# ADMINISTRATIVE RULES AND REGULATIONS SUBCOMMITTEE OF THE ARKANSAS LEGISLATIVE COUNCIL

Room A, MAC Little Rock, Arkansas

Tuesday, August 14, 2018 1:00 p.m.

- A. Call to Order.
- **B.** Reports of the Executive Subcommittee.
- C. Reports on Administrative Directives for the Quarter ending June 30, 2018 Pursuant to Act 1258 of 2015.
  - 1. Arkansas Parole Board (William Bowman)
  - 2. Department of Community Correction (Dina Tyler)
  - **3.** Department of Correction (Solomon Graves)
- D. Rules Filed Pursuant to Ark. Code Ann. § 10-3-309.
  - 1. <u>DEPARTMENT OF CAREER EDUCATION, ADULT EDUCATION</u> (Dr. Charisse Childers and Trenia Miles)
    - a. <u>SUBJECT</u>: Adult Education Program Policies Update

**DESCRIPTION:** The Adult Education Policies and Procedures have been updated to align more effectively with state and federal laws, especially the Workforce Innovation and Opportunity Act (WIOA) and to take into account changes in the federally-approved Test of Adult Basic Education (TABE).

• In the *Service Delivery Area* policy, a statement was added to indicate "If a program is unwilling or unable to provide needed services in its designated service area, the Adult Education Division may assign or approve another program to do so."

• In the *Enrollment* policies, the required TABE scores have been changed to indicate the NRS Level required due to gradelevel equivalent score no longer being available. Also, survey and battery options are no longer available for the TABE test, therefore, they have been removed.

• In *Enrollment Policy: Private, Parochial or Home School Minimum Age,* a requirement of passing the Arkansas Civics Examination was added.

• In *Enrollment Policy: Private, Parochial or Home School Minimum Age*, #2 (Level A, current form, Survey or Complete Battery) was removed.

• A *Civics Test Requirement* policy has been added to address Act 478 of 2017 the need for changes in the Local Education Agency administering a program.

• In the *Standardized Testing Policy*, a note was added to include all versions of National Reporting Services (NRS)-approved tests.

• In the *Reporting Student Data* policy, the language was updated to reflect NRS terms adopted under WIOA.

• In the *Salaries for Adult Education Personnel* policy, it is noted that increases in line with those provided for LEA staff outside of adult education are allowed.

• In the *Adult Education Director/Coordinator Qualifications* policy, experience requirements were added and verbiage was updated for the requirement of academic progress toward Adult Education licensure. Additionally, the phrase "paid with adult education funds" was removed, and the time frame for completing Adult Education licensure was changed from four to three years to align with the requirements of the Arkansas Department of Education.

• In the *Full-Time Adult Education Teacher Qualifications* policy, the time frame for completing Adult Education licensure was changed from four to three years to align with the requirements of the Arkansas Department of Education.

• In the *Waivers for Adult Education Teachers without an Educator's License* policy, the time frame for completing Adult Education licensure was changed from four to three years to align with the requirements of the Arkansas Department of Education.

**<u>PUBLIC COMMENT</u>**: No public hearing was held. The public comment period expired on July 5, 2018. The Department provided the following summary of the public comment that it received and its response thereto:

### **Regina Olson, Director, Arkansas Tech-Ozark Campus Adult Education**

I would like to make two comments regarding the Underage policies on pages 13-15. Upon review of the policies, I would like to clarify something regarding underage.

(1) In the most recent Advisory Board meeting, we discussed having underage students be required to make a level 5 on the TABE, which could be accomplished via a TABE level of A or D. I would like for that conversation to be considered in the policies. (2) Page 15 2) states "If administered the TABE test (Level A, current form, Survey or Complete Battery)" Survey or Complete Battery could be removed as the new TABE does not have both survey and complete battery options (it has already been changed on page 13, #3). AGENCY RESPONSE: The Department of Career Education, Adult Education Division received your email concerning the proposed Adult Education Policy changes on June 29, 2018. It was received within the time frame for written comments on the proposed rule. Your email has been read and will be considered as we move forward on the decisions related to the rule. Specifically, there is a plan to remove the text ("Level A, current form, Survey or Complete Battery") on page 15. Thank you for your comment and your support of Adult Education and the students we serve.

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

I see on Page 17 where the Policy update includes the limitation pursuant to Arkansas Code Annotated § 6-16-149(c)(3), as amended by Act 478 of 2017, § 1, that only those eighteen (18) and younger must pass the civics test when seeking a high school equivalency diploma; however, on Page 16, the update purports to require documentation of passing from "[s]tudents age 16 or above." Is the Department comfortable with the clarity provided to those reading and trying to comply with the rules? **RESPONSE:** The policy on Page 16 is applicable only to those "16 or above, enrolled in a private, parochial or home school" who desire to take the General Educational Development (GED) test. Those who are no longer required to be enrolled in school due to exceeding the age of compulsory attendance would not necessarily be held to any of the requirements listed, except for the passing of the Civics test. We could, however, clarify the statement below by adding (applicable to those age 16-18) to the civics requirement to make it clearer: "Provide documentation of having passed the Arkansas Civics Examination as required by Act 478 of 2017."

Are these policies being promulgated by the Career Education and Workforce Development Board? **RESPONSE:** Yes. These policies have been reviewed and approved to go on public review by the Career Education and Workforce Development Board.

The proposed effective date is pending legislative review and approval.

FINANCIAL IMPACT: There is no financial impact.

**LEGAL AUTHORIZATION:** The authority and responsibility of the Department of Career Education and the Career Education and Workforce Development Board ("Board") shall include general control and supervision of all programs of vocational, technical, and occupational education in secondary institutions. See Ark. Code Ann. § 25-30-107(b)(1). Pursuant to Arkansas Code Annotated § 25-30-102(c)(2)(A)-(B), the Board shall administer the career education and workforce development programs administered by the Board and shall adopt rules to administer the Board and the programs developed by the Board. The proposed changes include revisions made in light of Act 478 of 2017, sponsored by Representative Bruce Cozart, which required the passage of the civics portion of the naturalization test used by United States Citizenship and Immigration Services before a student may receive a high school diploma or a high school equivalency diploma from a state entity.

# 2. <u>DEPARTMENT OF CAREER EDUCATION, OFFICE OF SKILLS</u> <u>DEVELOPMENT</u> (Cody Waits)

# a. <u>SUBJECT</u>: Special Policies and Procedures for Secondary Technical Centers

**DESCRIPTION:** The rules and regulations for Secondary Technical Centers (STC) cover many areas ranging from updating and removing outdated language, removal of reports no longer necessary, reducing requirements to start a STC, removing barriers that would prevent industry professionals from acting in an instructor or director role, and adding language to reflect our normal operating procedure that has not been stated in rules to date. To highlight a few of the areas where changes were made, see the below bulleted points:

• Relax requirements associated with the startup of a STC by reducing the number of programs required from 6 programs down to 3 promoting quality over quantity. Also, prioritize STC approval to areas not currently being served by a STC. Changes were also made to reflect the transition from hard copy application submissions to electronic submissions.

• Removal of unnecessary requirements for the position of Director for a STC making it more accessible for individuals from the private sector/industry to fill these roles.

• Areas of common practice already being utilized in our processes are in place but were not stated in our rule such as verification of enrollment by the Office of Skills Development (OSD), STCs submitting a proposed annual budget, and all revenue being disclosed on the annual expenditure report.

• Stated that expenses associated with the maintenance and operations of a STC or satellite, shall not be paid by vocational center aid or training fees.

• Definitions were added to pages 8-9.

The goal of these changes is to remove barriers that hinder the operation of a STC yet provide the Department of Career Education as well as the State of Arkansas the necessary information we require to ensure the program is operating efficiently and effectively. The changes to the rule being presented have no fiscal impact on funding as the STC will still be funded as they have been for the last 16 years. Part of the strategic plan for the Office of Skills Development is to provide access to a STC for all school districts in the state of Arkansas. By relaxing requirements associated with the number of programs a STC must begin with, and by providing a STC the flexibility to go out and hire individuals from industry, we believe this will assist in the great progress that has been made over the last three and half years to serve all students in the state.

**<u>PUBLIC COMMENT</u>**: No public hearing was held. The public comment period expired on July 5, 2018. The Department received no public comments.

The proposed effective date is pending legislative review and approval.

FINANCIAL IMPACT: There is no financial impact.

**LEGAL AUTHORIZATION:** A multidistrict vocational center, referred to as a secondary technical center in the instant rules, shall be administered in accordance with the guidelines and policies established by the Career Education and Workforce Development Board ("Board"). *See* Ark. Code Ann. § 6-51-303(b).<sup>1</sup> Pursuant to Arkansas Code Annotated § 25-30-102(b)(1), the Board shall have general supervision of all programs regarding vocational, technical, and occupational education. The Board shall administer the career education and workforce development programs administered by the Board and shall adopt rules to administer the Board and the programs developed by the Board. *See* Ark. Code Ann. § 25-30-102(c)(2)(A)–(B).

# 3. <u>DEPARTMENT OF EDUCATION</u> (Lori Freno, item a; and Courtney Salas-Ford, item b)

# a. <u>SUBJECT</u>: Code of Ethics for Arkansas Educators

**DESCRIPTION:** These rules provide a code of ethics and enforcement measures for Arkansas teachers and administrators.

<sup>&</sup>lt;sup>1</sup>Although section 6-51-303 refers to the Board as the State Board of Career Education, the State Board of Career Education was renamed the Career Education and Workforce Development Board in 2015. *See* Act 892 of 2015, § 5.

The proposed rules reflect changes pursuant to Act 564 of 2017. Under Act 564, nonlicensed teachers are now subject to the Code of Ethics, and these proposed rules add sanctions for those teachers. Other changes to the rules include definitions, procedures, some reorganization of the rules, and provisions authorized under Ark. Code Ann. § 6-17-428, as amended by Act 1090 of 2015. *Revisions to this summary following public comment periods are italicized*.

The most substantive changes are as follows:

#### Section 4.00 – Applicability

4.02 Educators employed under a waiver from licensure are added to this section.

4.03 Preservice teachers are added to this section pursuant to Ark. Code Ann. § 6-17-428, as amended by Act 1090 of 2015

#### Section 5.00 – Definitions

5.07 Adds to the definition of "Educator" persons who are educators employed under a waiver from licensure and preservice teachers (Act 564 of 2017)

5.07.2 Adds "as a teacher of record or an administrator" to make provision consistent with law.

5.11 Includes the statutory composition of the Ethics Subcommittee

5.12 Adds a definition of Ethics Hearing Subcommittee (Act 1090 of 2015), including a member who represents nonlicensed educators

5.14 Adds a definition of Hearing Officer (Act 1090 of 2015)

5.16 Adds a new definition of "Impairment"

5.17 - 5.20 Are new definitions of sanctions for ethical violations by nonlicensed educators that are substantially equivalent to the sanctions for licensed educators.

5.27 Adds a definition for preservice teachers (Act 1090 of 2015)

5.41 Amends the definition of "take action" to include the "preponderance of the evidence" standard

5.42 Adds a definition of "Valid educator's license" that indicates that the complaint process continues when a license expires after the date of the alleged ethics violation.

5.43 Adds a definition of "waiver from licensure" (Act 564 of 2017)

# Section 6.00 - The Code of Ethics for Arkansas Educators

This section makes changes to Standards 2 and 8. Standard 8 is substantially revised to include e-cigarettes and similar products and a provision for impairment due to the abuse or misuse of prescription medication or other "authorized substances."

#### Section 7.00 – Recommended Disciplinary Action

This section adds the disciplinary actions for violations of the Code of Ethics by nonlicensed teachers throughout the section. The section also removes the "written warning," as there is already a private letter of caution that serves as a warning. Former Section 8 is stricken and its provisions are incorporated into the new Section 11.

7.01.1 Is amended to include the "preponderance of the evidence" standard

7.01.3 Is amended to allow a recommendation to the State Board to include an agreement of the parties

#### **Repealed Section 8.00**

This former section for the Procedures for the Investigative Process and Final Determination of Alleged Ethics Violations is repealed and its provisions are incorporated into new Section 11.

#### Section 8.00 – Fines and Fees

License application fees are set by the PLSB, but have been removed from these rules. The PLSB will recommend fees to the State Board for approval and are included in the Rules Governing Educator Licensure.

Fees for licensure applications are non-refundable.

Fines for ethical violations are increased up to \$500 under Act 564 and are listed in (New) Appendix B.

#### Section 9.00 – Disclosure of Records

This section has been substantially revised to provide clear information to the educator concerning the confidentiality of records and the disclosure of sanctions that are assessed by the State Board under these rules.

# Section 10.00 – Mandatory Filing of Allegation and Ethics Violations Review

This section contains revisions to clarify the required reporting of an ethics violation by a supervisor concerning the sexual abuse of a student by an educator.

# Section 11.00 – Procedures for the Investigation of an Ethics Complaint

This section incorporates old Section 8.00 and former Appendix A to provide one section for the investigative procedures.

# Section 12.00 – Procedures for the Initial Determination and Recommendation of the Ethics Subcommittee

This section incorporates old Section 8.00 and former Appendix A to provide one section for the Ethics Subcommittee procedures.

12.03 Is substantially rewritten to remove the requirement for the educator to "accept" – the educator only needs to reject and request an evidentiary hearing

12.03.1 Provides for the State Board's removal of a case from its consent agenda

# 12.03.5 Provides that the ethics complaint process will continue if the license expires after the date of the alleged ethics violation.

# Section 13.00 – Motions before the Ethics Subcommittee or Ethics Hearing Subcommittee

This section incorporates provisions concerning motions from former Appendix A and expands the provisions.

# Section 14.00 – Evidentiary Hearings

This section incorporates provisions concerning evidentiary hearings from former Appendix A and expands the provisions. An Ethics Hearing Subcommittee conducts evidentiary hearings, and may do so with the assistance of a Hearings Officer.

14.04 Is substantially rewritten to remove the requirement for the educator to "accept" – the educator only needs to reject and request State Board review.

14.04.2.1 Provides for the State Board's removal of a case from its consent agenda.

# Section 15.00 – Subpoenas

This section incorporates provisions concerning subpoenas from former Appendix A and expands the provisions to clarify issues concerning the service of subpoenas.

# Section 16.00 – State Board Review

This section incorporates provisions *for the State Board to request a subsequent review and for the State Board* review of evidentiary hearing decisions from former Appendix A.

*The section also* expands the provisions to clarify issues concerning State Board procedures for the review hearing. Provisions for the submission of written objections and briefs, oral argument, testimony, and notices are revised.

#### Section 17.00 – Appeal to Circuit Court

This section is added to provide information to educators concerning the appeal of a State Board decision.

#### **Appendices:**

• Former Appendix A – Procedures for the Investigative Process and Final Recommendation for Disposition of an Ethics Complaint – Removed in favor of incorporating those provisions in the body of the rules

• New Appendix A – Summary of the Timeline for the Ethics Complaint Process – Added to provide a helpful explanation of how the statutory timelines work with the procedures under the rules

• New Appendix B – List of Actions & Applicable Fines – Revised to increase fines as authorized in Act 564 of 2017.

• *Former Appendix B – List of Applicable Fees* – Removed. A new license fee schedule will be recommended from the PLSB to the State Board for approval.

• Appendix C – Explanations and Guidance to Clarify the Intent of the Code of Ethics – Contains new guidance on Standards 1 and 2. Standard 6 adds guidance for nonlicensed educators.

• New Appendix D – Sanction Guidelines for Ethical Violations – The appendix contains a rubric for guiding decisions of the Ethics Subcommittee and Ethics Hearing Subcommittee.

• *Former Allegation of Violation Form* – This form is removed from the rules and will be provided on the ADE website when revised and approved by the PLSB.

**PUBLIC COMMENT:** A public hearing was held on September 27, 2017. The public comment period expired on October 21, 2017. Substantive changes were made, and a second public hearing was held on June 6, 2018. The second public comment period expired on June 13, 2018. The Department provided the following summary of the public comments that it received and its responses thereto:

# Lucas Harder, Arkansas School Boards Association Date Received: October 16, 2017

**Comment:** 3.02: Since the new plan is to have a "student-focused learning system," I would recommend changing "student-centered" to "student-focused."

Agency Response: "Student-centered" has been changed to "student-focused" wherever it appears in the rules.

Comment: 5.05: Professional Licensure Standards Board has been shortened to PLSB in both prior and following definitions and so I would recommend shortening it here to match. Agency Response: This change has been made.

Comment: 5.08: I would recommend amending "virtual school" to read "virtual public school" as it is possible to read "virtual school" to include a virtual school for private students. Agency Response: This change has been made.

Comment: 5.28: In the sixth [last] sentence, "As s A result" should have the lone "s" removed. Agency Response: This change has been made.

Comment: 5.37: Sexual abuse was moved from § 12-18-103(18)(D) to § 12-18-103(20)(D). Agency Response: This change has been made.

Comment: 10.01: Because "public school" is not defined, I would recommend changing this to read "A supervisor at an Arkansas public educational setting." Agency Response: This change has been made.

**Comment:** 11.02.1: There is an "of" missing from between "violation" and "the." Agency Response: This change has been made.

**Comment:** 11.04.3: The arrangement of the first sentence here seems a little confusing. I would recommend changing it for clarity to, "Determined by the Ethics Subcommittee as credible and if true, would constitute a violation by an Arkansas educator of the Code of Ethics as set forth in these rules." The second sentence doesn't seem to belong here. By placing it here, I would expect that the numbered section that would follow would be 11.04.3.1. By having the next section number be 11.05, I'm left wondering if something was left out. I would recommend moving it down to 11.05 and renumber the current 11.05 and following so that it's clear those all fall underneath it.

Agency Response: The recommended change to 11.04.3 has been made. The phrase "An allegation shall be processed as follows:" should have been deleted and that change has been made.

**Comment:** 11.06.5.1: There is a "the" missing from in front of "educator."

Agency Response: This change has been made.

**Comment:** Appendix C: In the paragraph immediately before Standard 1, I would recommend changing "student-centered" to "student-focused."

Agency Response: This change has been made.

**Comment:** Appendix C Standard 1: In the second paragraph of the guidance, because the entire definition of "attribute" from § 6-18-514 is not included here, I would recommend amending the language to "an actual or perceived attribute" to account that the attribute does not have to be actual but can be a perceived one such as a student who is perceived as being homosexual or transgender but does not identify as homosexual or transgender. **Agency Response:** The language has been changed to include a reference to § 6-18-514.

**Comment:** Appendix C: In the Standard 3 Guidance, Arkansas Bureau of Legislative Audit was changed to just Arkansas Legislative Audit in 2015. **Agency Response:** This change has been made.

**Comment:** Commas are missing between "employment" and "promotion" and between "promotion" and "or." **Agency Response:** This change has been made.

**Comment:** Appendix C: In the Standard 6 guidance, A.C.A. § 6-15-438 should be replaced with § 6-15-2907. **Agency Response:** The language "under Ark. Code Ann. §§ 6-15-438, 6-17-410(d)(1)(A)(iii)" is changed to read "by law."

# Anonymous Caller Date Received: October 23, 2017

**Comment:** 7.01 currently says: The Ethics Subcommittee or Ethics Hearing Subcommittee is authorized to recommend to the State Board <u>a Level 1 Public Notification for a nonlicensed</u> <u>educator, or for a licensed educator, a written reprimand or the</u> probation, suspension, revocation, <del>or</del> nonrenewal, or <u>non-issuance</u> of <u>a teaching an educator's</u> license <del>or the issuance of a reprimand</del> <del>or warning</del>. Should "a Level 1 Public Notification" be "Levels of Public Notification"? **Agency Response:** Yes, and the change has been made.

#### Tripp Walter, Arkansas Public School Resource Center Date Received: June 13, 2018

**Comment:** (*Via phone call*) Section 5.07.2 does not track the language of the statute, which reads in multiple locations "an individual employed under a waiver from licensure as a teacher of record or an administrator." **Agency Response:** A change has been made to more accurately reflect the statutory language.

Rebecca Miller-Rice, an attorney with the Bureau of Legislative Research, asked the following questions, during the first public comment period:

<u>Section 7.04</u> – Is the reason for precluding an appeal from a private letter of caution because it is not considered a sanction in that it is not placed in an educator's licensure file? **RESPONSE:** Yes.

<u>Section 9.08.2</u> – Is there a conflict between this section and section 9.01 regarding written reprimands, where the latter provides that written reprimands will be reported to ADE but not publicly viewable in AELS, but the former provides that orders of written reprimands will be publicly available on the ADE website, but removed after two years? **RESPONSE:** I would call it a difference, but not a conflict. The orders are viewable on the ADE website, but not identified when someone looks up a particular educator's account on AELS.

<u>Section 10.01</u> – Arkansas Code Annotated § 6-17-428(p)(2)(B) provides that an educator in a supervisory role in an "Arkansas school" shall file an ethics complaint under the circumstances set forth in the statute, whereas the rule as written provides that a supervisor at an "Arkansas public school" shall file. Was there a reason for the distinction made by the rule? **RESPONSE:** No reason. That can be changed to remove the word "public."

<u>Section 12.03.1</u> – Should the request in writing be for an evidentiary hearing before the Ethics <u>*Hearing*</u> Subcommittee? **RESPONSE:** Yes, and we will correct that.

<u>Section 12.03.5</u> – Is this section duplicative of Section 12.03.1? **RESPONSE:** Yes, and we will remove the duplicative 12.03.5. The proposed effective date is pending legislative review and approval.

**FINANCIAL IMPACT:** The Professional Licensure Standards Board (PLSB) will need to add programming to the Arkansas Educator Licensure System (AELS) to accommodate adding the new sanctions for non-licensed educators to the PLSB database and to the reporting capabilities in AELS. Therefore, the Department estimates that the financial impact will be \$5,000 -\$10,000 in special revenue in the current fiscal year.

**LEGAL AUTHORIZATION:** These proposed rules include revisions brought about by Act 1090 of 2015, sponsored by Representative James Ratliff, which amended provisions of the Arkansas Code concerning educator ethics violations, and Act 564 of 2017, sponsored by Representative DeAnn Vaught, which amended the Arkansas Code concerning the Professional Licensure Standards Board. Pursuant to Arkansas Code Annotated § 6-17-422, the Professional Licensure Standards Board ("PLSB") shall establish a code of ethics for administrators and teachers, including those employed under a waiver from licensure as a teacher of record or as an administrator, in educational environments for students in prekindergarten through grade twelve (preK - 12), including procedures and recommendations for enforcement as provided in subsection (h)(3) of the statute. See Ark. Code Ann. § 6-17-422(h)(3)(A)(i), as amended by Act 564 of 2017, § 4. The PLSB shall further establish procedures for receiving and investigating an ethics complaint; enforcing the code of ethics; granting and conducting hearings concerning ethical violations; and publicizing notifications equivalent to the recommendations for enforcement of the code of ethics. See Ark. Code Ann. § 6-17-428(b)(1)(A), as amended by Act 564, § 6. The PLSB may also recommend to the State Board of Education, and the State Board may approve, the monetary fees to be paid by a person for the issuance, reissuance, fine, or penalty associated with the process, procedures, or enforcement of requirements necessary to issue or maintain an Arkansas teaching license; under no circumstances shall any one (1) specific fee or fine exceed five hundred dollars (\$500). See Ark. Code Ann. § 6-17-422(h)(3)(C)(i)-(ii), as amended by Act 564, § 4.

b. <u>SUBJECT</u>: Arkansas Educational Support and Accountability Act; Repeals: Monitoring of Arkansas Comprehensive School Improvement Plans; Access to Public School Information on Arkansas Comprehensive School Improvement Plans; Arkansas Comprehensive Testing, Assessment and Accountability Program (ACTAAP) and the Academic Distress Program; Assessment Scores for Students Attending the Arkansas School for Mathematics, Sciences and the Arts of the University of Arkansas

**DESCRIPTION:** These proposed new rules implement the Arkansas Educational Support and Accountability Act (AESAA) established by Ark. Code Ann. § 6-15-2901 et seq. (Act 930 of 2017). The AESAA replaces the previous state accountability system, the Arkansas Comprehensive Testing, Assessment and Accountability Program (ACTAAP). These rules set forth requirements for academic standards, the statewide student assessment system, student-focused learning systems, effective educators, the levels of support provided to school districts, and the Department's authority to assume control of a school district. Each section is specifically addressed below:

4.00 – Arkansas Academic Standards

• Requires the Department of Education to develop academic standards.

- Requires instruction to be based on the standards.
- Sets forth the process for review of the standards.

5.00 – Statewide Student Assessment System

• Sets forth the assessments required for each grade level and student-specific population.

• Sets forth the requirements governing administration and security of required assessments.

• Requires the Department to establish performance levels for each assessment.

6.00 – Student-Focused Learning System

• Requires school districts to develop and implement a student-focused learning system.

• Requires schools to develop Student Success Plans for all students entering the 8<sup>th</sup> grade, by the end of the 8<sup>th</sup> grade year, and sets forth plan requirements.

7.00 – Equitable Access to Excellent Educators

• Requires districts to use Department-provided programs for recruiting, hiring, retaining, and developing effective teachers and leaders.

• Sets forth reporting requirements for schools and districts.

8.00 – Levels of Support for Public School Districts

• Requires the Department to provide differentiated levels of support to all school districts.

• Sets forth the process for determining what support the Department will provide.

• Sets forth the requirements for school-level improvement plans and district support plans.

• Sets forth the process for identifying a school district as in need of level 5 – intensive support and the authority of the State Board of Education over these districts, including assuming control of the district.

#### Summary of changes made after public comment period:

2.00 – Legislative Findings and Purpose

• Language revised to add clarity.

3.00 – Definitions

• Definitions of "Academic Growth" and "Comprehensive support" revised to add clarity.

#### 5.00 – Statewide Student Assessment System

5.07.1 added language from statute.

• 5.12.1.2 revised description of a "college and career readiness assessment."

• Corrected title of referenced ADE rules and statutory citation.

8.00 – Levels of Support for Public School Districts

- 8.05.4 corrected time frame.
- 8.09.2 and 8.09.3 revised to clarify process for openenrollment charter schools.

The following rules are repealed: Monitoring of Arkansas Comprehensive School Improvement Plans; Access to Public School Information on Arkansas Comprehensive School Improvement Plans; Arkansas Comprehensive Testing, Assessment and Accountability Program (ACTAAP) and the Academic Distress Program; Assessment Scores for Students Attending the Arkansas School for Mathematics, Sciences and the Arts of the University of Arkansas

**<u>PUBLIC COMMENT</u>**: A public hearing was held on April 19, 2018. The public comment period expired on May 15, 2018. The Department provided the following summary of the public comments that it received and its responses thereto:

#### Jennifer Wells, APSRC

**Comment:** Sec 3.01: Substitute "assessed points" for "moments." **Agency Response:** Comment considered. No changes made.

**Comment:** Secs 3.13 & 3.14: Open-enrollment public charter schools are included in the definitions of both "Public School" in 3.13 and "Public School District" in 3.14 (as outlined in Ark. Code Ann. § 6-15-2903). It is unworkable for the term to be both. **Agency Response:** Open-enrollment public charter schools are included in the definition of "public school district" for purposes of these rules only. Public charter schools are treated similarly to public school districts in multiple situations including, but not limited to, granting waivers and distributing funds. Language was added to Sections 8.09.2 and 8.09.3 to clarify when charters are distinguished from public school districts. All other requirements of the rules apply to public charter schools.

**Comment:** Sec. 5.16: The term "district test coordinator" is a defined term, so it should be defined before its first usage. Here, it is not defined until Sec. 5.18. Additionally, it should be capitalized consistently. **Agency Response:** District Test Coordinator is defined in Sec. 3.05; however, Sections 5.16 through 5.19 were renumbered for additional clarity. Capitalization changes made.

**Comment:** Sec 8.02.1.1: There is not an identified level for the term "targeted." **Agency Response:** Targeted support is defined in Sec. 3.19. No changes made.

**Comment:** Sec 8.02.1.1: "Comprehensive support" is not identified as a term for a level: the list includes "General," "Collaborative," "Coordinated," "Directed," and "Intensive." It would be confusing to include the term "Comprehensive support." **Agency Response:** Comprehensive support is defined in Sec. 3.04. No changes made.

#### David Gupta, College Board

**Comment:** Revise 5.12.1.2 as follows: Earn other postsecondary credentials including, but not limited to, industry recognized credentials or technical certifications that allow a student to embark on a career. **Agency Response:** Section amended.

#### Lucas Harder, Arkansas School Boards Association

**Comment:** 2.02.1: Because the language here is not a direct quote from the cases, "school district board of directors to meet its burden" is never exactly set forth here so I would recommend including language from 2.01.2 or 2.01.3 to describe the burden a district is responsible for as the average reader is not going to know the case law. **Agency Response:** Language revised.

**Comment:** 3.01: The language here is written more as a statement than as a definition and doesn't match the style of the other definitions. To make it more closely match the statutory language and the other definitions, I would recommend changing it to read: "Academic Growth" means calculation of the change in student achievement over two or more moments in time by using a value-added model. **Agency Response:** Language revised.

**Comment:** 3.04: I would recommend changing it to read "as being within the lowest" as I could see the language as written to be interpreted as only applying to the absolute lowest of the schools within the 5% rather than all those within the 5%. **Agency Response:** Language revised.

**Comment:** 5.16: The code citation should actually be 6-15-2901 et seq. **Agency Response:** Revised.

**Comment:** 8.05.4: A.C.A. § 6-15-2914(d)(2) requires that SDSPs be posted to the district's website no later than ten (10) days after submission to the Department rather than the twenty (20) stated here. **Agency Response:** Revised.

**Comment:** 8.07.5.4: "[W]hy the school district shall not be classified" should instead read "why the school district should not be classified." **Agency Response:** Revised.

#### **Cory Biggs, ForwARd Arkansas**

**Comment:** ForwARd Arkansas is supportive of these new Rules, as they are generally consistent with the recommendations made in

ForwARd's 2015 report, A New Vision for Arkansas Education. Agency Response: Comment considered. No changes made.

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

<u>Section 2.00</u> – This section is entitled legislative intent; however, the statute upon which the rules are premised are entitled "Legislative findings." I am hesitant to equate the two where the General Assembly did not specifically state its intent as such. The exception here would be Section 2.01.4, which appears premised on Ark. Code Ann. § 6-15-2912 and expressly states legislative intent. **RESPONSE:** Language revised.

<u>Section 2.01.2</u> – Should "its" be "the State's" as "its" could be taken to mean the General Assembly's duty? **RESPONSE:** Language revised.

<u>Section 2.01.3</u> – Similarly, it is the State's responsibility to ensure the opportunity, not specifically the General Assembly? **RESPONSE:** Language in 2.01 revised to provide clarity.

<u>Section 2.03</u> – Should "qualified and" precede "effective educators" as provided in Ark. Code Ann. § 6-15-2912(b) on which the section appears to be based? **RESPONSE:** Language revised.

<u>Section 3.01</u> – Does the method of calculation proposed as "over two or more moments in time" conflict with the definition of "academic growth" set forth in Ark. Code Ann. § 6-15-2903(1), which specifies the calculation of academic progress from "one school year to the next"? **RESPONSE:** No; the current "moments in time" used are from one school year to the next.

<u>Section 3.03</u> – Should "criterion-referenced" precede measurements, as provided in Ark. Code Ann. § 6-15-2903(2) on which the section appears to be based? **RESPONSE:** The definitions do not conflict.

<u>Section 3.08</u> – Is there a reason the Department opted not to use the definition of "English learner" as set forth in Ark. Code Ann. § 6-15-2903(6)? **RESPONSE:** The definitions do not conflict. <u>Section 3.18</u> – Was there a reason the Department did not use the definition of "superintendent" as defined in Ark. Code Ann. § 6-13-109(b) or § 6-17-2502(4)? **RESPONSE:** Since openenrollment charter schools do not typically have boards of directors, these definitions would not be inclusive of charter schools.

<u>Section 5.07</u> – Should this include reference to the subjects of "English language arts, mathematics, and science" as provided in Ark. Code Ann. § 6-15-2907(a)(2)? **RESPONSE:** Language revised.

<u>Section 5.08</u> – Will the "procedures established" be done so through rule promulgation? **RESPONSE:** Assessment procedures, set forth in applicable assessment administration manuals and materials, includes information required by Ark. Code Ann. § 6-15-2907 and assessment-specific protocols issued by the test developer. This information is not promulgated as a rule.

<u>Section 5.09.1</u> – Will the "guidelines" be established by rule? **RESPONSE:** The guidelines are not mandatory and thus, will not be established by rule.

<u>Section 5.11.2</u> – How will the "student performance levels" be established? **RESPONSE:** Ark. Code Ann. § 6-15-2910 requires the Department to recommend student performance levels to the State Board for approval.

<u>Section 5.12.1</u> – Was there a reason the Department opted not to track the definition set forth in Ark. Code Ann. § 6-15-2903(2)? **RESPONSE:** The definition in Section 3.03 aligns with the definition in 6-15-2903(2). The information in Sec. 5.12.1 is supplementary to this definition.

<u>Section 6.04.1</u> – Was there a reason the Department did not use the definition set forth in Ark. Code Ann. § 6-15-2903(12)? **RESPONSE:** The definition in Section 3.16 aligns with the definition in 6-15-2903(12). The information in Sec. 6.04.1 is supplementary to this definition.

<u>Section 8.05.4</u> – Is there a reason that this section specifies twenty (20) days when the statute on which the rule appears premised, Ark. Code Ann. § 6-15-2914(d)(2), provides that the plan shall be

posted no later than ten (10) days? **RESPONSE:** Language revised.

The proposed effective date is pending legislative review and approval.

FINANCIAL IMPACT: There is no financial impact.

**LEGAL AUTHORIZATION:** The instant proposed rules are being promulgated as a result of Act 930 of 2017, sponsored by Senator Jane English, which amended provisions of the Arkansas Code concerning the Public School State Accountability System. Pursuant to Arkansas Code Annotated § 6-15-2904, as amended by Act 930, § 2, the Department of Education shall develop and implement a comprehensive accountability system for Arkansas public schools and school districts that: (1) establishes clear academic standards that are periodically reviewed and revised; (2) maintains a statewide student assessment system that includes a variety of assessment measures; (3) assesses whether all students have equitable access to excellent educators; (4) establishes levels of support for public school districts; and (5) maintains information systems composed of performance indicators that allow the department to identify levels of public school district support and generate reports for the public. The State Board of Education is authorized to and shall: approve academic standards for each content area and a statewide student assessment system, including without limitation performance levels for statewide assessments; promulgate rules to implement the comprehensive accountability system for Arkansas public schools and school districts and the Arkansas Educational Support and Accountability Act ("Act"), codified at Ark. Code Ann. §§ 6-15-2901 through 6-15-2918, as amended by Act 930; and take any other appropriate action required or authorized by the Act. See Ark. Code Ann. § 6-15-2905.

# 4. <u>DEPARTMENT OF HUMAN SERVICES, COUNTY OPERATIONS</u> (Mary Franklin and Kristie Hayes)

a. <u>SUBJECT</u>: Section F-180: Exceptions to the 90-Day waiting Period for ARKids-B Applicants with Additional Health Insurance Coverage **DESCRIPTION:** Section MS F-180, Other Health Insurance Coverage, is updated to comply with federal regulations regarding exceptions to the 90-day waiting period for ARKids-B applicants with additional health insurance coverage.

**<u>PUBLIC COMMENT</u>**: The Department did not hold a public hearing. The public comment period ended on July 14, 2018. The Department received no comments.

The proposed effective date of the rules is September 1, 2018.

**<u>FINANCIAL IMPACT</u>**: There is no financial impact as the policy change only adds exemptions to existing policy.

**LEGAL AUTHORIZATION:** The Department 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." Arkansas Code Annotated § 20-76-201(12). DHS is also authorized to promulgate rules as necessary to conform to federal rules that affect its programs as necessary to receive any federal funds. *See* Ark. Code Ann. § 25-10-129(b).

Generally, ARKids First health insurance provides two coverage options: ARKids A is Medicaid for children and offers benefits to low-income families and ARKids B provides coverage for families with higher incomes. The Department avers that this rule is required to comply with a federal regulation regarding exceptions to the 90-day waiting period for ARKids B applicants with additional health insurance coverage.

A federal regulation that addresses state plan requirements and substitution under group health plans, 42 CFR 457.805, provides that a state plan must include reasonable procedures to ensure that health benefits coverage provided under the state plan<u>https://www.law.cornell.edu/definitions/index.php?width=840</u> <u>&height=800&iframe=true&def\_id=0ee6decb9fbea492a8e56070c</u> <u>ea59b1a&term\_occur=3&term\_src=Title:42:Chapter:IV:Subchapte</u> <u>r:D:Part:457:Subpart:H:457.805</u> does not substitute for coverage provided under group health plans. However, a state may not impose a period of uninsurance which exceeds 90 days from the date a child otherwise eligible for CHIP is disenrolled from coverage under a group health plan. A waiting period may not be applied to a child following the loss of eligibility for and enrollment in Medicaid or another insurance affordability program. If a state elects to impose a period of uninsurance following the loss of coverage under a group health plan under this section, such period may not be imposed in the case of any child if: (i) The premium paid by the family for coverage of the child under the group health plan exceeded five (5) percent of household income;

(ii) The child's parent is determined eligible for

advance payment of the premium tax credit for enrollment in a Qualified Health Plan (QHP) through the Exchange because the Employer-Sponsored Insurance (ESI) in which the family was enrolled is determined unaffordable;

(iii) The cost of family coverage that includes the child exceeds 9.5 percent of the household income;

(iv) The employer stopped offering coverage of dependents (or any coverage) under an employer-sponsored health insurance plan;
(v) A change in employment, including involuntary separation, resulted in the child's loss of employer-sponsored insurance (other than through full payment of the premium by the parent under COBRA);

(vi) The child has special health care needs; or

(vii) The child lost coverage due to the death or divorce of a parent.

# 5. <u>DEPARTMENT OF HUMAN SERVICES, MEDICAL SERVICES</u> (Tami Harlan)

# a. <u>SUBJECT</u>: Prosthetics 1-18 and Section V 2-18

**DESCRIPTION:** Effective September 1, 2018, Arkansas Medicaid Prosthetics Manual and appropriate forms have been updated to comply with Act 372 of 2017 adding Advanced Practice Registered Nurse (APRN) authorization for durable medical equipment (DME).

**<u>PUBLIC COMMENT</u>**: The Department did not hold a public hearing. The public comment period ended on July 10, 2018. The Department received no comments.

The proposed effective date of the rules is September 1, 2018.

FINANCIAL IMPACT: There is no financial impact.

**LEGAL AUTHORIZATION:** The Department 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." Arkansas Code Annotated § 20-76-201(12).

If a signature by a physician is required to authorize durable medical equipment, Act 372 of 2017, sponsored by Representative Mary Bentley, allows the requirement to be fulfilled by an advanced practice registered nurse or a physician assistant. *See* Ark. Code Ann. § 17-80-120(a).

# 6. <u>INSURANCE DEPARTMENT</u> (Allen Kerr and Booth Rand)

# a. <u>SUBJECT</u>: Rule 118: Pharmacy Benefits Managers Regulation

**DESCRIPTION:** This rule implements Act One (1) and Act Three (3) of the Second Extraordinary Session of 2018 by the Ninety-First (91st) Arkansas General Assembly, "An Act To Create The Arkansas Pharmacy Benefits Manager Licensure Act," (hereafter, the "PBM Licensure Act") which authorizes the Arkansas Insurance Commissioner ("Commissioner") to issue rules to regulate the licensure and activities of pharmacy benefits managers ("PBMs").

The Commissioner is required to issue a rule implementing the PBM Licensure Act on or before September 1, 2018. The PBM Licensure Act authorizes the Commissioner to issue rules establishing the licensing, fees, application, financial standards, and reporting requirements of pharmacy benefits managers subject to the PBM Licensure Act. In addition, the Commissioner is authorized to issue rules governing the financial solvency, network adequacy, maximum allowable cost practices, compensation, rebates and other matters of pharmacy benefits managers subject to the PBM Licensure Act.

The proposed Rule has the following key features:

• For financial and licensure filings, requires filing of identification and location information, organizational documents, and SOS registration, regulatory contact, audited annual financial information, generic standardized contracts, a description of its

MAC compliant processes and appeal processes, anti-gag compliance procedures, historical license denial or suspension information, and other standard licensure application information.

• Requires for licensure, a \$1,000,000.00 surety bond. This amount can be lowered by Commissioner in the event the business operations of the PBM in the state would make this amount unreasonable.

• Requires for licensure, a \$1,000.00 filing fee.

• Provides a licensure (and renewal of licensure) review, approval and disapproval procedure with a right to a hearing by the PBM as an aggrieved party.

• Provides a financial and licensure standard of review for license under (1) financially hazardous condition, (2) rule or state law violation or pattern of misconduct, or (3) failure to submit licensure information.

• Prohibits contracts violating and waiving violations of 23-92-506(c) (payment retroactivity), 23-92-507 (anti-gag clause), 4-88-1004 (anti-clawback), and 17-92-507 (MAC).

• Prohibits contracts violating 23-92-506(b)(2) (fees) and 23-92-506(b)(3)(cert. standards) unless approved by Commissioner. Establishes procedure for PBM to have Commissioner review and approve otherwise prohibited language with a right to an administrative hearing.

• Requires health insurers to file network adequacy of pharmacies under Rule 106 PCP standards.

• Establishes requirements for discretionary review of compensation or reimbursement review by Commissioner under adverse impact analysis on network adequacy [10% or more to Rule 106(5)(F)].

• Applies the examination requirements placed on insurers to PBMs other than the regular time period of examinations.

• Captures MAC appeals and challenges activity and requires reporting of spread pricing as detailed in Section 9 of the Rule.

• Has a transition licensing period to adjust to the timing of the new rule.

- Has a penalties provision tied to Trade Practices penalties.
- Has effective date 1-1-2019.

**<u>PUBLIC COMMENT</u>**: The Arkansas Insurance Department (AID) held a public hearing on July 11, 2018. The public comment period ended on July 11, 2018. AID provided a summary of the public comments and its responses shown below:

#### **Public Comments Summary**

The following are responses from AID related to public comments for proposed Rule 118, Pharmacy Benefits Managers. AID is herein responding to comments which address specific content related issues, or specific language, derived from the initially filed rule. Although received, reviewed and counted, in terms of gauging the public interest in the Rule, AID is not responding herein to comments which are simply general statements for or against the Rule, or comments, which urge support for or against a particular organization's comments. Also, where one organization raised the same concerns as another, AID will not duplicate the same response here under every organization's section here. Please consult the entire Public Comments Summary. These are also merely explanatory notes and should not be considered binding statements or interpretations of the PBM Licensure Act or proposed Rule.

Pharmacy Care Management Association, July 11, 2018.

Section 4(8) pass-through pricing definition needs to be removed

because it is not used in the Rule.

AID: We removed that definition.

Section 4(20) references fees in the spread pricing model

definition, and fees are a separate and distinct issue [from spread pricing practices].

AID: We removed the last sentence in that definition but are keeping the spread-pricing definition.

Sections 5(A)(7) and 5(A)(10) should include Provider Manuals which address the MAC law and clawback law practices.

*AID: We added Provider manuals to the list of items we can review for contracting compliance.* 

Section 5(A)(13) is unclear whether it is asking about assumption of insurance risk or operational business risk.

*AID:* We are referring to assumption of risk for the covered benefit (prescription drug) and added this clarification.

Section 5(A)(15) includes reporting terminations for "dishonest" activities, and is too broad and not defined.

AID: We removed the word, "dishonest."

Section 5(A)(15) needs a corrective plan step for curing initial licensure and renewal issues.

AID: We added a corrective plan to cure administrative deficiencies; however, only for financial issues which may be curable, and failure to submit information. PBMs which are denied for violations of the law have adequate appeal procedures to contest those determinations.

Section 5(D) needs to also adopt § 23-61-107 (a)(4) confidentiality standards for material transactions.

AID: We added this for reporting of financial material transactions. We are not removing 23-61-103 which is needed to maintain confidentiality for examinations and investigations. Section 6(A)(3), related to the standard evaluating fees, and certification standards, the phrase "objective evidence," is extreme and unnecessary.

*AID:* We will describe it as "specific and detailed," the intent of this section is the same, and that is, we do not want merely conclusory statements or representations that a fee or standard improves quality or reduces costs.

Section 7(B). Reimbursement must be evaluated in the aggregate.

AID: Although we envision reviewing or measuring the entire reimbursement transactions with pharmacies as one barometer to ensure network adequacy, we are keeping the current language, to allow our network adequacy staff sufficient flexibility to determine the adequacy of pharmacy reimbursement.

Section 7(B)(1). The Rule should reflect that PBMs contract with "pharmacies" not individual "pharmacists."

AID: we made the correction throughout the Rule, replacing "pharmacies," with "Pharmacists or Pharmacies." This is consistent with the PBM Licensure Act.

Section 7(B)(2)(b) should keep a consistent standard of review, in that the impact on pharmacy participation in health plans, should be either on a state-wide basis, or "in a significant geographical area."

AID: We agree and adopted this change.

Section 7(B)(2)(b) should address or provide a timeframe of measurement related to the 10% reduction and should consider removing the phrase, "solely, due to a reduction in compensation." *AID: We intend for the time frame specifics to be explained and addressed by our network adequacy division, after issuance of this rule. For issues related to reasons for pharmacy termination, AID intends to work with the PBMs and plans to track, monitor and gather sufficient information from the pharmacy, to determine whether compensation reduction, was the sole reason for the termination.* 

Section 7(B)(2) should count or consider the times the same pharmacy submitted prescriptions without any issue, not just the declinations, in network adequacy measurements.

AID: Although, in general, we intend for the network adequacy division to address the extent to which, if any, the overall

prescriptions serviced by a pharmacist in reviewing declinations, however the Department may want to review declinations for certain drugs, or may want to review individual or geographic levels of pharmacies should the need arise.

AID should make confidential information gathered during a compensation review under Section 7.

AID: We added a confidentiality Section in 7(B)(6).
Section 7(B)(5) should be consistent and refer to "adverse impact."
AID: We agree and now refer to "adverse impact."
Section 9 related to MAC and Spread reporting, is pre-empted by
Federal law and PCMA v Rutledge.

AID: AID will follow or adhere to federal law; however, it is our understanding that for the MAC law reporting, in terms of finality of this ruling, the Eighth Circuit Case may be appealed. Secondly, on spread reporting the obligation, as well as compensation review mechanism, these are also aimed at the healthcare insurers or HMOs. Finally, it is our understanding that the validity or legality of the Provider Licensure Act, as to other requirements which are not MAC law related, either in part, or in its entirety, as to group ERISA plans is not before the Court(s). AID is not a party to such proceedings but will defer to the subsequent rulings of the Court(s).

Pharmaceutical Research and Manufacturers of America (Pharma), June 29, 2018

Pharma submitted various rule section additions which require tracking, reporting and monitoring by AID of PBM rebates. *AID: AID believes tracking or monitoring rebates is important; however, at this time, we believe adding these sections would involve a significant, substantive change to the rule, possibly necessitating re-noticing the public rule. Given that our priority at* 

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this time has been providing licensing standards, financial solvency standards, and addressing compensation and contracting issues in a rule requiring issuance before September 1 of this year, we would prefer addressing this at a later time.

<u>The Surety & Fidelity Association of America, July 5, 2018</u> The Surety & Fidelity Association of America ("SFAA") has concerns with the availability of the bond amount and in addition that the amount of the bond may be excessive for a PBM with limited net worth and working capital.

AID: We believe from our research with surety bond issuers that this amount is available. This amount was copied from the State of Kentucky. We are willing however to work with PBMs as to language issues triggering the bond amounts; however, we borrowed the same language used in other States. As to it being excessive relative to the size of operations of the PBM in this State, the Commissioner may reduce the amounts for smaller PBMs, please see Section 5(B)(4): "The Commissioner may however reduce the amount of the bond requirement in Section 5(A)(2) if the amount required is unreasonable relative to the size of the PBM's business operations in this State and would cause a significant financial hardship."

# National Association of Mutual Insurance Companies, July 10, 2018

The National Association of Mutual Insurance Companies (NAMIC) supports the (PBM Licensure Act) Legislation and AID Rule, for specifically excluding workers' compensation plans.

#### Arkansas Pharmacists Association, July 2, 2018

Section 11 limits penalties, actions, or orders for violations of this Rule, to § 23-66-209 and 210, and thus a violation of Rule 118 would only result in a Cease and Desist order

AID: We have corrected this by designating that a violation of this Rule shall be considered an unfair and deceptive Act under 23-66-206 which would trigger all of the penalties, actions, including monetary fines, revocation and suspension under 23-66-210 and 209. There is no need to copy and paste the entire 23-66-210 statute.

Section 23-92-506(b)-(d) set forth specific practices the PBM may not engage in, yet with the Exceptions of Section 6(B) and Section (7)(C) there is no express prohibition of the practices set forth in 23-92-506(b)-(d)

AID: We disagree. Starting with 23-92-506 (b)(1) prohibits deceptive advertising and marketing, See Section 6(b); 23-92-506(b) (2) restricts fees, See Section 6(A) (3); 23-92-506(b) (3) restricts certification standards. See Section 6(A)(3).

23-92-506(b)(4) on affiliate reimbursement restriction. See Section 7(C).

There is no specific complaint mechanism process under the Rule to provide a mechanism for pharmacists to notify of violations. *AID: There is no need for a pharmacist specific complaint mechanism. Our consumer services division and legal division accept, review and investigate medical provider complaints, physicians, and hospitals on a daily basis without a specific provider type process. Pharmacists can file their complaints with either the Arkansas Insurance Department Consumer Services Division or Legal Division.*  Suggestion to add a new section to evaluate pass-through and spread pricing.

AID: We are not evaluating pass-through pricing at this time; however, if that becomes an issue we may consider it for later rulemaking.

Exclusion of Medicare Advantage Plans and Medicare Programs. Section 4(4)(B)(vii) excludes from the definition of "health benefit plan," "Medicare Advantage Plans or Medicare programs which provide pharmacy or prescription drug coverage. This exclusion needs to be removed because it is not in the PBM Licensure Act. AID: We agree the exclusion is not in the PBM Licensure Act. It is added out of an abundance of caution to avoid possible preemption claims or actions. In addition, this is consistent with AID's history of not applying State based network laws and medical mandates, to Medicare Advantage plans, due to federal preemption under the Medicare Modernization Act, and rules issued by CMS. Our position has been, at least for Medicare Advantage Plans, the networking requirements and benefit requirements are regulated by CMS, however AID may regulate the financial solvency and licensing of the marketing representatives. AID should adopt the pharmacy network standards, in its compensation review of adverse impact, for Medicare Part D set forth in 42 CFR 423.120(a)(1).

AID: Our staff considered these metrics; however, given these might be considered substantive or significant metric distance reductions from a PCP's, and what was in the filed rule, requiring re-notice, we would prefer to possibly address this later, as our network adequacy division develops and reviews data on terminations and compensation following issuance of this Rule. AID should provide in the Rule that a "PBM shall provide a reasonably adequate network for the provision of prescription drugs for a health benefit plan that shall provide for convenient patient access to pharmacies within a reasonable distance from the patient's residence."

AID: Our view of this issue is that the health insurers and HMOs, simply contract with PBMs, for drug networks, and it is these entities which should ultimately be responsible for establishing adequate networks to provide benefits for their members. There should be a provision for commissioner investigation, action, hearing and penalties for violations of network access requirements.

AID: The rule provides ample examination and investigation authority for the Commissioner to review compliance with the PBM Act and this proposed Rule.

APA suggests various language changes to the PCP metrics under Rule 106(5)(B)(2).

AID: We reviewed these suggested changes, and at this time,
because they may be viewed as substantive changes to the
proposed Rule, requiring re-notice, we would defer to reviewing
them, for change, possibly, at a later time, as our network
adequacy division reviews implementing the PCP metrics.
APA suggests there should be tests in Proposed Rule 118 that
determine prospectively whether compensation is sufficient to
provide prospectively whether compensation is sufficient on initial
application, renewed application and during the year.
AID: It is not the desire or policy of the Department to preapprove, or review medical provider compensation programs, or
contracting in advance, which have not yet gone into effect, and,

for pharmacies, without seeing an adverse impact.

The adverse impact of 10% is confusing in terms of its relationship with the 80% tolerance in Rule 106.

AID: We agree, and have removed the 10% requirement and the standards or requirements are entirely what a PCP or physician's metrics are.

The last two paragraphs in Section 7(B)(2)(b) appear negated by Section 7(B)(5) restricting review of compensation to compliance with Rule 106 network adequacy.

AID: We disagree, the adverse impact standards must first exist to ultimately implicate the Rule 106 metrics, and corrective actions under Rule 106(7)(B)(5).

Section 7(B)(5) of the proposed Rule merely refers back to 23-66-210 that is limited to a Cease and Desist Order.

AID: We do not see this reference but see a reference to Ark. Code Ann. §§ 23-61-201, which is our examinations provision.

Arkansas Pharmacy Association, Second Comment, July 6, 2018 APA submitted language for Section 11. Hearings and Penalties. *AID response: We believe we have adequately addressed this in restating it:* 

Violations of this Rule shall constitute an unfair or deceptive act under Ark. Code Ann. §23-66-206; therefore, the penalties, actions or orders, including but not limited to monetary fines, suspension, or revocation of license, as authorized under Ark. Code Ann. §§ 23-66-209 and 23-66-210, shall apply to violations of this Rule.

#### America's Health Insurance Plans, July 10, 2018

America's Health Insurance Plans ("AHIP") advises that litigation preempts the applicability of this Rule to Certain Insurers and PBMS.

AID response: Please see our response to this issue previously in the section addressing PCMA comments.

Proposed Rule 118 exceeds the scope of the PBM Licensure Act by requiring various actions and reporting to be the responsibility of health insurers.

AID response: We believe there is adequate authority in the rule to apply those various requirements under our general powers to effectuate provisions of the Arkansas Insurance Code and Rules. *As stated in the rule, for both reporting and pharmacy* compensation review, because prescription drug benefits and networks are a significant component of a health benefit plan issued by the healthcare insurers, the healthcare insurers should have responsibility or share responsibility for administration of the prescription drug benefits to ensure there are adequate pharmacies participating for members purchasing these benefits from health insurance policies, and that, if compensation reductions cause disruption or lack of adequacy, the healthcare insurers should help share responsibility for correction. Section 7 requires healthcare insurers to file and report its pharmacy network in lieu of the PBMs obligation to do so under the PBM licensure Act, and this exceeds the scope of the PBM Licensure Act.

AID response: We disagree. The purpose of this provision was not to overly burden the healthcare insurers but to provide that a PBM should not have to file pharmacy network information if the healthcare insurer already provides this network information to us.
Section 8 allows for examinations on healthcare insurers for compliance with provisions of the Rule, and it is not equitable to hold insurers responsible for compliance with statutory mandates which do not apply to them.

AID response: We disagree, in our examination of a PBM compensation program, it may be imperative for AID to also have access to and to review the entire prescription drug compensation program, including reviewing the facets of it, issued or contracted by the healthcare insurer.

Section 9(C)(2) requires PBMs and Healthcare Insurers to joint coordinate to facilitate the PBMS required filing of a report on state funded payments under 4-88-803. This exceeds the authority of the PBM licensure Act to apply it to healthcare insurers. *AID response: We disagree. The report will necessitate a comparison between what the healthcare insurer paid the PBM and what the PBM paid the pharmacist in drug reimbursement programs; given this dynamic it is imperative for the healthcare insurer or HMO to contribute to the data in the report, for its information item.* 

Section 9(A)(2)(c) requires tracking and monitoring of various items which is beyond the scope of this Act but also will be difficult to track or report.

AID response: We do not believe requesting data to determine if there are compliant MAC processes exceeds the scope of the Act, as it is in the Act that AID enforce compliance. The report simply allows us to see if the PBM has developed compliant MAC processes. Secondly, we understand that some of the tracking and reporting may involve resource issues, but, we believe the various parties can obtain this information. AHIP: Proposed Rule 118 Lacks sufficient protections for Health Insurers following Loss of PBM Licensure

AID: We disagree. We believe the health insurers would already be aware of, or notified of any significant loss of licensure by one of its PBM for ongoing administrative actions we are undertaking. AHIP: Section 4(8), (20), Section 5(A)(7), Section 5(A)(10), Section 5(A)(13), Section 5(A)(15), Section (5)(D), please see same corrections we have made in PCMA section in this document.

AHIP requests removing 4-88-1004 in Section 6(A)(3)(A) be stricken because is not intended to protect patient rights, and its application exceeds statutory scope.

AID: We disagree. The anti-Clawback law in § 4-88-1105, is also prohibited by law, just as the other listed prohibitions. Clawback is regulated by AID. PBMs should not have contractual provisions in violation of the clawback prohibition.

Section 6(A)(3)(A) should be expanded to permit contractual language for issues not contemplated by the Act.

AID: We understand the concerns, however the Act does not address this, but only review of prohibited contracts for fees and certification standards.

Section 7(B)(1) needs trade secret information protection needed. *AID response: We added additional protections at the end of that section.* 

Section 7(B)(1) ignores the fact that health insurers are not party to contracts between PBMs and Pharmacists and do not set reimbursement rates for pharmacies unless the health plan has an integrated PBM.

AID response: We agree that the health insurers are not setting the reimbursement rates between PBMs and Pharmacists, however, as

stated previously, PBMs are vendors in contract with the healthcare insurers. Healthcare insurers are ultimately responsible for providing prescription drug benefits to consumers who have purchased health insurance policies and therefore should have some responsibilities to ensure their exist adequate pharmacy networks.

AHIP page 6 suggested corrections and clarifications to Section 7(B)(2), related to definition needed for service areas, and for the phrase, "reduction in compensation or reimbursement," and that invoices reflect actual "net" price a pharmacy paid.

AID response: We modified the rule that AID will issue a bulletin after review and development of the service area metric by the network adequacy division staff. For the other phrasing concerns, the network adequacy staff and Department will try to clarify or provide specifics in a bulletin.

AHIP, we have significant concerns on Section 7(B)(4), regarding how the database in this section will protect proprietary and confidential information.

AID response: We added the full host of confidentiality protections at the end of that Section.

AHIP: Section 7(B)(5) exceeds legislative Scope as it applies to healthcare insurers.

AID response: See early comments related to the jurisdiction by the Department over healthcare insurers here because they are ultimately responsible to consumers who buy those policies for providing drug benefits.

AHIP: Section 7(C) requests adding the MAC list statute.

AID: We agree and have done so.

AHIP: Section 8(A)(2) has a citation error.

AID: We agree and have added an et. seq.

AHIP: Section 9(B)(2) should address a failure of the PSAO to effectuate an appeal.

AID: See the recent amendment to this Section. Section 9(C)(1) should remove Arkansas works from the spread pricing law reporting requirements.

AID response: We disagree, at this time, believe that an argument can be made it is a program which is state funded due to matching.

Comment from Todd Burrow, July 10, 2018

Requests adding more specific language in Rule 118, on reimbursement formula pharmacies not allowing Maximum Allowable Cost or generic effective rate as a basis of payment. *AID Response: We could not do this by rule, unless there is a change in the MAC law.* 

On claims adjudicated below cost, the Commissioner needs the ability to verify the PBMs claims on the cost of the drug in question, this should include specific NDC number, wholesale house, the price, date and quantity in warehouse.

AID Response: We believe we have adequate investigative powers to request such information in the event of a MAC compliance review.

Comment related to the health plans ABCBS, Ambetter and Qualchoice repaying for all of the below cost losses which were inflicted "illegally" by these plans.

AID Response: We have not investigated or concluded this, but will be glad to visit with the APA or pharmacists about these concerns.

Comment related to fines going to the PBMs who lost funds owed to the pharmacy and the time required to file the appeal. *AID Response: This would require a change in the law.* 

#### Comment from Joseph Burrow, July 11, 2018

Comment that the fines need to be significant to comport with the fact that some PBMs are multi-million dollar companies. AID Response: The fines and penalties we attach here to our TPA in this Rule, for violations to be considered trade practice violations and deceptive acts are the highest or largest fine section in the Arkansas Insurance Code.

# Comment from Adam Wheeler, July 11, 2018 Comment in favor of the APA draft suggestions.

#### Comment from James Sheets, July 11, 2018

Comment complaining of accreditation standards higher than those of the pharmacy board, and requiring access to drugs limited to 10 pharmacies or less, and delaying tactics on applications for specialty network certifications. *AID Response: Thank you, we will review these specialty* 

contracting standards and your issues as we regulate this industry.

# Comment from Jack Lemley, July 11, 2018

Complaint on specialty contract limitations on limited distribution drugs and complaint on the "anti-competitive environment from "vertical integration of CVS/Optum/Humana. *AID Response: We are monitoring the vertical integration issues* 

AID Response: We are monitoring the vertical integration issues and anti-competitive structures.

# Comment from Qualchoice, June 19, 2018 QCA comment: what is the impact of the <u>PCMA vs. Rutledge</u> Decision related to Act 900?

*AID response: See AID's previous response in this Public Comments Summary.* 

QCA comment related to receiving advance notice of when a PBM may lose its license.

*AID response: See AID's response to this concern in the AHIP section.* 

QCA comment on Section 7(B)(2)(b)

AID response: See response in AHIP section. We intend to issue a bulletin on what is meant by service area and address these other issues after our staff analyzes the best approach.

QCA Comment on Section 9(C) issues.

AID Response: See response to this issue made to AHIP. And the report due date should be timed to coincide with the QHP rate filing deadline.

QCA Comment to make confidential compensation review between Healthcare insurer and PBM.

AID Response. See added sections for confidentiality provided after public comments, we believe there is sufficient confidentiality protections to make that review confidential.

Comments 15E are AID network adequacy staff comments we are not adopting because these would involve substantive changes to the rule.

Arkansas Blue Cross and Blue Shield, July 5, 2018 Arkansas Blue Cross and Blue Shield comment, Proposed Rule 118 exceeds the scope of the PBM Licensure Act by requiring various actions and reporting to be the responsibility of health insurers. AID Response: See Page 7 in this document to response to AHIP on this issue.

# AID Summary List of Changes made to the initially filed rule and Explanation from Post Hearing Comments

#### **Page One:**

#1. We added § 23-61-108, which was mistakenly omitted, and typically in every rule we issue, this is our implied power to issue rules needed for the effective implementation of the insurance code, to provide additional statutory jurisdiction, out of an abundance of caution.

#### **Page Four:**

#2. Removed definition of Pass through Pricing and renumbered.

#### **Page Five:**

#3. Removed un-needed sentence that spread pricing may include an administrative fee, as administrative fees are not an issue for us in spread-pricing, per se.

#### Page Six:

#4. Both items on Page six are the adding of language to include MANUALS to the list of items governing contractual terms or practices between the PBMs and pharmacies.

#### **Page Seven:**

#5. Clarified that assumption of risk, is the risk related to the coverage of the drug benefit, and is not financial, pricing risks.#6. Removed a license application reporting requirement related to terminations of contracts for dishonesty, as dishonesty is too broad and general.

## Page Eight:

#7. For denied initial licensure and renewals, permitted the Commissioner to impose, a corrective action plan to cure or correct deficiencies under Section 5(B)(3)(A) or (C) of this Rule.

## **Page Nine:**

#8. Added additional confidentiality protections to the PBMs for their financial information.

#9. Changed "pharmacist," to "Pharmacist or Pharmacies" where needed throughout the rule. The health plans indicate the PBMs

only contract with pharmacies. The APA believes the contracts are with pharmacists or pharmacies. The Act uses, "Pharmacist or Pharmacy." So we are following the Act.

#10. Removed the phrase, "objective evidence," due to ambiguity issues, and replaced the phrase with "specific and detailed."

# Page 10:

#11. Fixed wrong citation.

# Page 11:

#12. Removed the reference to 10% and tied the network adequacy requirements strictly to whatever the requirements are to PCPs in Rule 106. This reduces the confusion of whether the rule was adding additional tolerances to the PCP 80% compliance.

#### Page 12:

#13. Made network adequacy violation tied to "adverse impact," to be consistent with the initial part of that Section.

#14. Added a confidentiality section for materials obtained during compensation reviews, investigations or examinations under that Section.

#15. Added MAC law reference due to the fact that it is that statute rather than the PLA Act which has the MAC requirements.

## Page 14:

#16. Added a provision not penalizing a PBM for failures to effectively appeal by a pharmacy services administrative organization (PSAO).

## Page 16:

#17. Fixed issue for APA to permit monetary fines to apply in the trade practices act and not just cease and desist order(s).

Arkansas law required the Commissioner to file final rules implementing the Pharmacy Benefits Manager Licensure Act by September 1, 2018. The proposed effective date of the rules is January 1, 2019.

**FINANCIAL IMPACT:** The proposed rule requires PBMs to maintain a \$1 million cash surety bond for financial solvency safety. The department does not believe the cost of such bond financially impacts the PBMs relative to their substantial size, revenue, and business operations in this state. The proposed rule may also impose some additional costs on PBMs devoted to new

regulatory compliance requirements, although the department believes the cost of these duties would not financially impact a PBM in any significant way.

**LEGAL AUTHORIZATION:** Arkansas Code Annotated § 23-61-108 authorizes the Insurance Commissioner to make reasonable rules and regulations necessary to carry out any provision of the Arkansas Insurance Code.

During the Second Extraordinary Session of 2018, Representative Michelle Gray sponsored Act 1, and Senator Ronald Caldwell sponsored Act 3, both of which created the Arkansas Pharmacy Benefits Manager Licensure Act. Under the Act, the Commissioner has the authority to adopt rules relating to licensing, application fees, financial solvency requirements, pharmacy benefits manager network adequacy, prohibited market conduct practices, data reporting requirements, compliance and enforcement concerning Maximum Allowable Cost Lists, rebates, compensation, and lists of health benefit plans administered by a pharmacy benefits manager in this State. See Ark. Code Ann. § 23-92-509. The Act required the Insurance Department to issue rules to regulate the licensing, fees, application, financial standards, and reporting requirements of pharmacy benefits managers, and to file the final rule on or before September 1, 2018. See Ark. Code Ann. § 23-92-504(b).

Further, the Commissioner has authority to issue a rule establishing prohibited practices of pharmacy benefits managers providing claims processing services or other prescription drug or device services for health benefit plans. *See* Ark. Code Ann. § 23-92-506(e). The Commissioner shall enforce the provisions of the Act and may examine or audit the books and records of a pharmacy benefits manager processing claims processing services or other prescription drug or device services for a health benefit plan to determine compliance. *See* Ark. Code Ann. § 23-92-508.

# 7. <u>STATE PLANT BOARD</u> (Mary Smith, item a; and Jamey Johnson, item b)

a. <u>SUBJECT</u>: Regulations on the Industrial Hemp Research Program in Arkansas **DESCRIPTION:** This new rule allows for the establishment of industrial hemp research projects to assess the agricultural and economic potential of industrial hemp production in Arkansas.

The 2014 Farm Bill provides for research on the growth, cultivation, or marketing of industrial hemp inside pilot programs set up in states where industrial hemp is legal. The Arkansas Industrial Hemp Act was passed by the Arkansas Legislature and became effective in August 2017, authorizing the Plant Board to adopt regulations to administer the industrial hemp research program in Arkansas. Industrial hemp has many potential uses that could have an economic impact, and research projects will help identify which uses would be a good fit for Arkansas. These proposed regulations were developed after studying other states' industrial hemp research program regulations and meeting with interested persons in our state that wish to participate in industrial hemp research. The regulations outline the permitting processes for application to grow or process industrial hemp in a research format.

**<u>PUBLIC COMMENT</u>**: No public hearing was held. The public comment period expired on June 15, 2018. The Board provided the following summary of the comments that it received and its responses thereto:

**Bryan Taylor** submitted a comment regarding approved seed for planting, proposing additional language requiring greater protection for variety owners. **RESPONSE:** The agency feels this can be addressed in the policy/guidance instructions and in the application process, rather than adding to the regulations.

**Mitch Day** submitted a comment regarding adding clarity for sample destruction/creation and record keeping as it applies to laboratories involved with tissue culture. **RESPONSE:** The agency feels the need to study this for the initial year, and add instructions in our policy/guidance materials requiring labs that grow or provide tissue culture/clonal materials to submit creation/destruction reports and have the record keeping and labeling practices in place.

**Tommy Cauley** submitted comments on licensing, land use restrictions, site access, pesticide use, sample collection, laboratory testing, restrictions on sale or transfer, and license suspension/revocation, stating these restrictions are too strict and industrial hemp should be treated as any other crop. **Rex Petty** also submitted a general comment about the regulations being too strict. **RESPONSE:** The agency felt the need for these regulations to be strict because of federal laws listing industrial hemp as a controlled substance. If federal laws change, these regulations can be revisited in the future.

Katie Mullins and Frank Egan had comments on costs for participants and questioned if any monies were available from the AR industrial hemp program fund or from other tax breaks/incentives/subsidies. **RESPONSE:** The agency feels additional fees will need to be set to be able to continue this program for future years. Currently the Arkansas Industrial Hemp Act only sets an application fee (non-refundable) and a license fee. The agency is not aware of any additional incentives or funds available to participants.

Several comments were received in favor of the regulations and expressing appreciation for the efforts involved in crafting legislation and regulations that will give Arkansas an additional component to our economy. **RESPONSE:** The agency expressed appreciation for their support and cooperation.

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

<u>Section 8</u> – Regarding site access, was there a reason the Board did not include the provision of Ark. Code Ann § 2-15-408(c)(2)(B)(ii), which provides that "[u]nless a deficiency is found, the board shall make no more than two (2) physical inspections of the production fields of an industrial hemp licensee"? **RESPONSE:** Section 8 dealing with access is not limited to just ASPB visits. The section that stipulates no more than two visits without cause refers to regulatory visits by ASPB inspectors. I don't think it is appropriate to reference a limit on the number of visits by cooperating agencies due to the possible interests of law enforcement entities.

<u>Section 15</u> – Regarding subsection (A)'s provisions for immediate revocation of a license without an opportunity for a hearing, Ark. Code Ann. § 2-15-411(b)(1) specifically provides that "[b]efore revocation of an industrial hemp grower license, the board *shall* provide the industrial hemp grower licensee *notice and an informal hearing* before the board to show cause why the license should not be revoked and the licensee's right to grow forfeited." (Emphasis added.) On what authority is the Board relying for its authority to immediately revoke a license without an opportunity for a hearing? **RESPONSE:** Section 15 does conflict with the statute and we will recommend removal of Paragraph A of that section. The removal will include all of the items in (A) Revocation and include the heading (B) Temporary Suspension. The text then will begin with "(1) The Arkansas State Plant Board shall notify a Licensed Grower ... ..."

The proposed effective date is pending legislative review and approval.

**FINANCIAL IMPACT:** The financial impact for the next fiscal year is \$50,000 in special revenue. The Board states that this is not new money, but a reallocation of existing resources.

For private individuals or entities subject to the rule, participation is not required; but if they apply, it will cost \$50 for a nonrefundable application fee. If permitted, it will cost \$200 for a license.

The total estimated cost by fiscal year to the state, county, and municipal government to implement the rule is unknown. The Board states that it will depend on the degree of participation or oversight undertaken.

**LEGAL AUTHORIZATION:** The instant rules implement Act 981 of 2017, sponsored by Representative David Hillman, which created the Arkansas Industrial Hemp Act and created a research program to assess the agricultural and economic potential of industrial hemp production in Arkansas. Pursuant to Arkansas Code Annotated  $\S$  2-15-404(a)(1), as amended by Act 981 of 2017, § 1, the State Plant Board ("Board") may adopt rules to administer the industrial hemp research program and to license persons to grow industrial hemp under the Arkansas Industrial Hemp Act, codified at Ark. Code Ann. §§ 2-15-401 through 2-15-412, as amended by Act 981, § 1. The Board may include as part of its rules the establishment of industrial hemp testing criteria and protocols. See Ark. Code Ann. § 2-15-404(a)(2), as amended by Act 981, § 1. The Board shall also adopt rules for applications for grants under Ark. Code Ann. § 2-15-412. See Ark. Code Ann. § 2-15-412(b), as amended by Act 981, § 1.

## b. <u>SUBJECT</u>: Regulations on Soil Amendment

**DESCRIPTION:** This rule provides specific guidelines that industry must follow to register a soil amendment. It maintains in writing, specific guidelines, research studies required, and published data involving the major agricultural crops grown in Arkansas. Data must be generated involving similar soils and environmental growing conditions found in Arkansas. The rule establishes a penalty matrix to be used if/when a violation of the rule is found.

**<u>PUBLIC COMMENT</u>**: No public hearing was held. The public comment period expired on May 28, 2018. The Board provided the following summary of the public comments that it received and its responses thereto:

**Scotts Company** asked to have labels list contents by volume rather than by weight. **RESPONSE:** A.C.A. 2-19-407 stipulates each container label show contents by net weight of the contents.

**Bayer Company** asked to have microbial product contents guarantee expressed as CFU/ml or CFU/g. **RESPONSE:** CFU/ml is a measurement of volume and is prohibited by 2-19-407. CFU/g is net weight measurement and is acceptable.

**Scotts** suggested not requiring inert products be guaranteed as percent but rather to list ingredients in descending order of predominance. **RESPONSE:** Guarantee is stipulated in 2-19-407.

**Bayer** and **Scotts** questioned the stipulation of supplying names of two laboratories validated to determine the content of active and inert ingredients (Methods of Determination-III.C.1.e). **RESPONSE:** Alternate language was developed to accommodate the concerns. "Provide the names of certified laboratories and published methods for the determination of active and inert ingredients if certified laboratories and published methods are available. If certified laboratories alternative laboratories, analytical methods, or both may be substituted with approval or the requirement waived with suitable justification (e.g., quantification requires only physical separation). [Certification implies 'currently certified' in representative chemical or biological methods by a laboratory proficiency program.]"

**Bayer** and **SBM Life Science Company** commented that requiring applicants to develop the stipulated scientific data would be a challenge. **RESPONSE:** The agency feels if a product cannot be shown by credible research and statistical analysis to offer a positive benefit to a producer, the product is no better than applying existing products or nothing at all.

**Bayer** suggested removing language stipulating the research methods, statistical analysis and positive results that would be subject to review peer review since these points were possibly made in other sections. **RESPONSE:** The agency feels in the interest in transparency and being completely clear on the intent of the rule, the section should remain as written.

**Bayer** suggested changing language stipulating that studies be conducted under conditions similar to real world production conditions and not accepting studies conducted under controlled environments or dissimilar growing conditions. The request was to allow any testing that was conducted to reach an 'adequate' number of trials. **RESPONSE:** It is imperative that testing be done under actual conditions and in areas that are judged to be similar to actual Arkansas conditions in order to adequately determine if tested products generate the claimed results.

**Scotts** suggested revising text that prohibits use of greenhouse and growth chamber trials to support claims of enhanced benefits from use of the products. **RESPONSE:** While some greenhouse trials may offer some indication of the performance of a product, the real response will be determined when tested under field conditions. Therefore, no adjustment was made to the existing language.

**Scotts** suggested certain hydroponic studies should be allowed. **RESPONSE:** The law and rule addresses soil amendments. Hydroponic studies do not measure responses under soil environments.

**Bayer** suggested removal of language requiring statistically defensible results with regard to measuring the frequency and degree of positive agronomic responses. **RESPONSE:** To be an actual positive response to the addition of an amendment, the results must show a statistical difference from the response of a 'check' treatment. The check could range from nothing added to addition of an alternate amendment product.

**Bayer** suggested removing language stipulating that private entity research results be closely scrutinized and accepted at face value due to the testing meeting the scientific standards of other reputable research institutions. **RESPONSE:** The agency feels results generated by disinterested third parties are critical to adequately measuring responses to candidate products and did not see the need to change the language.

**Bayer** and **Scotts Company** suggested altering language of the rule stipulating the preference for studies published in "reputable, scientific, peer-reviewed journals" to allow for inclusion of less rigorous reviewed publications. **RESPONSE:** The agency position is that to properly measure desired responses to adding a soil amendment, the results have to be subjected to stringent review and publication to the scientific community.

**Bayer** suggested that material submitted with the application for registration be altered to remove the requirement of having all the advertising and promotional material to be used in supporting the sale of a soil amendment product and only require examples of such material. **RESPONSE:** The agency feels this would open too wide a window to utilize material that would not adequately express tested and measured responses to an amendment product. Annual registration requirements would allow adjustments to promotional material presentation after submission of registration application documentation.

**SBM Life Science** suggested that only a list of the proposed claims to be used in advertisements and promotional material be submitted with the registration application. **RESPONSE:** The agency feels a simple list of claims is drastically insufficient to evaluate the advertising and promotional material to use in support of sales for an amendment product.

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

When exactly will these new requirements be used? In other words, will they be applied at the Board's discretion or will they be applicable to any and every soil amendment? Will all requirements be required to be filed, or are these merely examples of the types of documentation that will be required? **RESPONSE:** Once the new soil amendment rule is in place, applicants will be required to provide all pieces of the required information that is relevant to the candidate product. For example, if a product is designed to be applied in a dry formulation, there would not be any relevant data to provide with respect to liquid application methods. Yes, the rule will be applied to all candidate products.

<u>Section III.C.4.a.</u> – In this section, the proposed rule states that the Board is "required by law" to consider pertinent research from "other agencies of the state." To which law is the rule referring? **RESPONSE:** The law you asked about is: ACA § 20-20-206(a)(2).

Additional inquiries by Ms. Miller-Rice included the following:

Is the Board comfortable quoting and applying a provision from the Arkansas Pesticide Use and Application Act in its rules that appear to pertain specifically to the Soil Amendment Act of 1977? **RESPONSE:** I think we would be comfortable quoting the Pesticide Use and Application Act. Our feeling is by using a uniform standard across our rule promulgation efforts, it puts our rules on a more solid foundation.

No changes are being made to the penalty matrix contained in these rules, correct? **RESPONSE:** The penalty matrix is being formally established in this rule for soil amendments enforcement actions. In the past, and to my knowledge we have never had any occasion to assess a civil penalty, we depended more on putting a Stop Sale on products. However, as products become more sophisticated we have decided we need to have a more flexible mechanism to deal with different types of violations.

What specific legal authority are you all relying on to assess these civil penalties? **RESPONSE:** I would refer to the Plant Act of 1917, A.C.A. 2-16-203(b)(2)(A): "The Board shall by rule establish a schedule designating the minimum and maximum civil penalty that may be assessed under this section for violation of each statute, rule, or order over which it has regulatory control."

The proposed effective date is pending legislative review and approval.

**<u>FINANCIAL IMPACT</u>**: The Board states that entities wishing to register a product will be required to provide research data as specified in the rule. The cost for this is unknown.

There is no other financial impact.

**LEGAL AUTHORIZATION:** In accord with Arkansas Code Annotated § 2-19-407(c)(1)(A), the State Plant Board ("Board") may require proof of claims made for any soil amendment. In addition to the evidence of proof set forth in Ark. Code Ann. § 2-19-407(c)(2)(A), the Board may accept or reject other sources of proof as additional evidence in evaluating soil amendments. See Ark. Code Ann. § 2-19-407(c)(2)(C). Pursuant to Ark. Code Ann. § 2-19-406, the Board is authorized to adopt such rules and regulations as may be necessary to administer the Soil Amendment Act of 1977, codified at Ark. Code Ann. §§ 2-19-401 through 2-19-414, including methods of sampling, methods of analysis, and designation of ingredient forms, and to promulgate definitions of identity of products. The Board shall by rule establish a schedule designating the minimum and maximum civil penalty that may be assessed under the statute for violation of each statute, rule, or order over which the Board has regulatory control. See Ark. Code Ann. § 2-16-203(b)(2)(A). The Board may also promulgate any other regulation necessary to carry out the intent of the statute. See Ark. Code Ann. § 2-16-203(b)(2)(B).

# 8. <u>VETERINARY MEDICAL EXAMINING BOARD</u> (Dr. Doug Parker and Cara Tharp)

# a. <u>SUBJECT</u>: Livestock Embryo Transfer or Transplant and Livestock Pregnancy Determination

**DESCRIPTION:** Pursuant to Act 1074 of 2017, the rules are being updated to include a certification for individuals who engage in livestock embryo transfer or transplant and livestock pregnancy determination.

**<u>PUBLIC COMMENT</u>**: No public hearing was held. The public comment period expired on June 27, 2018. Public comments were received by the following:

Arkansas Cattlemen's Association Arkansas Livestock Marketing Association Bobby Bell Jason Davis Stevie Kee Randy Kimbrough William Mendenhall Milton Stewart (submitted duplicate) Eli Weatherley Charles Weeks Ricky White

The Arkansas Veterinary Medical Examining Board (the "Board") received eleven public comments and they all expressed a similar concern. The commenters were concerned that the rule was written to connect the procedure of embryo transfer or transplant directly to pregnancy determination. The commenters would like the two acts to be separate from one another. For example, pregnancy determination could be performed by a non-veterinarian embryo transfer technician regardless of the way the pregnancy occurred – artificial insemination, embryo transfer or naturally.

## **RESPONSE**

The Board appreciates all the comments that were received and has taken them into consideration. At this time, the Board does not feel that any changes need to be made to the proposed rule as it is written. This conclusion is based on the Board's reading of the statutory language used in Act 1074, which uses the word "and" conjunctively to connect livestock embryo transfer or transplant; and livestock pregnancy determination. The language used in the statute is the same language used in the proposed rule.

Jessica Sutton, an attorney with the Bureau of Legislative Research, asked the following question:

Regarding the definition of "qualified course," is the rule saying that an applicant having a Doctorate degree or Master of Science degree with an emphasis in animal reproductive physiology substitutes the requirement for a course? Or is this permitted because the idea is that such a person would have already taken such a course? The rules are not dispensing with the requirement of completion of a "qualified course taught by a livestock reproduction specialist on both livestock embryo transfer and livestock pregnancy determination," is it? **RESPONSE:** If we have an applicant that has either a Doctorate or Master of Science degree with an emphasis in animal reproductive physiology, the Board felt that either of those should be permitted as the "qualified course." No changes were made by the Board. The proposed effective date is September 1, 2018.

FINANCIAL IMPACT: There is no financial impact.

**LEGAL AUTHORIZATION:** The Veterinary Medical Examining Board is authorized to promulgate and enforce regulations necessary to establish recognized standards for the practice of veterinary medicine and to carry out the provisions of the Arkansas Veterinary Medical Practice Act. *See* Ark. Code Ann. § 17-101-203(7). These rules implement Act 1074 of 2017, sponsored by Senator John Cooper, which provides a certification for individuals who engage in livestock embryo transfer or transplant and livestock pregnancy determination.

# E. Adjournment.