Arkansas Department of Health
Proposed Amendments to Rules Pertaining to Arkansas Prescription Drug Monitoring Program
Public Comments Received

A public hearing was conducted December 8, 2015 at 10:00 a.m. in Room #L137 of the Arkansas Department of Health, 4815 West Markham, Little Rock, Arkansas. No oral comments were received during the hearing.

Written comments were received by the deadline prior to the hearing and follow.

Response to written comments from Laci Lyons received November 16, 2015:

Comment	Response
Please accept this as a public comment regarding this issue of prescription drug monitoring. 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	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

Comment	Response
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.	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.

Responses to written comments received from Bob Twillman, Ph.D., FAPM, Executive Director, American Academy of Pain Management on December 8, 2015:

Comment	**Response**
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." <u>We respectfully request that "heroin" be deleted from this definition</u>. <u>We also suggest the following as a better alternative definition</u> (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.	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.

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.	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.

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. <u>We cannot support this section as written and request that it be modified as below.</u> 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 <u>not</u> 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	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.

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.	No response required.

Response to verbal comments received at the Public Hearing on November 8, 2015:

Comment	**Response**
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.	Please see the response to the comments received from Laci Lyons, above.

Responses to verbal questions received from Ken Larson, Xerox Government Healthcare Services, at the public hearing on November 8, 2015:

Comments	**Responses**
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.	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.
Your program creates a coordinated effort between the listed parties.	Yes, that is correct.