

See page 2 for instructions for submitting comments

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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? YES

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

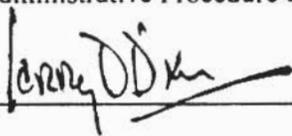
Are all facets of the rulemaking process designed solely for the purpose of, and so they have, as their primary effect, the protection of the public? YES

Does the proposed 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 Reference Service.

Signature of certifying officer  REC'D & FILED
SEP 21 2016

Date: September 21, 2016

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**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

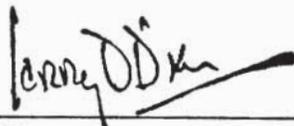
INTENDED ACTION: To add a new rule

SUBSTANCE OF PROPOSED ACTION: To add a new rule concerning the use of risk and abuse mitigation strategies by physicians who prescribe controlled substances.

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: Patricia E. Shaner, Office of General Counsel, Alabama State Board of Medical Examiners, Post Office Box 946, 848 Washington Avenue (36104), 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 Friday, November 4, 2016. Persons wishing to obtain copies of the text of this rule should contact Patricia E. Shaner, Office of General Counsel, (334-242-4116), PO Box 946, 848 Washington Avenue (36104), Montgomery, Alabama 36101-0946. A copy is also available at the Board's web site, www.albme.org. A public hearing to receive oral comments concerning the proposed Rule is scheduled on Thursday, October 20, at 2:00 p.m., at the offices of the Board of Medical Examiners, 848 Washington Avenue, Montgomery AL 36104.

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE: Friday, November 4, 2016

CONTACT PERSON AT AGENCY: Patricia E. Shaner



Larry D. Dixon, Executive Director

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

(1) Every physician licensed to practice in Alabama who distributes, prescribes, administers, or dispenses a Schedule II-V controlled substance to a patient shall incorporate risk and abuse mitigation strategies into the patient's treatment plan for the prevention of controlled substance diversion, abuse, misuse, addiction, and doctor-shopping.

(2) "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) Each physician is responsible for documenting the use of risk and abuse mitigation strategies in the patient's medical record.

(4) 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 and

recommends:

(a) That physicians use extra precaution, including using risk and abuse mitigation strategies, when a patient's opioid dosage exceeds 50 MME per day; and

(b) That patients receiving opioid dosages exceeding 90 MME per day be considered by physicians to be at a higher risk for abuse, adverse events, or both, and that the physician's risk and abuse mitigation strategy include active monitoring of that patient's prescription history through the PDMP.

(5) Each physician who prescribes controlled substances for the treatment of chronic pain shall review the PDMP to assess the patient's prescription history:

(a) Prior to initiating therapy;

(b) Prior to assuming or continuing the care of a patient who has previously been prescribed controlled substances; and

(c) At periodic intervals thereafter.

(d) This requirement shall not apply if one of the following conditions is met:

1. The controlled substance is prescribed or dispensed to a patient currently receiving hospice care; or

2. The controlled substance is prescribed or dispensed to a patient currently receiving care in or from a nursing home.

(6) Each physician who prescribes controlled substances for the treatment of acute pain shall review the PDMP to assess the patient's prescription history. This requirement shall not apply if one of the following conditions is met:

(a) The controlled substance is prescribed or dispensed to a patient for a treatment period not to exceed three (3) days and such prescription is non-renewable

without a PDMP check; or

(b) The controlled substance is prescribed or dispensed to a patient as part of an initial treatment for a surgical procedure and treatment does not exceed thirty (30) days.

(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, abuse, 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) Any physician that applies for or renews his or her Alabama Controlled Substances Certificate shall obtain a minimum of two (2) hours of Continuing Medical Education (CME) in prescribing controlled substances every three (3) years.

(9) A violation of this rule is grounds for the suspension, revocation, or restriction 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.