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WILLIAM H. TRICE III (1946-2014)

February 14, 2018

Ms. Donna K. Davis, Committee Staff
Bureau of Legislative Research
State Capitol Building, Room 315
Little Rock, AR 72201

RE: My Client: Arkansas State Medical Board
Proposed Amendment to Regulation 2.4

Dear Ms. Davis:

Enclosed are the following:

1. Two copies of the Mark-Up of the proposed Amendment to Regulation 2.4.
2. Two copies of the Proposed Regulation 2.4.
3. Two copies of the completed Questionnaire and Financial Impact Statement.
4. Two copies of a Summary.
5. Two copies of the Notice of Publication. .

I am also emailing all of this to you at donna@arkleg.state.ar.us, to the Governor's office, and the Secretary of State's office at register@sos.arkansas.gov and the State Library at statedocs@library.arkansas.gov.

Please schedule this for a hearing before the Committee of Legislative Council. Please notify me of the date and time. I wait to hear from you.

Respectfully,

Kevin M. O'Dwyer
Attorney for the Arkansas State Medical Board

KMO/jab

Enclosures

cc: Karen Whatley, Executive Director, Arkansas State Medical Board

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 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.

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 fifteen milligrams (15mg) 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 six (6) 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.

~~3. Check the prescriptive history of the patient on the Prescription Drug Monitoring Program at least every six (6) months;~~

~~4. Have a signed pain contract with the patient that states, at a minimum, the expectations of the prescriber for the behavior of the patient which may include:~~

~~a. A requirement for random urine drug screenings to help ensure that the patient is abiding by the requirements of the contract; and~~

~~b. A requirement for random pill counts to ensure compliance with the prescription.~~

~~ii. The requirements of this section shall not apply to a patient:~~

~~1. Whose pain medications are being prescribed for a malignant condition:~~

~~2. With a terminal condition;~~

~~3. Who is a resident of a licensed healthcare facility;~~

~~4. Who is enrolled in a hospice program; or~~

~~5. Who is in an inpatient or outpatient palliative care program.~~

ii. For prescribers licensed after December 31, 2015, 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.

~~This section shall apply to all prescribers licensed after December 31, 2015.~~

~~a. A prescriber who has been found by the Arkansas State Medical 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. The board, in its discretion, may remove this requirement after a period of time if the board deems removal of the requirement appropriate.~~

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:

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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.

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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.

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 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.

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 fifteen milligrams (15mg) 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 six (6) 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. For prescribers licensed after December 31, 2015, 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.

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QUESTIONNAIRE FOR FILING PROPOSED RULES AND REGULATIONS WITH THE ARKANSAS LEGISLATIVE COUNCIL

DEPARTMENT/AGENCY Arkansas State Medical Board

DIVISION

DIVISION DIRECTOR Karen Whatley, Executive Director

CONTACT PERSON Kevin M. O'Dwyer, Attorney

ADDRESS 211 S. Spring Street, Little Rock, AR 72201

PHONE NO. 501-372-4144 **FAX NO.** 501-372-7480 **E-MAIL** kodwyer@htolaw.com

NAME OF PRESENTER AT COMMITTEE MEETING Kevin M. O'Dwyer

PRESENTER E-MAIL kodwyer@htolaw.com

INSTRUCTIONS

A. Please make copies of this form for future use.
B. Please answer each question completely using layman terms. You may use additional sheets, if necessary.
C. If you have a method of indexing your rules, please give the proposed citation after "Short Title of this Rule" below.
D. Submit two (2) copies of this questionnaire and financial impact statement attached to the front of two (2) copies of the proposed rule and required documents. Mail or deliver to:

Donna K. Davis
Administrative Rules Review Section
Arkansas Legislative Council
Bureau of Legislative Research
One Capitol Mall, 5th Floor
Little Rock, AR 72201

****

1. What is the short title of this rule? Amendment to Regulation 2.4 to Define Excessive prescribing pursuant to the Center of Disease Control guidelines.

2. What is the subject of the proposed rule? The proposed Amendment is to better define excessive prescribing pursuant to the Center of Disease Control Guidelines.

3. Is this rule required to comply with a federal statute, rule, or regulation? Yes ☐ No X
   If yes, please provide the federal rule, regulation, and/or statute citation.

4. Was this rule filed under the emergency provisions of the Administrative Procedure Act?
   Yes ☐ No X
   If yes, what is the effective date of the emergency rule? N/A

   When does the emergency rule expire? N/A

   Will this emergency rule be promulgated under the permanent provisions of the Administrative Procedure Act?
   Yes ☐ No ☐

5. Is this a new rule? Yes ☐ No X
If yes, please provide a brief summary explaining the regulation. N/A

Does this repeal an existing rule? Yes ☐ No X
If yes, a copy of the repealed rule is to be included with your completed questionnaire. If it is being replaced with a new rule, please provide a summary of the rule giving an explanation of what the rule does. _____

Is this an amendment to an existing rule? Yes X No ☐
If yes, please attach a mark-up showing the changes in the existing rule and a summary of the substantive changes. **Note: The summary should explain what the amendment does, and the mark-up copy should be clearly labeled "mark-up."**

6. Cite the state law that grants the authority for this proposed rule? If codified, please give the Arkansas Code citation. Act 820 of 2017

7. What is the purpose of this proposed rule? Why is it necessary? The proposed Amendment is to better define excessive prescribing pursuant to the Center of Disease Control Guidelines.

8. Please provide the address where this rule is publicly accessible in electronic form via the Internet as required by Arkansas Code § 25-19-108(b). www.armedicalboard.org

9. Will a public hearing be held on this proposed rule? Yes X No ☐
If yes, please complete the following:

Date: April 5, 2018
Time: 8.30 a.m.
Place: 1401 W. Capitol Ave. Suite 340, Little Rock AR 72201

10. When does the public comment period expire for permanent promulgation? (Must provide a date.)
April 4, 2018

11. What is the proposed effective date of this proposed rule? (Must provide a date.)
April 6, 2018

12. Please provide a copy of the notice required under Ark. Code Ann. § 25-15-204(a), and proof of the publication of said notice. Please see attached. Proof of publication will be provided as soon as it is received.

13. Please provide proof of filing the rule with the Secretary of State and the Arkansas State Library as required pursuant to Ark. Code Ann. § 25-15-204(e). Please see attached email.

14. Please give the names of persons, groups, or organizations that you expect to comment on these rules? Please provide their position (for or against) if known. Arkansas Medical Society; Arkansas Osteopathic Association.

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY

DEPARTMENT Arkansas State Medical Board

DIVISION

PERSON COMPLETING THIS STATEMENT Kevin M. O'Dwyer, Attorney

TELEPHONE 501-372-4144 **FAX** 501-372-7480 **EMAIL:** kodwyer@htolaw.com

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 Amendment to Regulation 2.4 to Define Excessive prescribing pursuant to the Center of Disease Control guidelines

1. Does this proposed, amended, or repealed rule have a financial impact? Yes ☐ No X

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 X 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 X 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;
   N/A

   (b) The reason for adoption of the more costly rule;
   N/A

   (c) Whether the more costly rule is based on the interests of public health, safety, or welfare, and if so, please explain; and;
   N/A

   (d) Whether the reason is within the scope of the agency's statutory authority; and if so, please explain.
   N/A

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	N/A	General Revenue	N/A
Federal Funds		Federal Funds	
Cash Funds		Cash Funds	
Special Revenue		Special Revenue	
Other (Identify)		Other (Identify)	

Total _____ Total _____

(b) What is the additional cost of the state rule?

Current Fiscal Year		**Next Fiscal Year**	
General Revenue	N/A	General Revenue	N/A
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Total		Total	

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
$ N/A

Next Fiscal Year
$ N/A

---

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
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Next Fiscal Year
$ N/A

---

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 X

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.

QUESTIONNAIRE FOR FILING PROPOSED RULES AND REGULATIONS WITH THE ARKANSAS LEGISLATIVE COUNCIL

DEPARTMENT/AGENCY Arkansas State Medical Board

DIVISION

DIVISION DIRECTOR Karen Whatley, Executive Director

CONTACT PERSON Kevin M. O'Dwyer, Attorney

ADDRESS 211 S. Spring Street, Little Rock, AR 72201

PHONE NO. 501-372-4144 **FAX NO.** 501-372-7480 **E-MAIL** kodwyer@htolaw.com

NAME OF PRESENTER AT COMMITTEE MEETING Kevin M. O'Dwyer

PRESENTER E-MAIL kodwyer@htolaw.com

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Administrative Rules Review Section
Arkansas Legislative Council
Bureau of Legislative Research
One Capitol Mall, 5th Floor
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2. What is the subject of the proposed rule? The proposed Amendment is to better define excessive prescribing pursuant to the Center of Disease Control Guidelines.

3. Is this rule required to comply with a federal statute, rule, or regulation? Yes ☐ No X
   If yes, please provide the federal rule, regulation, and/or statute citation. _____

4. Was this rule filed under the emergency provisions of the Administrative Procedure Act?
   Yes ☐ No X
   If yes, what is the effective date of the emergency rule? N/A
   When does the emergency rule expire? N/A
   Will this emergency rule be promulgated under the permanent provisions of the Administrative Procedure Act?
   Yes ☐ No ☐

5. Is this a new rule? Yes ☐ No X
If yes, please provide a brief summary explaining the regulation. N/A

Does this repeal an existing rule? Yes ☐ No X
If yes, a copy of the repealed rule is to be included with your completed questionnaire. If it is being replaced with a new rule, please provide a summary of the rule giving an explanation of what the rule does. _____

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9. Will a public hearing be held on this proposed rule? Yes X No ☐
If yes, please complete the following:

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13. Please provide proof of filing the rule with the Secretary of State and the Arkansas State Library as required pursuant to Ark. Code Ann. § 25-15-204(e). Please see attached email.

14. Please give the names of persons, groups, or organizations that you expect to comment on these rules? Please provide their position (for or against) if known. Arkansas Medical Society; Arkansas Osteopathic Association.

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY

DEPARTMENT Arkansas State Medical Board

DIVISION

PERSON COMPLETING THIS STATEMENT Kevin M. O'Dwyer, Attorney

TELEPHONE 501-372-4144 **FAX** 501-372-7480 **EMAIL:** kodwyer@htolaw.com

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 Amendment to Regulation 2.4 to Define Excessive prescribing pursuant to the Center of Disease Control guidelines

1. Does this proposed, amended, or repealed rule have a financial impact? Yes ☐ No X

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 X 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 X 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;
   N/A

   (b) The reason for adoption of the more costly rule;
   N/A

   (c) Whether the more costly rule is based on the interests of public health, safety, or welfare, and if so, please explain; and;
   N/A

   (d) Whether the reason is within the scope of the agency's statutory authority; and if so, please explain.
   N/A

4. If the purpose of this rule is to implement a federal rule or regulation, please state the following:

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Total _____ Total _____

(b) What is the additional cost of the state rule?

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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 X

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:

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(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:
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(b) describes how the benefits of the rule meet the relevant statutory objectives and justify the rule's costs;

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(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;

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AMENDMENT TO REGULATION 2.4

SUMMARY

Amendment to Regulation 2.4 to Define Excessive prescribing pursuant to the Center of Disease Control guidelines.

AMENDMENT TO REGULATION 2.4

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