RULES AND REGULATIONS PERTAINING TO ARKANSAS PRESCRIPTION DRUG MONITORING PROGRAM

PHARMACY SERVICES BRANCH
CENTER FOR HEALTH PROTECTION

Effective March 2016
By the Arkansas State Board of Health
Arkansas Department of Health
Little Rock, Arkansas
Nathaniel Smith, MD, MPH

Rules and Regulations Pertaining to
Arkansas Prescription Drug Monitoring Program

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SECTION I – Authority

The following regulations have been hereby promulgated pursuant to Arkansas Code Annotated § 20-7-613.

SECTION II – Purpose

The purpose of these regulations is to protect the state health system and the citizens of Arkansas by:

(1) enhancing patient care by providing prescription monitoring information that will ensure legitimate use of controlled substances in health care, including palliative care, research, and other medical pharmacological uses;

(2) helping curtail the misuse and abuse of controlled substances;

(3) assisting in combating illegal trade in and diversion of controlled substances; and

(4) enabling access to prescription information by practitioners, law enforcement agents, and other authorized individuals and agencies and to make prescription information available to practitioners, law enforcement agents, and other authorized individuals and agencies in other states.

SECTION III – Definitions

As used in this section:

(1) "Controlled substance" means a drug, substance, or immediate precursor in Schedules II-V;

(2) "Dispense" means to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including without limitation, the prescribing, administering, packaging, labeling, or compounding necessary to prepare the controlled substance for that delivery;

(3) (A) "Dispenser" means a practitioner who dispenses.

(B) "Dispenser" does not include:

(i) A licensed hospital pharmacy when it is distributing controlled substances for the purpose of outpatient services, inpatient hospital care, or at the time of discharge from a hospital, except for a pharmacy owned by a hospital that has a retail pharmacy permit when the pharmacy is distributing controlled substances directly to the public;

(ii) A wholesale distributor of Schedule II-Schedule V controlled substances; or

(iii) A practitioner or other authorized person who administers a controlled substance;

(4) "Exchangeability" means the ability of the program to electronically share reported information with another state's prescription monitoring program if the information concerns the dispensing of a controlled substance either:

(A) To a patient who resides in the other state; or

(B) Prescribed by a practitioner whose principal place of business is located in the other state;

(5) "Investigation" means an active inquiry that is being conducted with a reasonable, good faith belief that the inquiry:

(A) Could lead to the filing of administrative, civil, or criminal proceedings; or

(B) Is ongoing and continuing and a reasonable, good faith anticipation exists for securing an arrest or prosecution in the foreseeable future;

(6) "Patient" means the person or animal who is the ultimate user of a controlled substance for whom a lawful prescription is issued and for whom a controlled substance is lawfully dispensed;

(7) "Practitioner" means:

(A) A physician, dentist, veterinarian, advanced practice nurse, physician assistant, pharmacist, scientific investigator, or other person licensed, registered, or otherwise permitted to prescribe, distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research in this state; and

(B) A pharmacy, hospital, or other institution licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research in this state;

(8) "Prescribe" means to issue a direction or authorization, by prescription, permitting a patient lawfully to obtain a controlled substance;

(9) "Prescriber" means a practitioner or other authorized person who prescribes a Schedule II, III, IV, or V controlled substance;

(10) "Prescription" means a controlled substance lawfully prescribed and subsequently dispensed;

(11) “Prescription drug monitoring program” means a program that collects, manages, analyzes, and provides information regarding Schedule II, III, IV, and V controlled substances as provided under the Uniform Controlled Substances Act, § 5-64-101 et seq., §§ 5-64-1101 -- 5-64-1103, the Food, Drug, and Cosmetic Act, § 20-56-201 et seq., or §§ 20-64-501 -- 20 64-513;

(12) “Schedule II” means controlled substances that are placed in Schedule II under § 5-64-205;

(13) “Schedule III” means controlled substances that are placed in Schedule III under § 5-64- 207;

(14) “Schedule IV” means controlled substances that are placed in Schedule IV under § 5-64- 209;

(15) “Schedule V” means controlled substances that are placed in Schedule V under § 5-64-211;

(16) “Ultimate user” means a person who lawfully possesses a controlled substance for:

(A) The person's own use;

(B) The use of a member of the person's household; or

(C) Administering to an animal owned by a person or by a member of the person's household.

(17) "Certified law enforcement prescription drug diversion investigator" means a certified law enforcement officer assigned by his or her law enforcement agency to investigate prescription drug diversion and who has completed a certification course in prescription drug diversion approved by the Arkansas Prescription Drug Advisory Committee and certified by the Arkansas Commission on Law Enforcement Standards and Training and who may access the Arkansas Prescription Drug Monitoring Program for prescriptions dispensed in Arkansas.

(18) “Delegate” means an agent or employee of the prescriber or dispenser to whom the prescriber or dispenser has delegated the task of accessing the data described in this subsection, but only if the agent or employee has been granted access by a delegate account, and for whose actions the authorizing prescriber or dispenser retains accountability.

(19) “Opioid” means a drug or medication that relieves pain, including without limitation:

(A) Hydrocodone;

(B) Oxycodone;

(C) Morphine

(D) Codeine;

(E) Heroin

(F) Fentanyl

(20) "Qualified law enforcement agency" means a law enforcement agency that has a certified law enforcement prescription drug diversion investigator and a chief, sheriff, or law enforcement chief executive officer who have successfully completed a certification course in prescription drug diversion approved by the commission.

SECTION IV – Requirements for the Prescription Drug Monitoring Program

(a) The State Board of Health shall create the Prescription Drug Monitoring Program upon the Department of Health's procuring adequate funding to establish the program.

(b) (1) Each dispenser shall submit to the department information regarding each Schedule II, III, IV, or V controlled substance dispensed.

(2) A dispenser located outside Arkansas and licensed and registered by the Arkansas State Board of Pharmacy shall submit to the department information regarding each Schedule II, III, IV, or V controlled substance prescription dispensed to an ultimate user whose address is within Arkansas.

(3) The board shall create a controlled substances database for the Prescription Drug Monitoring Program.

(c) Each dispenser required to report under subsection (b) of this section shall submit to the department by electronic means information that shall include without limitation the following:

(1) The dispenser's identification number;

(2) The date the prescription was filled;

(3) The prescription number;

(4) Whether the prescription is new or is a refill;

(5) The National Drug Code number for the controlled substance that is dispensed;

(6) The quantity of the controlled substance dispensed;

(7) The number of days' supply dispensed;

(8) The number of refills ordered;

(9) (A) A patient identifier.

(B) A patient identifier shall not be a social security number or a driver's license number;

(10) The patient's name;

(11) The patient's address;

(12) The patient's date of birth;

(13) The patient's gender;

(14) The prescriber's identification number;

(15) The date the prescription was issued by the prescriber; and

(16) The source of the payment for the prescription.

(d) Practitioners are encouraged to access or check the information in the controlled substance database created under this section before prescribing, dispensing, or administering medications.

(e) This section does not prohibit licensing boards from requiring practitioners to access or check the information in the controlled substance database as a part of a review of the practitioner's professional practice.

(f) (1) Each dispenser shall submit the required information in accordance with the Standard for Prescription Monitoring Programs of the American Society for Automation in Pharmacy (ASAP) Version 4 Release 2 September 2011, incorporated by reference.

(2) 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.

(3) A dispenser shall report the controlled substance dispensing information records required under Arkansas Code Annotated §§ 20-7-601 to -614 and these regulations weekly for the previous week, Sunday through Saturday. If controlled substances were not dispensed for the reporting period, the dispenser shall submit a Zero Report in accordance with ASAP Version 4 Release 2 September 2011.

(4) The department or the department’s contractor shall notify a 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.

(g) The department's process for patients to address errors, inconsistencies, and other matters in their record as maintained under this section, including in cases of breach of privacy and security shall comply with Sections 261 through 264 of the Health Insurance Portability and Accountability Act (HIPAA) of 1996, Public Law 104-191 (the Administrative Simplification provisions) and regulations 45 CFR Parts 160 and 164 ("the HIPAA Security and Privacy Rule") and the HITECH (Health Information Technology for Economic and Clinical Health) Act as enacted by the American Recovery and Reinvestment Act (ARRA) of 2009 (Pub. L. 111-5), pursuant to Title XIII of Division A and Title IV of Division B.

(h) The department shall limit access to only those employees whose access is reasonably necessary to carry out this section.

(i) A certified law enforcement prescription drug diversion investigator shall provide to the department the following information in order to be granted access to the Prescription Drug Monitoring Program:

(1) The identification credentials assigned by the department; and

(2) The case number of the investigation submitted on the investigator's law enforcement agency letterhead.

(3) The badge number of the investigator.

(4) A copy of the investigator's certification from the Arkansas Commission of Law Enforcement Standards and Training course in prescription drug diversion.

(j)(1) A qualified law enforcement agency shall submit to the department an annual report of the data accessed by all certified law enforcement prescription drug diversion investigators in the qualified law enforcement agency, including without limitation:

(A) Written verification that the inquiries were part of a lawful prescription drug diversion investigation as provided to the department through the case number of the investigation; and

(B) The disposition of the investigation.

(2) The department shall:

(A) Create a verification form for use under subdivision (j)(1) of this section; and

(B) Make the verification form available annually to the qualified law enforcement agency.

(3)(A) The verification form under subdivision (j)(1) of this section shall be submitted to the department within thirty (30) days of receipt of the form by the qualified law enforcement agency.

(B) Failure to submit a verification form under subdivision (j)(3)(A) of this section shall result in the immediate suspension of the access to the database by the qualified law enforcement agency and its certified law enforcement prescription drug diversion investigators until a determination is made by the department to allow continued access.

SECTION V – Prescription Drug Monitoring Program Advisory Committee

(a) The State Board of Health shall create the Prescription Drug Monitoring Program Advisory Committee upon the Department of Health's procuring adequate funding to establish the Prescription Drug Monitoring Program.

(b) The mission of the advisory committee is to consult with and advise the Department of Health on matters related to the establishment, maintenance, operation, and evaluation of the Prescription Drug Monitoring Program.

(c) The committee shall consist of:

(1) One (1) representative designated by each of the following organizations:

(A) The Arkansas Academy of Physician Assistants;

(B) The Arkansas Association of Chiefs of Police;

(C) The Arkansas Drug Director;

(D) The Arkansas Medical Society;

(E) The Arkansas Nurses Association;

(F) The Arkansas Optometric Association;

(G) The Arkansas Osteopathic Medical Association;

(H) The Arkansas Pharmacists Association;

(I) The Arkansas Podiatric Medical Association;

(J) The Arkansas Prosecuting Attorneys Association;

(K) The Arkansas Sheriffs Association;

(L) The Arkansas State Dental Association;

(M) The Arkansas Veterinary Medical Association;

(N) The State Board of Health;

(O) The Arkansas Public Defender Commission; and

(P) A mental health provider or certified drug and alcohol counselor; and

(2) One (1) consumer appointed by the Governor.

SECTION VI – Confidentiality

(a) Prescription information submitted to the Department of Health pursuant to Arkansas Code Annotated §§ 20-7-601 to -614 and these regulations is confidential and not subject to the Freedom of Information Act of 1967, § 25-19-101 et seq.

(b) (1) The controlled substances database and all information contained in the controlled substances database and any records maintained by the department or by an entity contracting with the department that is submitted to, maintained, or stored as a part of the controlled substances database is privileged and confidential, is not a public record, and is not subject to subpoena or discovery in a civil proceeding.

(2) Information in the controlled substances database may be accessed by:

(A) A certified law enforcement officer pursuant to a criminal investigation but only after the law enforcement officer obtains a search warrant signed by a judge that demonstrates probable cause to believe that a violation of federal or state criminal law has occurred, that specified information contained in the database would assist in the investigation of the crime, and that the specified information should be released to the certified law enforcement officer;

(B) A regulatory body engaged in the supervision of activities of licensing or regulatory boards of practitioners authorized to prescribe or dispense controlled substances;

(C) A person or entity investigating a case involving breaches of privacy involving the database or its records.

(D) A certified law enforcement prescription drug diversion investigator of a qualified law enforcement agency; or

(E) The Department of Human Services or the Crimes Against Children Division of the Department of Arkansas State Police if:

(i) The purpose of the database access is related to an investigation under the Child Maltreatment Act, § 12-18-101 et seq., and not pursuant to a criminal investigation by a certified law enforcement officer; and

(ii) The Department of Human Services has obtained a court order to access the database under § 12-18-621.

(c) This section does not apply to information, documents, or records created or maintained in the regular course of business of a pharmacy, medical, dental, optometric, or veterinary practitioner, or other entity covered by Arkansas Code Annotated §§ 20-7-601 to -614 and these regulations, and all information, documents, or records otherwise available from original sources are not immune from discovery or use in a civil proceeding merely because the information contained in the records was reported to the controlled substances database under Arkansas Code Annotated §§ 20-7-601 to -614 and these regulations.

(d) The department shall establish and enforce policies and procedures to ensure that the privacy and confidentiality of patients are maintained and that patient information collected, recorded, transmitted, and stored is protected and not disclosed to persons except as listed in Section VII – Providing Prescription Monitoring Information. The department's policies shall comply with Sections 261 through 264 of the Health Insurance Portability and Accountability Act (HIPAA) of 1996, Public Law 104-191 (the Administrative Simplification provisions) and regulations 45 CFR Parts 160 and 164 ("the HIPAA Security and Privacy Rule") and the HITECH (Health Information Technology for Economic and Clinical Health) Act as enacted by the American Recovery and Reinvestment Act (ARRA) of 2009 (Pub. L. 111-5), pursuant to Title XIII of Division A and Title IV of Division B.

(e) The Prescription Drug Monitoring Program shall establish and maintain a process for verifying the credentials and authorizing the use of prescription information by individuals and agencies listed in Section VII – Providing Prescription Monitoring Information. The application to access prescription information shall include information as needed by the department to verify the applicant's authority to use prescription information in compliance with Section VII.

SECTION VII – Providing Prescription Monitoring Information

(a) (1)(A) The Department of Health may review the Prescription Drug Monitoring Program information, including without limitation a review to identify information that appears to indicate whether a person may be obtaining prescriptions in a manner that may represent misuse or abuse of controlled substances.

(B) If information of misuse or abuse is identified, the department shall notify the practitioners and dispensers who prescribed or dispensed the prescriptions and the Little Rock, Arkansas Office of Diversion Control of the United States Drug Enforcement Administration.

(2)(A) The department may review the Prescription Drug Monitoring 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 a controlled substance.

(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.

(C) The department shall develop algorithms within the controlled substance database that would alert a practitioner if his or her patient is being prescribed opioids by more than three (3) physicians within any thirty-day period, if funding is available.

(3)(A) A prescriber who has been found by his or her licensing board to be in violation of a rule or law involving prescription drugs shall be required by the appropriate licensing board to register with the Prescription Drug Monitoring Program and access patient information before writing a prescription for an opioid.

(B) The licensing board, in its discretion, may remove this requirement after a period of time if the board deems removal of the requirement appropriate.

(b)The department shall provide information in the Prescription Drug Monitoring Program upon request and at no cost only to the following persons:

(1) (A) A person authorized to prescribe or dispense controlled substances for the purpose of providing medical or pharmaceutical care for his or her patients or for reviewing information regarding prescriptions that are recorded as having been issued or dispensed by the requester;

(B) A Delegate;

(2) A patient who requests his or her own prescription monitoring information;

(3) A parent or legal guardian of a minor child who requests the minor child's Prescription Drug Monitoring Program information;

(4) (A) A designated representative of a professional licensing board of the professions of the healing arts representing health care disciplines whose licensees are prescribers pursuant to an investigation of a specific individual, entity, or business licensed or permitted by that board.

(B) Except as permitted by subsection (a)(2) of this section, the department shall provide information under subsection (b)(4)(A) of this section only if the requesting board states in writing that the information is necessary for an investigation;

(5) The State Medical Examiner as authorized by law to investigate causes of deaths for cases under investigation pursuant to his or her official duties and responsibilities;

(6) Local, state, and federal law enforcement or prosecutorial officials engaged in the administration, investigation, or enforcement of the laws governing controlled substances required to be submitted under Arkansas Code Annotated §§ 20-7-601 to 614 and these regulations pursuant to the agency's official duties and responsibilities; and

(7) Personnel of the department for purposes of administration and enforcement of Arkansas Code Annotated § 20-7-607 and this section.

(c) Information collected under Arkansas Code Annotated §§ 20-7-601 to -614 and these regulations shall be maintained for three (3) years.

(d) The department may provide information to public or private entities for statistical, research, or educational purposes after encrypting or removing the patient's name, street name and number, patient identification number, month and day of birth, and prescriber information that could be used to identify individual patients, persons who received prescriptions from dispensers, or both.

SECTION VIII – Information Exchange with Other Prescription Drug Monitoring Programs

(a) The Department of Health may provide prescription monitoring information to other states' prescription drug monitoring programs, and the information may be used by those programs consistent with Arkansas Code Annotated §§ 20-7-601 to -614 and these regulations.

(b) The department may request and receive prescription monitoring information from other states' prescription drug monitoring programs and may use the information pursuant to Arkansas Code Annotated §§ 20-7-601 to -614 and these regulations.

(c) The department may develop the capability to transmit information to other prescription drug monitoring programs and receive information from other prescription drug monitoring programs employing the standards of exchangeability.

(d) The department may enter into written agreements with other states' prescription drug monitoring programs for the purpose of describing the terms and conditions for sharing of prescription information consistent with Arkansas Code Annotated §§ 20-7-601 to -614 and these regulations.

SECTION IX – Authority to Contract

(a) The Department of Health may contract with another agency of this state or with a private vendor, as necessary, to ensure the effective operation of the Prescription Drug Monitoring Program.

(b) A contractor shall be bound to comply with the provisions regarding confidentiality of prescription information as outlined in Arkansas Code Annotated §§ 20-7-601 to -614 and these regulations and shall be subject to the penalties specified in Arkansas Code Annotated §§ 20-7-601 to -614 and these regulations for unlawful acts.

SECTION X – Authority to Seek Funding

(a) The Department of Health may make application for, receive, and administer grant funding from public or private sources for the development, implementation, or enhancement of the Prescription Drug Monitoring Program.

(b) A fee shall not be levied against practitioners for the purpose of funding or complying with the Prescription Drug Monitoring Program.

SECTION XI – Unlawful Acts and Penalties

(a) (1) It is unlawful for a dispenser to purposely fail to submit prescription monitoring information as required under Arkansas Code Annotated §§ 20-7-601 to -614 and these regulations.

2) A violation of subdivision (a) (1) of this section is a Class B misdemeanor.

(b) (1) It is unlawful for a dispenser to purposely submit fraudulent prescription information.

(2) A violation of subdivision (b) (1) of this section is a Class D felony.

(c) (1) It is unlawful for a person authorized to receive prescription monitoring information to purposely disclose the information in violation of Arkansas Code Annotated §§ 20 7-601 to -614 and these regulations.

(2) A violation of subdivision (c) (1) of this section is a Class C felony.

(d) (1) It is unlawful for a person authorized to receive prescription drug monitoring program information to use such information in a manner or for a purpose in violation of Arkansas Code Annotated §§ 20-7-601 to -614 and these regulations.

(2) A violation of subsection (d) (1) of this section is a Class C felony.

(e) (1) It is unlawful for a person to knowingly obtain, use, or disclose or attempt to obtain, use, or disclose information by fraud or deceit from the Prescription Drug Monitoring Program or from a person authorized to receive information from the Prescription Drug Monitoring Program under Arkansas Code Annotated §§ 20-7-601 to -614 and these regulations.

(2) A violation of subdivision (e) (1) of this section is a Class C felony.

(f) In addition to the criminal penalties provided in this section, a dispenser or practitioner who uses or discloses confidential information received from the Prescription Drug Monitoring Program in a manner or for a purpose in violation of Arkansas Code Annotated §§ 20-7-601 to -614 and these regulations may be subject to disciplinary action by the dispenser's or practitioner's licensing board.

(g) In addition to the criminal penalties provided in this section, a law enforcement officer who uses or discloses confidential information received from the Prescription Drug Monitoring Program in a manner or for a purpose in violation of Arkansas Code Annotated §§ 20-7-601 to -614 and these regulations may be subject to disciplinary action by the law enforcement officer's agency or department.

(h) Arkansas Code Annotated §§ 20-7-601 to -614 and these regulations do not limit a person whose privacy has been compromised unlawfully under this section from bringing a civil action to address the breach of privacy or to recover all damages to which the person may be entitled per violation, including attorney's fees and costs.

SECTION XII – Privacy Rights Protected

Arkansas Code Annotated §§ 20-7-601 to -614 and these regulations do not give authority to any person, agency, corporation, or other legal entity to invade the privacy of any citizen as defined by the General Assembly, the courts, or the United States Constitution or the Constitution of the State of Arkansas other than to the extent provided in these regulations and Arkansas Code Annotated §§ 20-7-601 to -614.

SECTION XIII – Effective Date

(a) The Prescription Drug Monitoring Program shall become operational March 1, 2013, if full funding is available under Arkansas Code Annotated § 20-7-610 and Section X.

(b) The Director of the Department of Health may suspend operation of the program if adequate funding under Arkansas Code Annotated § 20-7-610 and Section X ceases.

SECTION XIV - Severability

If any provision of these rules or the application thereof to any person or circumstance is held invalid, such invalidity shall not affect other provisions or applications of these rules which can give effect without the invalid provisions or applications, and to this end the provisions hereto are declared severable.

SECTION XV – Repeal

All rules and parts of rules in conflict are hereby repealed.

CERTIFICATION

I certify that the foregoing Rules pertaining to the Arkansas Prescription Drug Monitoring Program were adopted by the Arkansas State Board of Health at a regular session in Little Rock, Arkansas, on this 28th day of January, 2016.

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Nathaniel Smith, MD, MPH
Secretary, Arkansas State Board of Health
Director, Arkansas Department of Health

RULES AND REGULATIONS PERTAINING TO THE ARKANSAS PRESCRIPTION DRUG MONITORING PROGRAM
WRITTEN FINDINGS OF FINANCIAL IMPACT
IN ACCORDANCE WITH ARK. CODE ANN. § 25-15-204(e)

1) A statement of the Rule's basis and purpose:

The amendments that have a financial impact are made to comply with Act 901 of 2015 which requires changes to the PDMP computer program.

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

The purpose of the amendments includes creating access, accountability, verification, and reporting components for certified law enforcement prescription drug diversion investigators who have been properly trained and certified in accordance with the Act. All of these amendments are required by Act 901 of 2015.

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 cost:

The current PDMP computer program does not support access for certified law enforcement prescription drug diversion investigators. Access for these investigators will not require a search warrant. This is anticipated to shorten the time needed for the investigative process. The cost to develop this new access is a onetime development fee.

4) A list of less costly alternatives to the proposed rule and the reason why the alternatives do not adequately address the problem to be solved by the proposed rule:

There are no less costly alternatives to this 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:

At this time, there have been no less costly alternatives proposed.

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

N/A

7) An agency plan for review of the rule no less than every ten (10) years to determine whether, based upon 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.

There are built in reviews of grant funding to ensure that the monies are being spent in accordance with the grant requirements. However, since this is a onetime cost, there is no need to set up a review outside of the standard grant review.

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY

DEPARTMENT Arkansas Department of Health

DIVISION Center for Health Protection

PERSON COMPLETING THIS STATEMENT Elizabeth Pitman

TELEPHONE NO. (501) 280-4034 **FAX NO.** (501) 661-2357 **EMAIL:** sarah.pitman@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.