EXHIBIT D-1

ARKANSAS STATE MEDICAL BOARD

1401 West Capitol, Suite 340, Little Rock, Arkansas 72201 • (501) 296-1802 • FAX (501) 603-3555
www.armedicalboard.org

TO: The House Committee on Public Health, Welfare, and Labor
The Senate Committee on Public Health, Welfare, and Labor

FROM: Karen Whatley, Executive Director, Arkansas State Medical Board KW

DATE: June 26, 2018

RE: Over Prescribing of Opioid Drugs

On June 13, 2018, the House and Senate Public Health, Welfare, and Labor Committees requested an update regarding the over prescribing of opioid drugs. This report is in response to that request. Karen Whatley, the Executive Director of the Arkansas State Medical Board, will attend the July 2 Senate and House Public Health Committee meeting to provide an oral report on this issue.

PDMP Report Cards

One issue which the committees requested information concerns how the new legislation on prescribing report cards is working and efforts that each prescribing board is making in following up and monitoring the activities of the over prescribers.

In April 2018, the Prescription Drug Monitoring Program (PDMP) sent out the first set of "report cards" to every prescriber who had prescribed at least one controlled drug within the period of October 2017 – March 2018. After receipt of the information, many prescribers contacted the PDMP and the Arkansas State Medical Board with questions about delegates, specialties, and who will see the information. The Executive Director spoke with Denise Robertson to confirm answers to these questions.

Many prescribers utilize delegates to check the PDMP on their patients. The reports cards did not completely attribute the checks the delegates had done to the prescribers because of the delegate's failure to properly attribute the check to the correct prescriber thus making it appear the prescriber was not properly checking the PDMP. Although a person may be a delegate for numerous prescribers, delegates only have one log-in identity but can assign a PDMP search to separate providers. In order to have the PDMP correctly attribute the searches, the delegate must properly assign the search to the correct provider.

Many physicians asked to whom they are being compared. The providers are compared to other providers in the same specialty. The providers selected their specialty when they set up their accounts. If a provider does not think his/her specialty is correct, he/she can go into the PDMP account and change information regarding specialty. E.g., if a person is a family medicine physician who has a large hospice practice, the specialty can be changed to family medicine/hospice/palliative medicine.

Unless provided by the physician, the Medical Board will not receive copies of these reports cards. Only if there are concerns about prescribing habits; no changes are made within one year; and the prescriber does not respond to the Department of Health regarding concerns will the PDMP provide the report cards to the Medical Board. The earliest this will occur is the second quarter of 2019.

Denise Robertson stressed that these initial report cards are to be used by the providers for self-assessment. If providers have any questions, they can contact the PDMP at the numbers provided in the email which contained the report card.

Pursuant to Act 820 of 2017, the Arkansas Department of Health (ADH) Director will work with stakeholders to develop prescribing criteria that will help to inform determinations of misuse or abuse from information in the Prescriber Comparison Reports. To remain in-line with other activity in the state, ADH is waiting to set criteria until it can be matched to pending Arkansas State Medical Board rule changes on excessive prescribing (to be described in more detail below).

Relevant AR PDMP data as of May 2018:

License Type	Number licensed in Arkansas who also practice in Arkansas*	Number Registered with AR PDMP	Average Number of Queries per Month	Number who Received a Prescriber Comparison Report**
Physician	6,120	5,545	319,430	3,299
Physician Assistant	454	353	7,750	234

* Physician assistant primary practice location is not currently tracked so the number presented is all physician assistants licensed in Arkansas.
** Arkansas physicians and physician assistants who wrote at least one opioid prescription and were registered with the AR PDMP during the six month reporting period.

PDMP Reports

Even though the Arkansas State Medical Board does not have access to the PDMP report cards, the Board can subpoena prescribing records from the PDMP regarding physicians who have been accused of over-prescribing. The information gained from the PDMP reports is used to request medical records from the physician for use in the investigation. In addition, the PDMP provides periodic updates to the Arkansas State Medical Board regarding the top prescribers in the state.

The PDMP also provides information to the Arkansas State Medical Board regarding physicians who have prescribed a controlled substance but who have not registered with the PDMP. The Board then contacts those physicians seeking an explanation for failure to follow Act 820. All physicians contacted to date registered for the PDMP within days of receiving the correspondence from the Medical Board. Failure to register for the PDMP and follow Act 820 can result in disciplinary action before the Medical Board.

Regulation 2

At the April 2018 meeting of the Arkansas State Medical Board, the Medical Board passed changes to Regulation 2 concerning the definition of excessive. The amendment passed the ALC Administrative Rules and Regulations Committee at the June meeting but was returned to that committee by the Arkansas Legislative Council on June 15, 2018. This amendment will be addressed again at the July 17, 2018 Rules and Regulations Committee meeting.

The primary changes to Regulation 2 are as follows:

4. The prescribing of excessive amounts of controlled substances to a patient including the writing of an excessive number of prescriptions for an addicting or potentially harmful drug to a patient. "Excessive" is defined as the writing of any prescription in any amount without a detailed medical justification for the prescription documented in the patient record.

    A. Chronic Pain: If there is documented medical justification, "excessive" is defined, pursuant to the Centers for Disease Control (CDC) guideline for prescribing opioids for chronic pain, as prescribing opioids at a level that exceeds ≥50 Morphine Milligram Equivalents (MME) per day, unless the physician/physician assistant documents each of the following:

        a. Objective findings, which include, but are not limited to, imaging studies, lab testing and results, nerve conduction testing, biopsy, and any other test that would establish pain generating pathology.

        b. Specific reasons for the need to prescribe ≥ 50 MME per day.

        c. Documented alternative treatment plans as well as alternative therapies trialed and failed prior to considering chronic opioid therapy.

        d. Documented risk factor assessment detailing that the patient was informed of the risk and the addictive nature of the prescribed drug.

e. Documented assessment of the potential for abuse and/or diversion of the prescribed drug.

f. That the Prescription Drug Monitoring Program had been checked prior to issuing the prescription.

g. A detailed clinical rationale for the prescribing and the patient must be seen in an in-person examination every three (3) months or every 90 days.

h. The definition of "excessive" as contained in this Regulation shall not apply to prescriptions written for a patient in hospice care, in active cancer treatment, palliative care, end-of-life care, nursing home, assisted living or a patient while in an inpatient setting or in an emergency situation.

i. Regular urine drug screens should be performed on patients to insure the patient is taking prescribed medications and is not participating or suspected in participating in diversion or abuse of non-prescribed medications. The treatment of chronic pain shall be consistent with the CDC guidelines as they relate to baseline drug testing, and at least annual follow up testing as warranted for treatment.

j. A pain treatment agreement must be signed and reviewed by the patient when initiating chronic opioid therapy. This agreement should discuss the following: informed risk and addictive nature of prescribed medications, outline the specific expectations between patient and physician, informed consent for periodic urine drug screenings and random pill counts with urine screening as well as the provisions for termination of opioid therapy.

B. Acute Pain: For treatment of acute pain, "excessive" is further defined as an initial prescription written for more than seven (7) days, without detailed, documented medical justification in the medical record. If the patient requires further prescriptions, they must be evaluated in regular increments with documented medical justification for continued treatment in medical record.

C. When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to > 50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to > 90 MME/day or carefully justify a decision to tritrate dosage to > 90 MME/day.

This proposed change was accepted by the Board after two public comment meetings in which members of the public spoke in opposition to the changes based on a fear their physicians would no longer prescribe any scheduled medications. After the February 2018 public comment meeting, the following information was placed on the Arkansas State Medical Board's website:

> Proposed Changes to Prescribing Regulations
>
> At the February 2018 meeting of the Arkansas State Medical Board, numerous public comments were taken regarding proposed changes to Regulation 2. Based on some of those comments, it was determined that some physicians may have misinterpreted the proposed definition of excessive and may be telling patients the Arkansas State Medical Board no longer allows physicians to prescribe certain controlled substances. This is not the case.
>
> The proposed changes do not require that physicians cease prescribing controlled substances. As with any prescription, there must be a documented, detailed medical justification for the prescription in the patient record. For those cases with the documented, detailed medical justification and for which the prescription is written for chronic pain, the change in Regulation 2 would adopt the CDC guidelines limiting the prescription to less than 50 Morphine Milligram Equivalents per day unless the physician documents certain findings in the file. Those findings are delineated in the proposed Regulation.
>
> For those persons being prescribed controlled substances for acute pain, the prescription limitation is 7 days unless there is detailed, documented medical justification in the patient record for a prescription of a longer duration.

The Arkansas State Medical Board is hopeful Regulation 2 will pass in July.

Continuing Medical Education

At the April 2018 meeting of the Arkansas State Medical Board, the Board passed an amendment to Regulation 17 regarding Continuing Medical Education (CME). During each renewal cycle, physicians and physician assistants are required to obtain 20 hours of CME. As a result of the amendment to Regulation 17, at least one hour of the 20 hours must concern the prescribing of opioids and benzodiazepines. That amendment was passed by the ALC Administrative Rules and Regulations Committee and affirmed by the Arkansas Legislative Council. Physicians and physician assistants must begin reporting this CME hour during the 2019 renewal cycle. There

are no exceptions to the requirement so all physicians and physician assistants regardless of their practice model must comply with the regulation.

All prescribers licensed after December 31, 2015, no matter whether they have been licensed in another state, within two years of being granted an Arkansas medical license must obtain three hours of prescribing education. This requirement was initially enacted by Act 1208 of the 2015 Regular Session. That Act required a minimum of two (2) hours of prescribing education. The Arkansas State Medical Board in amending Regulation 2(6) opted for a minimum of three hours of prescribing education. Physician assistants who wish to prescribe Hydrocodone Combination Products must complete at least five (5) hours of continuing education hours in the area of pain management. *See*, Regulation 24(10)(f).

AR Impact

The Arkansas State Medical Board has partnered with UAMS regarding AR Impact, a program designed to help Arkansas physicians better manage chronic pain patients and those who need their opioid dosage reduced. AR-IMPACT is a weekly free interactive tele-video program offering free CME credit. The first conference occurred May 2 and will continue to be held each Wednesday, from 12 to 1 p.m. The interactive conferences begin with a brief didactic presentation about an aspect of the care of these patients, followed by a case conference format where doctors can present their difficult cases for discussion with their peers and with our panel of subspecialists. A link to AR Impact is located on the Arkansas State Medical Board's website.

Pain Management Review Committee

The Pain Management Review Committee was created by statute in 2003. *See*, A.C.A. § 17-95-705. The committee is made up of physicians who work in the field of pain management. The committee reviews complaints relating to physicians treating chronic intractable pain. All complaints regarding over-prescribing are first reviewed by the pain committee. The pain committee provides opinions as to whether the Medical Practices Act was violated and if so, if the practitioner should appear before the Pain Committee or the full Board.

In the past year, the Pain Committee has agreed to review patient charts of those physicians seeking assistance in properly prescribing as well as to meet more frequently to educate physicians and prescribe corrective guidance for physicians with prescribing issues.