PROPOSED REGULATION

REGULATION NO. 2

The Arkansas Medical Practices Act authorizes the Arkansas State Medical Board to revoke or suspend the license issued by the Board to practice medicine if the holder thereof has been found guilty of grossly negligent or ignorant malpractice.
"Malpractice" includes any professional misconduct, unreasonable lack of skill or fidelity in professional duties, evil practice, or illegal or immoral conduct in the practice of medicine and surgery.

It shall include, among other things, but not limited to:

1. Violation of laws, regulations, and procedures governing payment to physicians for medical services for eligible public assistance recipients and/or other third party payment programs.

2. Participation in any plan, agreement, or arrangement which compromises the quality or extent of professional medical services or facilities at the expense of the public health, safety, and welfare.

3. Practicing fraud, deceit, or misrepresentation in the practice of medicine.

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 MED 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 of 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.

5. The prescribing of Schedule II controlled substances by a physician/physician assistant for his own use or for the use of his immediate family.

6. *The treatment of pain with dangerous drugs and controlled substances is a legitimate medical purpose when done in the usual course of medical practice. If the provisions as set out below in this Resolution are met, and if all drug treatment is properly documented, the Board will consider such practices as prescribing in a therapeutic manner, and prescribing and practicing medicine in a manner consistent with public health and welfare.

A. However, a physician/physician assistant who prescribes **narcotic agents Schedule 2 [except 2.6(e)], 3, 4, and 5, and to include the schedule drugs Talwin, Stadol, and Nubain, for a patient with pain not associated with malignant or terminal illness will be considered exhibiting gross negligence or ignorant malpractice unless he or she has complied with the following:

a. The physician/physician assistant will keep accurate records to include the medical history, physical examination, other evaluations and consultations, treatment plan objective, informed consent noted in the patient record, treatment, medications given, agreements with the patient and periodic reviews.

b. The physician/physician assistant will periodically review the course of schedule drug treatment of the patient and any new information about etiology of the pain. If the patient has not improved, the physician/physician assistant should assess the appropriateness of continued prescribing of scheduled medications or dangerous drugs, or trial of other modalities.

c. The physician/physician assistant will obtain written informed consent from those patients he or she is concerned may abuse controlled substances and discuss the risks and benefits of the use of controlled substances with the patient, his or her guardian, or authorized representatives.

d. The physician/physician assistant will be licensed appropriately in Arkansas and have a valid controlled substance registration and comply with the Federal and State regulations for the issuing of controlled substances and prescriptions, more especially the regulations as set forth in 21 Code of Federal Regulations Section 1300, et sequence.

B. Treatment of Chronic Nonmalignant Pain:

a. "Chronic nonmalignant pain" means pain requiring more than three (3) consecutive months of prescriptions for:
   i. An opioid that is written for more than the equivalent of ninety (90) tablets, each containing five milligrams (5mg) of hydrocodone;
   ii. A morphine equivalent dose of more than fifty milligrams (50mg) per day; or
   iii. In the specific case of tramadol, a dose of fifty milligrams (50mg) per tablet with a quantity of one hundred twenty (120) tablets;

"Opioid" means a drug or medication that relieves pain, including without limitation:
   iv. Hydrocodone;
   v. Oxycodone;
   vi. Morphine;
   vii. Codeine;
   viii. Heroin; and
   ix. Fentanyl;

"Prescriber" means a practitioner or other authorized person who prescribes a Schedule II, III, IV, or V controlled substance.

b. Patient evaluation – a patient who is being treated with controlled substances for chronic nonmalignant pain shall be evaluated at least one (1) time every three (3) months by a physician/physician assistant who is licensed by the Arkansas State Medical Board.

c. Prescriber requirements:
   i. For a patient with chronic nonmalignant pain, a prescriber, at a minimum and in addition to any additional requirements of the Arkansas State Medical Board, shall:
      1. Check the prescriptive history of the patient on the Prescription Drug Monitoring Program pursuant to Regulation 41;
      2. Follow the specific requirements of Regulation 19 and any and all

other regulations of the Arkansas State Medical Board pertaining to prescribing.

ii. within the first two (2) years of being granted a license in the state, a prescriber shall obtain a minimum of three (3) hours of prescribing education approved by the Arkansas State Medical Board. The education approved by the board under this section shall include:

1. Options for online and in-person programs; and

2. Information on prescribing rules, regulations, and laws that apply to individuals who are licensed in the state.

3. Information and instructions on prescribing controlled substances, record keeping and maintaining safe and professional boundaries.

7. A licensed physician/physician assistant engaging in sexual contact, sexual relations or romantic relationship with a patient concurrent with the physician/physician assistant-patient relationship; or a licensed physician/physician assistant engaging in the same conduct with a former patient, if the physician/physician assistant uses or exploits trust, knowledge, emotions or influence derived from the previous professional relationship, shows a lack of fidelity of professional duties and immoral conduct, thus exhibiting gross negligence and ignorant malpractice. A patient's consent to, initiation of, or participation in sexual relationship or conduct with a physician/physician assistant does not change the nature of the conduct nor the prohibition.

8. **Requiring minimum standards for establishing physician/physician assistant/patient relationships. A physician/physician assistant exhibits gross negligence if he provides and/or recommends any form of treatment, including prescribing legend drugs, without first establishing a proper physician/physician assistant-patient relationship.

A. For purposes of this regulation, a proper physician/physician assistant /patient relationship, at a minimum requires that:

1. A. The physician/physician assistant performs a history and an "in person" physical examination of the patient adequate to establish a diagnosis and identify underlying conditions and/or contraindications to the treatment recommended/provided, OR

B. The physician/physician assistant performs a face to face examination using real time audio and visual telemedicine technology that provides information at least equal to such information as would have been obtained by an in-person examination; OR

C. The physician/physician assistant personally knows the patient and the patient's general health status through an "ongoing" personal or professional relationship;

2. Appropriate follow-up be provided or arranged, when necessary, at medically necessary intervals.

B. For the purposes of this regulation, a proper physician/physician assistant-patient

relationship is deemed to exist in the following situations:

1. When treatment is provided in consultation with, or upon referral by, another physician/physician assistant who has an ongoing relationship with the patient, and who has agreed to supervise the patient's treatment, including follow up care and the use of any prescribed medications.

2. On-call or cross-coverage situations arranged by the patient's treating physician/physician assistant.

C. Exceptions – Recognizing a physician/physician assistant's duty to adhere to the applicable standard of care, the following situations are hereby excluded from the requirement of this regulation:

1. Emergency situations where the life or health of the patient is in danger or imminent danger.

2. Simply providing information of a generic nature not meant to be specific to an individual patient.

3. This Regulation does not apply to prescriptions written or medications issued for use in expedited heterosexual partner therapy for the sexually transmitted diseases of gonorrhea and/or chlamydia.

4. This Regulation does not apply to the administration of vaccines containing tetanus toxoid (e.g., DTaP, DTP, DT, Tdap, Td, or TT) or inactive influenza vaccines.

History: Adopted June 17, 1976; Amended March 13, 1997; Adopted December 3, 1998; Adopted April 6, 2001; Amended February 7, 2002; Amended April 3, 2008; Amended April 12, 2012; Amended December 14, 2015; Amended June 9, 2016, Effective September 6, 2016.