

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-.08  
Rule Title: Requirements for the Use of Controlled Substances for the Treatment of Pain

       New        Amend   X   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      

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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.

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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 *William J. Pelt*

Date: 5-15-2023 MAY 15 2023

LEGISLATIVE SVC AGENCY

ALABAMA STATE BOARD OF MEDICAL EXAMINERS

**NOTICE OF INTENDED ACTION**

**AGENCY NAME:** Alabama Board of Medical Examiners

**RULE NO. & TITLE:** 540-X-4-.08, Requirements for the Use of Controlled Substances for the Treatment of Pain


**INTENDED ACTION:** Repeal the rule

**SUBSTANCE OF PROPOSED ACTION:** The proposal is to repeal the rule as unnecessary.

**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 Kruger, Office of the General Counsel, Alabama State Board of Medical Examiners, Post Office Box 946, Montgomery, Alabama 36101-0946, by mail or email (bme@albme.gov), until and including July 5, 2023. Persons wishing to submit data, views, or comments in person should contact Carla Kruger by telephone (334-242-4116) during the comment period. Copies of proposed rules may be obtained at the Board's website, www.albme.gov.

**FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE:** July 5, 2023

**CONTACT PERSON AT AGENCY:** Carla Kruger

  
(Signature of officer authorized  
to promulgate and adopt  
rules or his or her deputy)

## REPEAL

### 540-X-4-.08 Requirements for the Use of Controlled Substances for the Treatment of Pain.

#### (1) Preamble.

(a) The Board recognizes that principles of quality medical practice dictate that the people of the State of Alabama have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. The Board encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing controlled substances.

(b) Inadequate pain control may result from physicians' lack of knowledge about pain management or an inadequate understanding of tolerance, dependence or addiction. Fears of investigation or sanction by federal, state and local regulatory agencies may also result in inappropriate or inadequate treatment of chronic pain patients. Accordingly, these requirements have been developed to clarify the Board's position on pain control, specifically as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

(c) The Board recognizes that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. The medical management of pain should be based on current knowledge and research and should include the use of both pharmacologic and non-pharmacologic modalities. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction.

(d) The Board is obligated under the laws of the State of Alabama to protect the public health and safety. The Board recognizes that inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Physicians should be diligent in preventing the diversion of drugs for illegitimate purposes.

(e) PHYSICIANS SHOULD NOT FEAR DISCIPLINARY ACTION FROM THE BOARD OR OTHER STATE REGULATORY OR ENFORCEMENT AGENCY FOR PRESCRIBING, DISPENSING OR ADMINISTERING CONTROLLED SUBSTANCES, INCLUDING OPIOID ANALGESICS, FOR A LEGITIMATE MEDICAL PURPOSE AND IN THE USUAL COURSE OF PROFESSIONAL PRACTICE. THE BOARD WILL CONSIDER PRESCRIBING, ORDERING, ADMINISTERING OR DISPENSING CONTROLLED SUBSTANCES FOR PAIN TO BE FOR A LEGITIMATE MEDICAL PURPOSE IF BASED ON ACCEPTED MEDICAL KNOWLEDGE OF THE TREATMENT OF PAIN. ALL SUCH PRESCRIBING MUST BE BASED ON CLEAR

DOCUMENTATION AND IN COMPLIANCE WITH APPLICABLE STATE OR FEDERAL LAW.

(f) The Board will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation. The goal is to reduce pain and/or improve patients' function.

(g) Physicians are referred to the Federation of State Medical Boards' Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain, July 2013, as amended from time to time, and the Drug Enforcement Administration Office of Diversion Control manual, Narcotic Treatment Programs Best Practice Guidelines, as amended from time to time.

(2) Requirements. The Board requires the following when a physician evaluates the use of controlled substances for pain control:

(a) Evaluation of the Patient. A medical history and physical examination must be conducted and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record should also document the presence of one or more recognized medical indications for the use of a controlled substance.

(b) **Treatment Plan.** The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of the patient. Alternative non-opioid treatment modalities or a rehabilitation program may be necessary and should be considered.

(c) **Informed Consent and Agreement for Treatment.** The physician shall discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is incompetent. Written agreements between physician and patient outlining patient responsibilities should be utilized for all patients with chronic pain, and should include:

1. Drug screening with appropriate confirmation;
2. A prescription refill policy; and
3. Reasons for which drug therapy may be discontinued (e.g., violation of agreement).
4. The patient should receive prescriptions from one physician and one pharmacy where possible.

(d) **Periodic Review.** At reasonable intervals based on the individual circumstances of the patient, the physician shall review the course of treatment and any new information about the etiology of the pain. The physician shall monitor patient compliance in medication usage and related treatment plans.

(e) Consultation. The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a co-morbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

(f) Medical Records. The physician shall keep accurate and complete records to include:

1. the medical history and physical examination;
2. diagnostic, therapeutic and laboratory results;
3. evaluations and consultations;
4. treatment objectives;
5. discussion of risks and benefits;
6. treatments;
7. medications (including date, type, dosage and quantity prescribed);
8. instructions and agreements; and
9. periodic reviews.

These records shall remain current, be maintained in an accessible manner, and be readily available for review.

(g) Compliance with Controlled Substances Laws and Regulations. To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and must comply with applicable federal and state regulations.

(3) Definitions. For the purposes of this rule, the following terms are defined as follows:

(a) Acute Pain. The normal, predicted, time-limited physiological response to nociceptive stimuli such as injury, trauma or illness.

(b) Addiction. Addiction is a neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction.

(c) Chronic Pain. A state in which pain persists beyond the usual course of an acute disease or healing of an injury (e.g., more than three months), and which may or may not be associated with an acute or chronic pathological process that causes continuous or intermittent pain over a period of months or years.

(d) Substance Abuse. Substance abuse is a maladaptive pattern of substance use manifested by recurrent and significant adverse consequences related to the repeated use of substances.

(e) Tolerance. Tolerance is the need for greatly increased amounts of a substance to achieve intoxication (or the desired effect) or a markedly diminished effect with continued use of the same amount of the substance.

**Author:** Alabama Board of Medical Examiners.



**Statutory Authority:** Code of Alabama 1975, §34-24-53

**History:** Approved for Publication: December 21, 1994. Comment Period Ending: March 7, 1995. Approved/Adopted: March 15, 1995. Effective Date: April 21, 1995. Amended/Approved for Publication: September 14, 1999. Adopted: December 15, 1999. Effective Date: January 24, 2000. Amended/Approved for Publication: September 18, 2013. Effective Date: December 19, 2013.