EXHIBIT H

DEPARTMENT OF HEALTH, CENTER FOR HEALTH PROTECTION

SUBJECT: Rules Pertaining to Arkansas Prescription Drug Monitoring Program

DESCRIPTION: The agency provided the following summary of the amendments to the Rules Pertaining to the Arkansas Prescription Drug Monitoring Program (PDMP):

- Removed the word "regulation" on pages 1 and 3 to comply with Act 315 if 2019.
- Updated the PDMP's new branch as the Department of Health's Substance Misuse and Injury Prevention Branch on page 1.
- Corrected the Table of Contents to include Section XIII.
- Inserted language allowing access by the Arkansas Medicaid Prescription Drug Program, as per Act 46 of 2017.
- Inserted language for mandatory usage of the Arkansas PDMP by prescribers, as mandated by Act 820 of 2017.
- Added two new members to the Arkansas Prescription Drug Monitoring Advisory Committee, as mandated by Act 820 of 2017.
- Inserted language allowing access by the Arkansas Office of Medicaid Inspector General, as mandated by Act 141 of 2019.
- Inserted language for development of prescribing criteria for controlled substances and reports to be generated to prescribers, dispensers, and licensing boards based upon this criteria, as mandated by Act 820 of 2017.
- Inserted language for implementation of real-time reporting by the Arkansas PDMP if funding and technology are available, as per Act 820 of 2017.
- Inserted additional language regarding information provided for research, as mandated by Act 688 of 2017.
- Inserted language regarding providing information to insurance carriers for the purpose of verifying prescriber or dispenser registration with the Arkansas PDMP, as mandated by Act 688 of 2017.
- Added language allowing for the exchange of data between the Arkansas PDMP and federal prescription drug monitoring programs, as mandated by Act 605 of 2019.
- Inserted language regarding the penalty for failure to use the PDMP, as mandated by Act 820 of 2017.

PUBLIC COMMENT: A public hearing was held on September 24, 2019. The public comment period expired on September 24, 2019.

The agency provided the following summary of the comments it received at the public hearing:

COMMENTER'S NAME: Rodney Baker
COMMENT #1: Mr. Baker asked if the date of January 1, 2019 in Section VII(a)(1)(D) was an accurate date for the rule update. **RESPONSE:** As mandated in Act 820 of 2017, "On or before January 1, 2019, the department shall contract with a vendor to make

the Prescription Drug Monitoring Program interactive and to provide same-day reporting in real-time, if funding and technology are available."

COMMENT #2: Mr. Baker questioned how a veterinarian is to query a patient in the Prescription Drug Monitoring Program web portal, specifically if the vet is mandated to query to animal patient or the human owner. **RESPONSE:** To comply with the mandatory use law enacted by Act 820 of 2017, the veterinarian is to search the web portal using the animal's name as the first name, the owner's last name, and the animal's date of birth. Searching in this manner will report only prescriptions filled under the animal's name and not human patient information.

COMMENT #3: In Section IV(d)(2)(C)(ii)(a), the language mentions "palliative care." Mr. Baker asked if a definition of "palliative care" could be added to the rules. On 9/27/2019 at 11:02 AM, Mr. Baker followed up via email on a suggested definition for "palliative care." "Palliative care" means an interdisciplinary approach to specialized medical and nursing care for patients with chronic conditions. It focuses on providing relief from the symptoms, pain, physical stress, and mental stress at any stage of illness. The goal is to improve quality of life for both the patient and their family.

RESPONSE: After reviewing Mr. Baker's suggestion on a definition and internal research on definitions for "palliative care" in current statute, the program suggests the addition of the definitions below:

> "Hospice" or "hospice care" means an autonomous, centrally administered, medically directed, coordinated program providing a continuum of home, outpatient, and home-like inpatient care for the terminally ill patient and family, employing an interdisciplinary team to assist in providing palliative and supportive care to meet the special needs arising out of the physical, emotional, spiritual, social and economic stresses which are experienced during the final stages of illness and during dying and bereavement, with such care being available 24 hours a day, 7 days a week and provided on the basis of need regardless of ability to pay.
>
> "Palliative care" means patient-centered and family-centered medical care offered throughout the continuum of an illness that optimizes quality of lige by anticipating, preventing, and treating the suffering caused by a serious illness to address physical, emotional, social, and spiritual needs and facilitate patient autonomy, access to information, and choice, including without limitation:
>
> (A) Discussion of the patient's goals for treatment;
> (B) Discussions of treatment options appropriate to the patient, including hospice care, if needed; and
> (C) Comprehensive pain and symptom management.

COMMENT #4: Mr. Baker pointed out the word "regulation" was found throughout the markup rules and commented that this needed to be changed to "rule." **RESPONSE:**

The program will remove the word "regulation" when referencing the Arkansas Code throughout the rules as mandated by Act 315 of 2019.

COMMENT #5: Mr. Baker pointed out that the information in Section VII(a)(2)(A) and the information in Section VII(a)(2)(B) was redundant. **RESPONSE:** The language in Section VII(a)(2)(A) – (B) is from past language and will not be edited.

Lacey Johnson, an attorney with the Bureau of Legislative Research, asked the following question and received the following response from the agency:

QUESTION: In § IV(d)(2)(D) and again in § VII(a)(1)(A)(i), the proposed rules reference the Director of the Department of Health. However, Act 910 of 2019 replaced "Director" with "Secretary" in the statutes that these sections are based on. Did the Department intentionally maintain the old language, or was this an oversight? **RESPONSE:** Oversight. Thank you!

The proposed effective date is pending legislative review and approval.

FINANCIAL IMPACT: The agency indicated that this rule does not have a financial impact.

LEGAL AUTHORIZATION: The State Board of Health has authority to promulgate rules implementing the Prescription Drug Monitoring Program Act. *See* Ark. Code Ann. § 20-7-613. These rule amendments implement provisions of various 2017 and 2019 acts that amended the Prescription Drug Monitoring Program Act.

Act 46 of 2017, sponsored by Representative Justin Boyd, amended the Prescription Drug Monitoring Program Act to allow access to the Arkansas Medicaid Prescription Drug Program. Act 688 of 2017, sponsored by Senator Missy Irvin, allows insurance carriers to obtain practitioner and dispenser information maintained by the Prescription Drug Monitoring Program and allows prescriber data to be used for research purposes. Act 820 of 2017, sponsored by then-Senator Jeremy Hutchinson, amends the Prescription Drug Monitoring Program to mandate that prescribers check the information in the Program when prescribing certain medications.

Act 141 of 2019, sponsored by Representative Boyd, amended the Prescription Drug Monitoring Program to allow access to the Office of Medicaid Inspector General. Act 605 of 2019, also sponsored by Representative Boyd, amended the law regarding information exchange with other prescription drug monitoring programs to authorize information exchange with federal prescription drug monitoring programs.

QUESTIONNAIRE FOR FILING PROPOSED RULES WITH THE ARKANSAS LEGISLATIVE COUNCIL

DEPARTMENT/AGENCY Arkansas Department of Health
DIVISION Center for Health Protection
DIVISION DIRECTOR Marisha DiCarlo
CONTACT PERSON Jamie Turpin, PharmD
ADDRESS 4815 W. Markham St. Slot 10, Little Rock, AR 72205
PHONE NO. 501-661-2162 **FAX NO.** 501-682-0427 **E-MAIL** jamie.turpin@arkansas.gov
NAME OF PRESENTER AT COMMITTEE MEETING Jamie Turpin, Laura Shue
PRESENTER E-MAIL jamie.turpin@arkansas.gov; Laura.shue@arkansas.gov

INSTRUCTIONS

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

Jessica C. Sutton
Administrative Rules Review Section
Arkansas Legislative Council
Bureau of Legislative Research
One Capitol Mall, 5th Floor
Little Rock, AR 72201

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1. What is the short title of this rule? Rules Pertaining to Arkansas Prescription Drug Monitoring Program

2. What is the subject of the proposed rule? Adding Legislative Amendments from 2017 and 2019

3. Is this rule required to comply with a federal statute, rule, or regulation? Yes X No ____

   If yes, please provide the federal rule, regulation, and/or statute citation. Please see attached summary of 2017 and 2019 Acts.

4. Was this rule filed under the emergency provisions of the Administrative Procedure Act? Yes_____ No X_____

   If yes, what is the effective date of the emergency rule? _____

   When does the emergency rule expire? _____

   Will this emergency rule be promulgated under the permanent provisions of the Administrative Procedure Act? Yes_____ No_____

5. Is this a new rule? Yes_____ No_X____ If yes, please provide a brief summary explaining the rule.

Does this repeal an existing rule? Yes_____ No__X____ If yes, a copy of the repealed rule is to be included with your completed questionnaire. If it is being replaced with a new rule, please provide a summary of the rule giving an explanation of what the rule does.

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

6. Cite the state law that grants the authority for this proposed rule? If codified, please give the Arkansas Code citation. Arkansas Code Ann.§§ 20-7-601 et seq

7. What is the purpose of this proposed rule? Why is it necessary? This will amend the rules to include the 2017 and 2019 legislative updates.

8. Please provide the address where this rule is publicly accessible in electronic form via the Internet as required by Arkansas Code § 25-19-108(b). https://www.healthy.arkansas.gov/images/uploads/rules

9. Will a public hearing be held on this proposed rule? Yes_X__ No_____
If yes, please complete the following:

Date:_____September 24, 2019_____

Time:_____09:00 A.M. CST_____

Place:_____Arkansas Department of Health, Dr. Joseph H. Bates Auditorium, 4815 W. Markham St., Little Rock, AR 72205 _____

10. When does the public comment period expire for permanent promulgation? (Must provide a date.)

___September 24, 2019 at 04:30 P.M._____

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

____TBD_____

12. Please provide a copy of the notice required under Ark. Code Ann. § 25-15-204(a), and proof of the publication of said notice. To be run in the Arkansas Democrat Gazette on August 23, 24, 25, 2019

13. Please provide proof of filing the rule with the Secretary of State as required pursuant to Ark. Code Ann. § 25-15-204(e).

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

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY

DEPARTMENT_____Arkansas Department of Health_____
DIVISION_____ Center for Health Protection_____
PERSON COMPLETING THIS STATEMENT___Jamie Turpin_____
TELEPHONE NO._501-661-2162_FAX NO.__501-682-0427_EMAIL:_jamie.turpin@arkansas.gov

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

SHORT TITLE OF THIS RULE_Rules Pertaining to Arkansas Prescription Drug Monitoring Program

1. Does this proposed, amended, or repealed rule have a financial impact?
   Yes _____ No __X_____

2. Is the rule based on the best reasonably obtainable scientific, technical, economic, or other evidence and information available concerning the need for, consequences of, and alternatives to the rule?
   Yes__X_____No_____

3. In consideration of the alternatives to this rule, was this rule determined by the agency to be the least costly rule considered? Yes___X_____ No_____

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

   (a) How the additional benefits of the more costly rule justify its additional cost;

   (b) The reason for adoption of the more costly rule;

   (c) Whether the more costly rule is based on the interests of public health, safety, or welfare, and if so, please explain; and

   (d) Whether the reason is within the scope of the agency's statutory authority, and if so, please explain.

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

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

Current Fiscal Year		**Next Fiscal Year**	
General Revenue	0	General Revenue	0
Federal Funds	0	Federal Funds	0
Cash Funds	0	Cash Funds	0
Special Revenue	0	Special Revenue	0

Other (Identify)_____0_____ Other (Identify)_____0_____

Total_____0_____ Total_____0_____

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

Current Fiscal Year **Next Fiscal Year**

General Revenue_____0_____ General Revenue_____0_____
Federal Funds_____0_____ Federal Funds_____0_____
Cash Funds_____0_____ Cash Funds_____0_____
Special Revenue_____0_____ Special Revenue_____0_____
Other (Identify)_____00_____ Other (Identify)_____0_____

Total_____ Total_____0_____

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

Current Fiscal Year **Next Fiscal Year**

$_____0_____ $_____0_____

_____

_____

_____

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

Current Fiscal Year **Next Fiscal Year**

$_____0_____ $_____0_____

_____

_____

_____

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

Yes_____ No___X_____

If YES, the agency is required by Ark. Code Ann. § 25-15-204(e)(4) to file written findings at the time of filing the financial impact statement. The written findings shall be filed simultaneously

with the financial impact statement and shall include, without limitation, the following:

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

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

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

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

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

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

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

Arkansas Department of Health

4815 West Markham Street • Little Rock, Arkansas 72205-3867 • Telephone (501) 661-2000
Governor Asa Hutchison
Nathaniel Smith, MD, MPH, Director and State Health Officer

SUMMARY OF PROPOSED AMENDMENTS TO RULES PERTAINING TO THE ARKANSAS PRESCRIPTION DRUG MONITORING PROGRAM

- To follow Act 315 of 2019, the removal of the word "regulation" on (pages 1 and 3)
- Updated the Prescription Drug Monitoring Program's new branch as the Department of Health's Substance Misuse and Injury Prevention Branch on (page 1)
- Corrected the Table of Contents to include Section XIII (page 2)
- As mandated by Act 46 of 2017, inserted language allowing access by the Arkansas Medicaid Prescription Drug Program (pages 6 and 12)
- As mandated by Act 820 of 2017 inserted language for mandatory usage of the Arkansas Prescription Drug Monitoring Program by prescribers (pages 7-8)
- As mandated by Act 820 of 2017, added two new members to the Arkansas Prescription Drug Monitoring Advisory Committee (page 11)
- As mandated by Act 141 of 2019, inserted language adding allowing access by the Arkansas Office of Medicaid Inspector General (page 12)
- As mandated by Act 820 of 2017 inserted language for development of prescribing criteria for controlled substances and reports to be generated to prescribers, dispensers, and licensing boards based upon this criteria (page 13)
- As mandated by Act 820 of 2017 inserted language for implementation of real-time reporting by the Arkansas Prescription Drug Monitoring Program if funding and technology are available (page 13)
- As mandated by Act 688 of 2017, inserted additional language regarding information provided for research (page 15)
- As mandated by Act 688 of 2017 inserted language regarding providing information to insurance carriers for the purpose of verifying prescriber or dispenser registration with the Arkansas Prescription Drug Monitoring Program (page 15)

- As mandated by Act 605 of 2019 inserted language allowing for the exchange of date between the Arkansas PDMP with federal prescription drug monitoring programs (page 15)
- As mandated by Act 820 of 2017, inserted language regarding the penalty for failure to use the Prescription Drug Monitoring Program (page 17)