APA-3
10/91

CERTIFICATION OF ADMINISTRATIVE RULES
FILED WITH THE LEGISLATIVE REFERENCE SERVICE
JERRY L. BASSETT, DIRECTOR

(Pursuant to Code of Alabama 1975, §41-22-6, as amended).

I certify that the attached is a correct copy of rules as promulgated and adopted on the 18th day of January, 2017, and filed with the agency secretary on the 18th day of January, 2017.

AGENCY NAME: Alabama State Board of Medical Examiners

_____ Amendment _____X_____ New _____ Repeal

Rule No. 540-X-4-.09

Rule Title: Risk and Abuse Mitigation Strategies by Prescribing Physicians

ACTION TAKEN: The rule was adopted with changes from the proposal due to comments received. See attached Public Notice.

NOTICE OF INTENDED ACTION PUBLISHED IN VOLUME XXXIV, ISSUE NO. 12, AAM, DATED SEPTEMBER 30, 2016.

Statutory Rulemaking Authority:

(Date Filed)
(For LRS Use Only)

REC'D & FILED

JAN 23 2017

LEGISLATIVE REF SERVICE

Certifying Officer or his or her Deputy

PUBLIC NOTICE

On January 18, 2017, the Alabama Board of Medical Examiners approved for final adoption, proposed rule 540-X-4-.09, Risk and Abuse Mitigation Strategies ("RMS") by Prescribing Physicians. This rule will become effective on March 9, 2017. In compliance with Ala. Code §41-22-5, the Alabama Board of Medical Examiners ("the Board") states the following:

I. Mandated use of RMS; use of controlled substances for the treatment of conditions other than pain.

Comments were received urging exemptions from the RMS for the use of controlled substances for conditions other than pain, such as psychiatric conditions. All controlled substances carry some risk of abuse or misuse, so RMS should be used as one element of a physician's "best practice" when prescribing controlled substances for any reason; however, the rule requires use of these strategies only when prescribing controlled substances for the treatment of pain.

Concerning the use of RMS in the treatment of cancer patients with controlled substances, the Board is of the opinion that the best practice when prescribing controlled substances for the treatment of acute, chronic, or cancer pain includes the use of medically appropriate RMS, which will vary from patient to patient at the discretion of the physician.

II. Morphine milligram equivalents (MMEs). The Board received comments expressing concern with the use of MMEs in any part of medical decision making, and concern about differences in MME calculators. Because the risk of adverse events occurring in patients who take controlled substances for pain increases as dosages increase, calculation of the MME daily standard, as encouraged by the Centers for Disease Control and Prevention, is necessary as a metric for prescribers to use. Recognizing that there are slight differences in MME calculators but also recognizing that some MME calculators are easier to use or more convenient to use, the Board does not recommend any one calculator. The Board will provide at its web site links to nationally recognized calculators.

The Board received comments which were specific to drugs such as tapentadol for which the FDA-approved daily dosage threshold should be followed rather than an MME based standard, because of the resulting clinically inadequate doses when the MME based standard is used. The Board has not placed limits on dosage amounts but is requiring certain RMS and PDMP checks for dosages over certain MMEs. These requirements are not overly burdensome and remain necessary for patient and public safety.

III. Burden of querying the Prescription Drug Monitoring Databank (PDMP). Comments were received 1) opposing requirements to query the PDMP when prescribing controlled substances "for the treatment of chronic pain"; 2) opposing the exemption from reviewing the PDMP when the controlled substance is prescribed for acute pain and does not exceed three days or is part of an initial treatment for a surgical procedure and does not exceed 30 days; 3) opposing the requirement to review the PDMP prior to initiating therapy with controlled substances for the treatment of chronic pain; and 4) urging an exemption from the PDMP requirements for the treatment of cancer pain.

Response:

1) This provision has been removed.

2) This provision has been removed.

3) This provision has been removed. The PDMP requirement is now based upon MME.

4) The rule provides an exemption for the treatment of active, malignant pain.

IV. **Continuing medical education (CME)**. The Board received comments opposing mandatory CME, opposing a different number of CME credits than those required for Qualified Alabama Controlled Substances Certificate holders, opposing the requirement for all Alabama Controlled Substances Certificate (ACSC) holders to obtain CME, and supporting mandatory CME but urging its earlier completion. It is in the interest of the public health and safety to require every physician holding an ACSC to obtain a minimum of two CME credits every two years as part of the licensee's yearly CME requirement. The burden of this requirement is minimal, when considering the risk of harm to patients by an uninformed physician and the requirement being incorporated into the existing twenty-five (25) hour yearly CME requirement.

V. **Broadness of rule**. Comments were received urging the Board to refine the rule by class of drug. Commenters stated that the rule is too broad to include all Schedules, that the rule should reflect the differences between/within drugs in the opioid class, and that the rule should only pertain to the prescribing of opioids. Physicians prescribing any controlled substances should be subject to the requirements in the rule. Non-opioid controlled substances are also diverted, abused, and misused. Additionally, the interaction of controlled substances with other medications or substances consumed by the patient can be harmful to the patient.

VI. **Anesthesiologists who do not write retail prescriptions should be excluded**. The RMS requirement only applies to the prescribing of controlled substances for the treatment of pain, and the PDMP requirement only applies to controlled substance prescriptions. However, the CME requirement does apply to all ACSC holders.

540-X-4-.09 Risk and Abuse Mitigation Strategies by Prescribing Physicians

(1) The Board recognizes that the best available research demonstrates that the risk of adverse events occurring in patients who use controlled substances to treat pain increases as dosage increases. The Board adopts the "Morphine Milligram Equivalency" ("MME") daily standard as set out by the Centers for Disease Control and Prevention ("CDC") for calculating the morphine equivalence of opioid dosages.

(2) It is the opinion of the Board that the best practice when prescribing controlled substances for the treatment of pain shall include medically appropriate risk and abuse mitigation strategies, which will vary from patient to patient. Examples of risk and abuse mitigation strategies include, but are not limited to:

(a) Pill counts;

(b) Urine drug screening;

(c) PDMP checks;

(d) Consideration of abuse-deterrent medications;

(e) Monitoring the patient for aberrant behavior;

(f) Providing a patient with opiate risk education prior to prescribing controlled substances; and

(g) Using validated risk-assessment tools, examples of which shall be maintained by the Board.

(3) For the purpose of preventing controlled substance diversion, abuse, misuse, addiction, and doctor-shopping, the Board sets forth the following requirements for the use of Alabama's Prescription Drug Monitoring Program (PDMP):

(a) For controlled substance prescriptions totaling 30 MME or less per day,

physicians are expected to use the PDMP in a manner consistent with good clinical practice.

(b) When prescribing a patient controlled substances of more than 30 MME per day, physicians shall review that patient's prescribing history through the PDMP at least two (2) times per year, and each physician is responsible for documenting the use of risk and abuse mitigation strategies in the patient's medical record.

(c) Physicians shall query the PDMP to review a patient's prescribing history every time a prescription for more than 90 MME per day is written, on the same day the prescription is written.

(4) Exemptions: The Board's PDMP requirements do not apply to physicians writing controlled substance prescriptions for:

(a) Nursing home patients;

(b) Hospice patients, where the prescription indicates hospice on the physical prescription;

(c) When treating a patient for active, malignant pain; or

(d) Intra-operative patient care.

(5) Due to the heightened risk of adverse events associated with the concurrent use of opioids and benzodiazepines, physicians should reconsider a patient's existing benzodiazepine prescriptions or decline to add one when prescribing an opioid and consider alternative forms of treatment.

(6) Effective January 1, 2018, each holder of an Alabama Controlled Substances Certificate (ACSC) shall acquire two (2) hours of *AMA PRA Category 1™* continuing medical education (CME) in controlled substance prescribing every two (2)

years as part of the licensee's yearly CME requirement. The controlled substance prescribing education shall include instruction on controlled substance prescribing practices, recognizing signs of the abuse or misuse of controlled substances, or controlled substance prescribing for chronic pain management.

(7) The Board recognizes that all controlled substances, including but not limited to, opiates, benzodiazepines, stimulants, anticonvulsants, and sedative hypnotics, have a risk of addiction, misuse, and diversion. Physicians are expected to use risk and abuse mitigation strategies when prescribing any controlled substance. Additional care should be used by the physician when prescribing a patient medication from multiple controlled substance drug classes.

(8) A violation of this rule is grounds for the suspension, restriction, or revocation of a physician's Alabama Controlled Substances Certificate or license to practice medicine.

Author: Alabama Board of Medical Examiners
Statutory Authority: Ala. Code §§ 34-24-53, 34-24-336, 20-2-54.1, and 20-2-214(2)
History: Approved for Publication: September 21, 2016. Adopted: January 18, 2017. Effective Date: March 9, 2017.