EXHIBIT M

DEPARTMENT OF HEALTH, CENTER FOR HEALTH PROTECTION

SUBJECT: Rules Pertaining to Arkansas Prescription Drug Monitoring Program

DESCRIPTION: The Arkansas Department of Health is amending the Rules Pertaining to the Arkansas Prescription Drug Monitoring Program. These rule amendments provide clarification of various language throughout the rule. The changes also provide alternate means of reporting and allow the Department to request prescription copies from dispensers for evaluation of data.

PUBLIC COMMENT: A public hearing was held on this rule on October 1, 2021. The public comment period expired October 1, 2021. The agency indicated that it received no public comments.

The proposed effective date is December 1, 2021.

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

LEGAL AUTHORIZATION: The Arkansas Department of Health maintains the Prescription Drug Monitoring Program database. *See* Ark. Code Ann. § 20-7-606(b)(1). As such, the Department may prescribe "transmission methods and frequency" for dispensers' submission of required information regarding controlled substance prescriptions. Ark. Code Ann. § 20-7-604(f). The State Board of Health has authority to promulgate rules implementing the Prescription Drug Monitoring Program Act. *See* Ark. Code Ann. § 20-7-613.

Arkansas Department of Health

4815 West Markham Street • Little Rock, Arkansas 72205-3867 • Telephone (501) 661-2000
Governor Asa Hutchinson
José R. Romero, MD, Secretary of Health

PROPOSED REVISIONS TO THE RULES PERTAINING TO THE ARKANSAS PRESCRIPTION DRUG MONITORING PROGRAM

August 13, 2021

PURPOSE

The Arkansas Department of Health (Department) is seeking Governor Hutchinson's review of proposed amendments to the Rules Pertaining to the Arkansas Prescription Drug Monitoring Program.

BACKGROUND

Pursuant to A.C.A. § 20-7-613 the Department has authority to promulgate rules for the Arkansas Prescription Drug Monitoring Program. These rules protect the state health system and the citizens of Arkansas by enhancing patient care by providing prescription monitoring information that will ensure legitimate use of controlled substances in health care.

KEY POINTS

The proposed rule:

- Makes miscellaneous corrections to references and descriptions
- Inserts definitions for clarification
- Makes revisions mandated by Act 62 of 2021

DISCUSSION

The Department's Center for Health Protection is initiating the process for the revision of the Arkansas State Board of Health Rules Pertaining to the Arkansas Prescription Drug Monitoring Program (PDMP). The following revisions are being proposed:

- Updated the Cover page to reflect new Secretary of Health "Jose Romero" (Page 1)
- Updated Table of Contents (Page 2)
- Arranged Definitions Section alphabetically. (Page 3-10)
- Insertion a definition for "Drug Overdose" (Page 9)

- Inserted language under definition "Exchangeability" to include instances where a provider deems an out of state search is warranted. (Page 8)
- Inserted language under Section IV (b)(2), to clarify the reporting of controlled substances by federal dispensers located in Arkansas and out of state federal dispensers mailing into Arkansas. (Page 10)
- Inserted language in Section IV (c) to allow for other means of reporting (specifically to allow vet clinics to fax or mail in forms) (Page 11)
- Inserted language in Section IV (d) to specify the process for reporting controlled substance dispensations for an animal/veterinary patient. (Page 11)
- Inserted language in Section IV (e), to encourage the usage of the PDMP during medication reconciliation. (Page 12)
- Inserted language in Section IV (g) (1 and 3) to allow for future updated ASAP formats to be reported to the PDMP, if approved by the PDMP. (Page 13)
- Inserted language to allow the department to notify a prescriber/dispenser of a patient drug overdose. (Page 18)
- As mandated by Act 62 of 2021, language was added to Section VII(a)(2) to allow the department to request prescription copies from dispensers for evaluation of data. (Page 18)
- In Section XIII (b), removed the "Director" and added "Secretary" (Page 22)
- Updated the certification page to reflect new Secretary of Health "Jose Romero" (Page 23)

RECOMMENDATION

We recommend that the proposed amendments to the Rules Pertaining to the Arkansas Prescription Drug Monitoring Program be approved as proposed by the Department.

QUESTIONNAIRE
FOR FILING PROPOSED RULES WITH THE ARKANSAS LEGISLATIVE COUNCIL

DEPARTMENT/AGENCY Arkansas Department of Health
DIVISION Center for Health Protection
DIVISION DIRECTOR Jamie Turpin, PharmD, Prescription Drug Monitoring Program Administrator
CONTACT PERSON Laura Shue
ADDRESS 4815 West Markham, Slot 31 Little Rock, AR 72205
PHONE NO. (501) 661-2297 **FAX NO.** (501) 661-2357 **E-MAIL** laura.shue@arkansas.gov
NAME OF PRESENTER AT COMMITTEE MEETING Laura Shue, General Counsel
PRESENTER E-MAIL 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
D. Rule" below.
E. Submit two (2) copies of the 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?**

3. **Is this rule required to comply with a federal statute, rule, or regulation? Yes☐ No☑**

   If yes, please provide the federal rule, regulation, and/or statute citation.

4. **Was this rule filed under the emergency provisions of the Administrative Procedure Act?**

   Yes☐ No☑

   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☑ If yes, please provide a brief summary explaining the rule.**

Does this repeal an existing rule? Yes☐ No☑ 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☑ 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.**

A.C.A. § 20-7-613

7. **What is the purpose of this proposed rule? Why is it necessary?**

Provides clarification of various language throughout the rule. Provides alternate means of reporting. Allows the Department to request prescription copies from dispensers for evaluation of data.

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/

9. **Will a public hearing be held on this proposed rule? Yes ☐ No ☑ If yes, please complete the following:**

Date: _____

Time: _____

Place: _____

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

_____

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

12/01/2021

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.** _____

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.**

Unknown

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY

DEPARTMENT Arkansas Department of Health
DIVISION Center for Health Protection
PERSON COMPLETING THIS STATEMENT
TELEPHONE NO. (501) 661-2297 **FAX NO.** (501) 661-2357 **EMAIL:** laura.shue@arkansas.gov

To comply with Ark. Code Ann. § 25-15-204(e), please complete the following Financial Impact Statement and file two (2) 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☑**

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☑ 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☑ 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		General Revenue	
Federal Funds		Federal Funds	
Cash Funds		Cash Funds	
Special Revenue		Special Revenue	
Other (Identify)		Other (Identify)	
Total	$ 0.00	Total	$ 0.00

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

Current Fiscal Year		Next Fiscal Year	
General Revenue		General Revenue	
Federal Funds		Federal Funds	
Cash Funds		Cash Funds	
Special Revenue		Special Revenue	
Other (Identify)		Other (Identify)	
Total	$ 0.00	Total	$ 0.00

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
$	$

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
$	$

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 ☐

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.

State of Arkansas
93rd General Assembly
Regular Session, 2021

A Bill

HOUSE BILL 1107

By: Representative Boyd
By: Senator Bledsoe

For An Act To Be Entitled

AN ACT TO AMEND THE PRESCRIPTION DRUG MONITORING PROGRAM ACT; AND FOR OTHER PURPOSES.

Subtitle

TO AMEND THE PRESCRIPTION DRUG MONITORING PROGRAM ACT.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF ARKANSAS:

SECTION 1. Arkansas Code § 20-7-607(a)(2), concerning providing prescription monitoring information under the Prescription Drug Monitoring Program Act, is amended to read as follows:

(2)(A) The department may:

(i) Review ~~review~~ the program information, including without limitation a review to identify information that appears to indicate whether a prescriber or dispenser may be prescribing or dispensing prescriptions in a manner that may represent misuse or abuse of controlled substances; and

(ii) Require prescribers or dispensers, or both, to provide physical copies of written or electronic prescriptions upon request to validate data submitted to the program in order to evaluate the information reported by the program.

(B) If information of misuse or abuse is identified, the department may notify the professional licensing board of the prescriber or dispenser only after the relevant professional licensing board has provided the department with the parameters for triggering a notification from the

department to the professional licensing board.

APPROVED: 2/4/21