that agency's rules under Item D.