EXHIBIT H

DEPARTMENT OF HEALTH, CENTER FOR HEALTH PROTECTION

SUBJECT: Arkansas Prescription Drug Monitoring Program

DESCRIPTION: The proposed amendments update the rules and regulations to comply with Acts 901 and 1208 of 2015, as follows:

1. The Prescription Drug Monitoring Program may notify the professional licensing board of prescribers or dispensers of 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, only after the licensing board has provided parameters for triggering a notification.

2. A prescriber or dispenser may delegate access to the Prescription Drug Monitoring Program to persons under his or her supervision or employment.

3. A certified law enforcement prescription drug investigator may access the Prescription Drug Monitoring Program by using an investigative case number.

4. The Little Rock, Arkansas Office of Diversion Control of the United States Drug Enforcement will be notified if information appears to indicate that a person may be obtaining prescriptions in a manner that may represent misuse or abuse of controlled substances.

5. The Arkansas Prescription Drug Monitoring Program shall develop algorithms to alert a practitioner if his or her patient is being prescribed opioids by more than three physicians within any thirty day period, if funding is available.

PUBLIC COMMENT: A public hearing was held on December 8, 2015. The public comment period expired on December 8, 2015. The Department received the following comments:

COMMENT: Laci Lyons:
My husband recently began taking a prescription to control an attention disorder. We've been together over a decade, and it's evident that he should have been on this medicine since childhood. He is more focused, more productive, sleeping better, and has fewer mood swings. Science is wonderful.

My concern is that he has been required to return to the doctor each month to obtain a refill for his medication, which is Schedule II. Though only 3

months in, I can see the expense of this adding up quickly. We are currently spending $20/month on the co-pay and an additional $15/month for the prescription. The hidden costs of time, childcare, gas, etc. also add up as my husband must trek to the opposite corner of town to see our doctor. As many (I would assume) have pointed out, requiring people with attention disorders to remember to schedule an office visit in advance of running out of medicine each month is ridiculous. The current "monitoring program" creates undue stress on the majority of patients who are simply procuring and taking much-needed medicine.

Please encourage some common sense initiatives to be included in any changes made to the AR PDMP. After some period of time or number of visits, can my husband and our board certified physician be trusted? Surely after jumping through all the hoops to first get the prescription, and then to get it refilled, my family won't have to deal with this visit-the-doc-every-month nonsense for the rest of his life.

I understand that many medicines can be abused to the detriment of society. However, policies which over-regulate or create undue financial barriers have detrimental effects as well.

RESPONSE:
The Arkansas Prescription Drug Monitoring Program is a valuable tool for prescribers. The prescriber is able to view the controlled substance history of their patients for a more informed decision when prescribing these medications. This ensures correct use, safety and curtails misuse and abuse. The situation that you present is an issue of Schedule II prescription writing protocol instituted by your physician. Recent changes in Drug Enforcement Administration scheduling and rampant prescription drug abuse have elicited changes in the way some prescribers write for these medications.

Please see (c) below regarding the State Board of Health's role in regulating the practice of medicine:

A.C.A. § 20-7-109
§ 20-7-109. Powers--Rules and regulations--Restrictions
(a)(1) Power is conferred on the State Board of Health to make all necessary and reasonable rules and regulations
of a general nature for:
(A) The protection of the public health and safety;
(B) The general amelioration of the sanitary and hygienic conditions within the state;
(C) The suppression and prevention of infectious, contagious, and communicable diseases;

(D) The proper enforcement of quarantine, isolation, and control of such diseases; and
(E) The proper control of chemical exposures that may result in adverse health effects to the public.
(2) All rules and regulations promulgated pursuant to this subsection shall be reviewed by the House Committee
on Public Health, Welfare, and Labor and the Senate Committee on Public Health, Welfare, and Labor or
appropriate subcommittees thereof.
(b) However, if a patient can be treated with reasonable safety to the public health, he or she shall not be removed
from his or her home without his or her consent, or the consent of the parents or guardian in the case of a minor,
and the rules and regulations, when made, shall be printed in pamphlet form, with such numbers of copies as
may be necessary for the distribution of the information to health bodies, health and sanitary officers, and the
public generally.
(c) *The board shall not regulate the practice of medicine or healing nor interfere with the right of any citizen to*
employ the practitioner of his or her choice.

As this Act states, the Board of Health cannot regulate the prescription protocols of any physician in the state of Arkansas.

COMMENT: Dr. Bob Twillman, Executive Director, American Academy of Pain Management:
Section III(19): The proposed amendments to this regulation would define opioid to mean "...a drug or medication that relieves pain, including without limitation: hydrocodone, oxycodone, morphine, codeine, heroin, and fentanyl." While it is true that heroin is an opioid, heroin is classified as a Schedule I drug with no accepted medical use. Therefore, it is inappropriate to include it as an example of a "medication that relieves pain." We respectfully request that "heroin" be deleted from this definition.

We also suggest the following as a better alternative definition (note the slight change in terminology from "opioid" to "opioid analgesic"):

"Opioid Analgesic" means a drug that issued to alleviate moderate to severe pain that is either an opiate (derived from the opium poppy) or opiate-like (synthetic drugs). Examples include: morphine, codeine, fentanyl, meperidine, and methadone.

Sections IV(i) and VI(b)(2)(D): We do not oppose law enforcement receiving PMP reports in appropriate situations; however, in order to ensure appropriate privacy of patient records, these officers should only be able to obtain PMP data after obtaining a court order pertaining to a *bona fide* investigation rather than merely submitting credentials and *any* case number (we do not feel that the "verification form" process later mandated by this section sufficiently addresses this issue). Further, the officers should not be granted unfettered access to the PMP; rather, they should be given PMP reports pertaining to the person(s) named by the court order. Mandating that law enforcement obtain an appropriate court order to access PMP data will ensure that one's highly personal medical history is treated with at least as much protection as their bank records, thus appropriately protecting citizens' right to privacy while balancing the need of law enforcement access.

In concert with this concern, we recommend that this section be amended to require that law enforcement officers/agencies obtain a court order to access the database. We acknowledge, and appreciate, that a court order is to be required of the Department of Human Services in their own PMP requests under Section VI(b)(2)(E), and we strongly encourage you to require the same under Section VI(b)(2)(D) in order to appropriately protect citizens' right to privacy while balancing the need for law enforcement access.

Section VII(a): This section would mandate and/or allow that unsolicited PMP reports be sent to practitioners, dispensers, licensing boards, and law enforcement under certain circumstances, and further, would allow the Department of Health unfettered access to peruse the PMP for possible wrongdoing. We cannot support this section as written and request that it be modified as below.

We request that you rework this provision so that it reflects the following:

- When possible misuse or abuse of a controlled substance is indicated by the PMP, reports should be sent to that patient's prescribers so that they may address the issue with their patient, reevaluate the treatment plan, and make any necessary consultations or referrals. The reports should not be sent to the licensing boards or law enforcement agencies unless they are sent in a de-identified manner.
- These unsolicited reports shall be confidential, not considered a public record, not admissible as evidence in a civil or criminal proceeding, and shall not be the basis for investigation by a licensure board.

This section would also require a "prescriber who has been found in violation of a rule or law involving prescription drugs" to access the prescription monitoring program before writing a prescription for an

opioid. We find this requirement to be a bit bizarre, given that, presumably, a "prescriber who has been found in violation of a rule or law involving prescription drugs" was found in violation because he or she *intentionally* acted in such a manner. It is unclear how requiring a PMP check would prevent such a prescriber from again choosing to act inappropriately. In short, checking the PMP might mitigate against incautious or negligent prescribing, but it does nothing to mitigate against intentional malfeasance. We recommend deleting this provision.

Section VII(b)(1)(B): We fully support this provision which allows prescribers to designate authorized clinicians in their practices to obtain patient reports from the PMP. Allowing assigned and authorized delegates to check the PMP assists in reducing the misuse, abuse, and diversion of controlled substances by addressing the time challenges that prescribers and dispensers have when they are the only ones able to obtain reports.

RESPONSE:
The definition of Opioid was added pursuant to Act 1208 of 2015, which defines "opioid" as a drug or medication that relieves pain, to include heroin. Any change to this definition would require statutory change.

Access to the PMP by "Certified Law Enforcement Prescription Drug Diversion Investigators" is granted by Act 901 of 2015. That Act also puts in place the safeguards of the verification form and the formalized training and certification of these officers. In order to modify this Section of the PMP Rules, there must be a statutory change.

This provision was added pursuant to Act 1208 of 2015. The Department will continue to abide by its own internal policy and HIPAA when accessing PMP data. Further the PMP Act and the Rules address how PMP data can be used in Court proceedings and who may access it. To modify these provisions would require statutory change.

COMMENT: Verbal comments received at public hearing:
I just feel that the added parts in here are very intrusive to privacy. All of the additions.

It has become harder for a chronically ill patient that is on controlled substances to live a normal life because everything is becoming so intrusive; everybody is watching that person closely. It's kind of personal to me, because my mother is chronically ill and she is on these prescriptions, and I go and I get them filled for her. I used to. And, we've had to do a lot of this so that I can go and get her medication for her because she is in a state where she can't go out and get them herself. And, I think this has really caused a problem for the *real* sick person, the person

who is needing the prescriptions. This has caused more problems lately, in the past two years.

RESPONSE:
See response to Laci Lyons above.

COMMENT: Ken Larson, Xerox Government Healthcare Services: Looks like this is policy to enhance what's already in place, for detection and correlation to find where there might be abnormalities in prescription filing. Enhancement is granting law enforcement to what you find already.

Your program creates a coordinated effort between the listed parties.

RESPONSE:
The change is creating a new way for Certified Law Enforcement Prescription Drug Diversion Investigators to access the database without first obtaining a search warrant.

The proposed effective date is March 1, 2016.

CONTROVERSY: This is not expected to be controversial.

FINANCIAL IMPACT: The financial impact will be $124,824 in Department of Justice grant funds to implement Act 901 in the current fiscal year.

LEGAL AUTHORIZATION:

This rule implements Acts 1208 and 901 of 2015. Arkansas Code Annotated § 20-7-613 authorizes the Department to promulgate rules to administer the Prescription Drug Monitoring Program Act.

QUESTIONNAIRE FOR FILING PROPOSED RULES AND REGULATIONS WITH THE ARKANSAS LEGISLATIVE COUNCIL AND JOINT INTERIM COMMITTEE

DEPARTMENT/AGENCY Department of Health

DIVISION Center for Health Protection

DIVISION DIRECTOR Renee Mallory

CONTACT PERSON James Myatt

ADDRESS 4815 West Markham St., Slot 25, Little Rock, Arkansas 72205

PHONE NO. (501) 661-2325 **FAX NO.** (501) 661-2769 **E-MAIL** james.myatt@arkansas.gov

NAME OF PRESENTER AT COMMITTEE MEETING Robert Brech

PRESENTER E-MAIL robert.brech@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:

Donna K. Davis
Administrative Rules Review Section
Arkansas Legislative Council
Bureau of Legislative Research
One Capitol Mall, 5th Floor
Little Rock, AR 72201

****

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

2. What is the subject of the proposed rule? Amendments needed to follow Acts 1208 and 901 of 2015.

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 regulation. _____

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? To follow Acts 1208 and 901 of 2015.

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). www.arkansas.gov

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

Date: December 8, 2015
Time: 10:00 A.M.
Place: Arkansas Dept. of Health, 4815 West Markham, Little Rock, AR

10. When does the public comment period expire for permanent promulgation? (Must provide a date.)
December 8, 2015

11. What is the proposed effective date of this proposed rule? (Must provide a date.)
Tentatively March 1, 2016

12. Do you expect this rule to be controversial? Yes ☐ No ☒
If yes, please explain. _____

13. 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 James Myatt

TELEPHONE NO. (501) 661-2325 **FAX NO.** (501) 661-2769 **EMAIL:** james.myatt@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 and Regulations Pertaining to the 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	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)	$124,824 Department of Justice Grant Funds to implement Act 901	Other (Identify)	0
Total	$124,824	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 ☐

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.