EXHIBIT H

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 Donnie Smith
CONTACT PERSON James Myatt, PD
ADDRESS 4815 West Markham, Slot 31, Little Rock, AR 72205
PHONE NO. 501-661-2325 **FAX NO.** 501-661-2769 **E-MAIL** james.myatt@arkansas.gov
NAME OF PRESENTER AT COMMITTEE MEETING James Myatt, PD
PRESENTER E-MAIL james.myatt@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
Room 315, State Capitol
Little Rock, AR 72201

****

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

2. What is the subject of the proposed rule? To establish the Arkansas Prescription Drug Monitoring Program

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.
These regulations establish the Arkansas Prescription Drug Monitoring Program in conformance with Act 304 of 2011.

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If yes, a copy of the repealed rule is to be included with your completed questionnaire.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 Arkansas Code citation.

Ark. Code Ann. § 20-15-109; Act 304 of 2011

7. What is the purpose of this proposed rule? Why is it necessary?
To establish the Arkansas Prescription Drug Monitoring Program. Regulations are required by Act 304 of 2011.

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).

http://www.healthy.arkansas.gov/aboutADH/Pages/RulesRegulationsProposed.aspx

9. Will a public hearing be held on this proposed rule? Yes ☒ No ☐

If yes, please complete the following:

Date: January 8, 2013

Time: 10:00 a.m.

Place: Arkansas Department of Health, Room 2508, 4815 West Markham, Little Rock, AR

10. When does the public comment period expire for permanent promulgation? (Must provide a date.) January 8, 2013

11. What is the proposed effective date of this proposed rule? (Must provide a date.) March 1, 2013

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.
Ark. Academy of Physicians Assistants, Ark. Association of Chiefs of Police, Ark. Drug Director, Ark. Medical Society, Ark. Nurses Association, Ark. Optometric Association, Ark. Osteopathic Medical Association, Ark. Pharmacists Association, Ark. Podiatric Medical Association, Ark. Prosecuting Attorneys Association, Ark. Sheriffs Association, Ark. Dental Association, Ark. Veterinary Medical Association, Ark. Public Defenders Commission, Certified Drug Counselors

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY

DEPARTMENT Department of Health

DIVISION Center for Health Protection, Pharmacy Services Branch

PERSON COMPLETING THIS STATEMENT James Myatt, PD

TELEPHONE NO. 501-661-2325 **FAX NO.** 501-661-2769 **EMAIL:** james.myatt@arkansas.gov

To comply with Act 1104 of 1995, please complete the following Financial Impact Statement and file two copies with the questionnaire and proposed rules.

SHORT TITLE OF THIS RULE Arkansas Prescription Drug Monitoring Program

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

2. Does this proposed, amended, or repealed rule affect small businesses? Yes ☒ No ☐
   If yes, please attach a copy of the economic impact statement required to be filed with the Arkansas Economic Development Commission under Arkansas Code § 25-15-301 et seq.

3. If you believe that the development of a financial impact statement is so speculative as to be cost prohibited, please explain.

4. If the purpose of this rule is to implement a federal rule or regulation, please give the incremental cost for implementing the rule. Please indicate if the cost provided is the cost of the program.

Current Fiscal Year		**Next Fiscal Year**	
General Revenue	NA	General Revenue	NA
Federal Funds		Federal Funds	
Cash Funds		Cash Funds	
Special Revenue		Special Revenue	
Other (Identify)		Other (Identify)	
Total		Total	

5. What is the total estimated cost by fiscal year to any party subject to the proposed, amended, or repealed rule? Identify the party subject to the proposed rule and explain how they are affected.

Current Fiscal Year $ NA

Next Fiscal Year $ NA

Pharmacies will provide the department with access to their information on controlled substances prescriptions dispensed.

6. What is the total estimated cost by fiscal year to the agency to implement this rule? Is this the cost of the program or grant? Please explain.

Current Fiscal Year $ 245,000

Next Fiscal Year $ 343,000

This is the program cost. The program is funded by a federal grant in FY13 & FY14.

ECONOMIC IMPACT STATEMENT OF PROPOSED RULES OR REGULATIONS

EO 05-04: Regulatory Flexibility

Department: Health

Division: Center for Health Protection,. Pharmacy Services Branch

Contact Person: James Myatt, P.D.

Date: November 19, 2012

Contact Phone: 501-661-2751

Contact Email: james.myatt@arkansas.gov

Title or Subject: Arkansas Prescription Drug Monitoring Program

Benefits of the Proposed Rule or Regulation

1. Explain the need for the proposed change(s). Did any complaints motivate you to pursue regulatory action? If so please explain the nature of such complaints.

   According to the CDC's November 4, 2011 MMWR report, Arkansas ranked among the second highest group of states nationally in overall drug overdose deaths in 2008 (13.1 per 100,000), with 5.1 per 100,000 deaths resulting from nonmedical use of opioid pain relievers (OPR), and among the highest group nationally in the rate of kilograms of OPR sold per 10,000 people in 2010 (8.7). In 2011, the Arkansas Crime Laboratory performed approximately 1250 autopsies; of these autopsies, drug intoxication, either from prescription or illicit drugs or a combination thereof, was the primary cause of death in 1 of 9 cases. Drugs, including prescription drugs, were a contributory cause of death in 1 of 4 cases; this problem is twice as great as it was 5 years ago.

   Act 304 of 2011 was passed by the Arkansas Legislature to establish a prescription drug monitoring program in Arkansas. The program is authorized to collect, monitor and analyze electronically transmitted dispensing data for controlled substances submitted by pharmacies.

2. What are the top three benefits of the proposed rule or regulation?

   - Enhancing patient care by providing prescription monitoring information that will ensure legitimate use of controlled substances in health care.
   - Helping combat the misuse, abuse, illegal trade and diversion of controlled substances.
   - Enabling access to prescription information by practitioners, law enforcement agents, and other authorized individuals.

3. What, in your estimation, would be the consequence of taking no action, thereby maintaining the status quo?

   Arkansas's alarming rate of prescription drug abuse would continue, leaving Arkansas citizens at increased risk for substance abuse and its devastating consequences. There would not be the opportunity for collaboration between the state's medical, pharmacy, law enforcement, crime information services and others to address prescription drug abuse, misuse and fraud. The state would not have the information needed to intervene and make referrals for early treatment

services and to develop educational and outreach materials for prescribers, dispensers, and the general public.

4. Describe market-based alternatives or voluntary standards that were considered in place of the proposed regulation and state the reason(s) for not selecting those alternatives.

   In order to accurately determine the scope of the problem and develop strategies to address abuse and misuse of controlled substances, it is critical to have complete information on all controlled substances dispensed. It is necessary to obtain this information from all pharmacies. There is not a centralized source for this information. By creating a state database, the department will be able to gain an understanding of the magnitude of the prescription drug abuse problem and develop effective interventions and educational tools.

Impact of Proposed Rule or Regulation

5. Estimate the cost to state government of collecting information, completing paperwork, filing, recordkeeping, auditing and inspecting associated with this new rule or regulation.

   Approximately $350,000 per year

6. What types of small businesses will be required to comply with the proposed rule or regulation? Please estimate the number of small businesses affected.

   756 Arkansas pharmacies total
   390 estimated number of Arkansas pharmacies that are independents
   400 out of state pharmacies

7. Does the proposed regulation create barriers to entry? If so, please describe those barriers and why those barriers are necessary.

   No

8. Explain the additional requirements with which small business owners will have to comply and estimate the costs associated with compliance.

   Pharmacies will report weekly on all controlled substances dispensed. This will be accomplished by giving the department access to their information on controlled substances prescriptions dispensed. Pharmacies are currently required by the Arkansas State Board of Pharmacy to record this information on a daily basis. The process has been designed to minimize the impact on pharmacies and there are no direct costs to the pharmacies.

9. State whether the proposed regulation contains different requirements for different sized entities, and explain why this is, or is not, necessary.

   No, requirements do not vary based on the size of the pharmacy. The information needed is the same for all sizes of pharmacies.

10. Describe your understanding of the ability of small business owners to implement changes required by the proposed regulation.

    Pharmacies will enroll in the program, granting the department access to their information on controlled substances prescriptions dispensed.

11. How does this rule or regulation compare to similar rules and regulations in other states or the federal government?

    The program will collect information in accordance with the Standards of the American Society for Automation in Pharmacy (ASAP). All states with an active Prescription Monitoring Program are using the ASAP standards-- 43 states at this time.

12. Provide a summary of the input your agency has received from small business or small business advocates about the proposed rule or regulations.

    The Arkansas Pharmacists Association, Arkansas Board of Pharmacy, Arkansas Medical Society, and other health care professional organizations, law enforcement and attorney groups were involved in the development of the program legislation and regulations.

Arkansas Department of Health

4815 West Markham Street • Little Rock, Arkansas 72205-3867 • Telephone (501) 661-2000
Governor Mike Beebe
Paul K. Halverson, DrPH, FACHE, Director and State Health Officer

SUMMARY OF PROPOSED RULES PERTAINING TO
ARKANSAS PRESCRIPTION DRUG MONITORING PROGRAM

The rules adopt the purpose and definitions as set out in Act 304 OF 2011.

Requirements for the Prescription Drug Monitoring Program as established in the Act, such as the requirement for a dispenser outside Arkansas to report if the patient's address is in Arkansas and the information to be submitted, are included. Each dispenser is required to report the following information for each controlled substance prescription dispensed to an ultimate user whose address is within Arkansas:

- The dispenser's identification number;
- The date the prescription was filled;
- The prescription number;
- Whether the prescription is new or is a refill;
- The National Drug Code number for the controlled substance that is dispensed;
- The quantity of the controlled substance dispensed;
- The number of days' supply dispensed;
- The number of refills ordered;
- A patient identifier.
  A patient identifier shall not be a social security number or a driver's license number;
- The patient's name;
- The patient's address;
- The patient's date of birth;
- The patient's gender;
- The prescriber's identification number;
- The date the prescription was issued by the prescriber; and
- The source of the payment for the prescription.

The methods for transmitting the required information are as follows:

- Information shall be submitted in accordance with the Standard for Prescription Monitoring Programs of the American Society for Automation in Pharmacy (ASAP) Version 4 Release 2 September 2011.
- Data shall be submitted via CD-ROM, a secure File Transfer Protocol (FTP), Virtual Private Network (VPN), https: or other methods approved by the Prescription Drug Monitoring Program.
- Reports shall be submitted weekly for the previous week, Sunday through Saturday. If controlled substances were not dispensed for the reporting period, the dispenser will submit a Zero Report in accordance with ASAP Version 4 Release 2 September 2011.
- The department or the department's contractor shall notify the dispenser of an error in data reporting. Upon receiving notification of an error in data reporting, the dispenser shall take appropriate measures to correct the error and transmit the corrected data to the department or the department's contractor within 14 days of being notified of the error.

The department will create a process for patients to address errors, inconsistencies, and other matters in their record, including cases of breach of privacy and security, which complies with the Health Insurance Portability and Accountability Act (HIPAA) and the Health Information Technology for Economic and Clinical Health Act (HITECH).

The Prescription Drug Monitoring Program Advisory Committee is established as designed by the Act to consult with and advise the Department of Health on matters related to the establishment, maintenance, operation, and evaluation of the program.

In conformance with the Act, prescription information submitted to the department for the Prescription Drug Monitoring Program is confidential and is not subject to the Freedom of Information Act of 1967, § 25-19-101 et seq. The data is privileged and confidential, is not a public record, and is not subject to subpoena or discovery in a civil proceeding. Access to PDMP data is further delineated for law enforcement, licensing or regulatory boards, and others in accordance with the law.

The department will establish and enforce policies to ensure that the privacy and confidentiality of patients are maintained in compliance with the Health Insurance Portability and Accountability Act (HIPAA) and the Health Information Technology for Economic and Clinical Health Act (HITECH).

The department shall establish a process to verify the credentials of those requesting to use prescription information. The application will include information as needed by the department to verify the applicant's authority to use the prescription information in compliance with Section VII of Act 304.

The department's authority to exchange information with other states' prescription drug monitoring programs, to use a contractor and to seek funding is included as outlined in the Act.

As established in the Act, unlawful acts and concurrent penalties are incorporated in the regulations.

Privacy rights are protected and the effective date of the Prescription Drug Monitoring Program is set as March 1, 2013, if funding is available, consistent with the Act.