Arkansas Department of Health

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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.

RULES AND REGULATIONS PERTAINING TO ARKANSAS PRESCRIPTION DRUG MONITORING PROGRAM

PHARMACY BRANCH
CENTER FOR HEALTH PROTECTION

Effective _____
By the Arkansas State Board of Health
Arkansas Department of Health
Little Rock, Arkansas
Paul Halverson, DrPH, FACHE

DRAFT 10/19/2012

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

These regulations are intended to protect the state health system and the citizens of Arkansas by establishing a state prescription drug monitoring program 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; and

(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.

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.

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; or

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

(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) 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.

(2) If information of misuse or abuse is identified, the department shall notify the practitioners and dispensers who prescribed or dispensed the prescriptions.

(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 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;

(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 § 20-7-207 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 herewith 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 _____ day of _____, 201_.

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Paul K. Halverson, DrPH, FACHE
Secretary, Arkansas State Board of Health
Director, Arkansas Department of Health