

APA-1
Revised 4/2018

TRANSMITTAL SHEET FOR
NOTICE OF INTENDED ACTION

Control 540 Department or Agency Alabama State Board of Medical Examiners
Rule No. 540-X-4-09
Rule Title: Risk and Abuse Mitigation Strategies by Prescribing Physicians

New Amend Repeal Adopt by Reference

Would the absence of the proposed rule significantly harm or endanger the public health, welfare, or safety? NO

Is there a reasonable relationship between the state's police power and the protection of the public health, safety, or welfare? YES

Is there another, less restrictive method of regulation available that could adequately protect the public? NO

Does the proposed rule have the effect of directly or indirectly increasing the costs of any goods or services involved and, if so, to what degree? NO

Is the increase in cost, if any, more harmful to the public than the harm that might result from the absence of the proposed rule? NO

Are all facets of the rulemaking process designed solely for the purpose of, and so they have, as their primary effect, the protection of the public? YES

Does the proposed action relate to or affect in any manner any litigation which the agency is a party to concerning the subject matter of the proposed rule? NO

Does the proposed rule have an economic impact? NO

If the proposed rule has an economic impact, the proposed rule is required to be accompanied by a fiscal note prepared in accordance with subsection (f) of Section 41-22-23, Code of Alabama 1975.

Certification of Authorized Official

I certify that the attached proposed rule has been proposed in full compliance with the requirements of Chapter 22, Title 41, Code of Alabama 1975, and that it conforms to all applicable filing requirements of the Administrative Procedure Division of the Legislative Services Agency.

Signature of certifying officer *Angela J. Dorman* REC'D & FILED
Date: 5/22/18

**ALABAMA STATE BOARD
OF MEDICAL EXAMINERS**

NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama State Board of Medical Examiners

RULE NO. & TITLE: 540-X- 4-.09, Risk and Abuse Mitigation Strategies by Prescribing Physicians

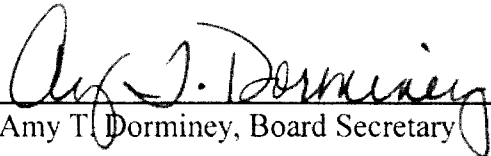
INTENDED ACTION: To amend the rule

SUBSTANCE OF PROPOSED ACTION: To add an example of risk and abuse mitigation strategies concerning naloxone

TIME, PLACE, MANNER OF PRESENTING VIEWS: All interested persons may submit data, views, or arguments concerning the proposed new rule(s) and regulation(s) in writing to: Carla H. Kruger, Office of the General Counsel, Alabama State Board of Medical Examiners, Post Office Box 946, Montgomery, Alabama 36101-0946, by mail or in person between the hours of 8:30 a.m. and 4:30 p.m., Monday through Friday, until and including July 5, 2018. Persons wishing to obtain copies of the text of this rule and submit data, views, or comments or arguments orally should contact Carla H. Kruger, by telephone (334-242-4116) during said period in order to set up an appointment for a hearing respecting such oral data, views, or arguments. Additionally, the intended action is available at the Board's web site, www.albme.org.

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE: July 5, 2018

CONTACT PERSON AT AGENCY: Carla H. Kruger



Amy T. Dorminey, Board Secretary

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; and

(h) Physicians should consider co-prescribing naloxone in patients deemed to be appropriate by the clinical determination of the treating physician.

(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) credits 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. Amended/Approved: May 16, 2018.