APA-1
6/93

TRANSMITTAL SHEET FOR NOTICE OF INTENDED ACTION

Control 540 Department or Agency Alabama State Board of Medical Examiners
Rule No. 540-X-4-.07
Rule Title: Guidelines for the Use of Controlled Substances for the Treatment of Pain
_____ New __X__ 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

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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 Reference Service.

Signature of certifying officer _____

Date: Sept. 19, 2013

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6/93

ALABAMA STATE BOARD
OF MEDICAL EXAMINERS

NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama State Board of Medical Examiners

RULE NO. & TITLE: 540-X-4-.07, Guidelines for the Use of Controlled Substances for the Treatment of Pain

\INTENDED ACTION: To amend the rule

SUBSTANCE OF PROPOSED ACTION: To amend the guidelines to create more accountability on the part of the licensee

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, 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 Monday, November 4, 2013. Persons wishing to obtain copies of the text of this rule and submit data, views, or comments or arguments orally should contact Patricia E. Shaner, 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.

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE: November 4, 2013

CONTACT PERSON AT AGENCY: Patricia E. Shaner, Esq.

Larry D. Dixon, Executive Director

RULES OF THE ALABAMA STATE BOARD OF MEDICAL EXAMINERS

540-X-4-.07 ~~Guidelines~~ 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 ~~guidelines~~ 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. ~~Physicians are referred to the *U.S. Agency for Health Care and Research Clinical Practice Guidelines* for a sound approach to the management of acute pain (Acute Pain Management Guideline Panel. Acute Pain Management: Operative or Medical Procedures and Trauma. *Clinical Practice Guideline.* AHCPR Publication No. 92-0032. Rockville, Md. Agency for Health~~

~~Care Policy and Research. U.S. Department of Health and Human Resources, Public Health Service. February 1992) and cancer-related pain (Jacox A, Carr DB, Payne R, et al. Management of Cancer Pain. *Clinical Practice Guideline No. 9.* AHCPR Publication No. 94-0592. Rockville, Md. Agency for Health Care Policy and Research. U.S. Department of Health and Human Resources, Public Health Service. March 1994).~~ 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. ~~Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity and duration of the pain.~~ 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 ~~SCIENTIFIC~~ MEDICAL KNOWLEDGE OF THE TREATMENT OF PAIN ~~OR IF BASED ON SOUND CLINICAL GROUNDS~~. ALL SUCH PRESCRIBING MUST BE BASED ON CLEAR DOCUMENTATION ~~OF UNRELIEVED PAIN~~ AND IN COMPLIANCE WITH APPLICABLE STATE OR FEDERAL LAW.

~~(f) Each case of prescribing for pain will be evaluated on an individual basis. The Board will not take disciplinary action against a physician for failing to adhere strictly to the provisions of these guidelines, if good cause is shown for such deviation.~~

~~The physician's conduct will be evaluated to a great extent by the treatment outcome, taking into account whether the drug used is medically and/or pharmacologically recognized to be appropriate for the diagnosis, the patient's individual needs – including any improvement in functioning – and recognizing that some types of pain cannot be completely relieved.~~

(~~g~~f) The Board will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation~~, rather than on the quantity and chronicity of prescribing~~. The goal is to ~~control the patient's~~ reduce pain and/or improve patients' function. ~~for its duration while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors. The following guidelines are not intended to define complete or best practice, but rather to communicate what the Board considers to be within the boundaries of professional practice.~~

(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) ~~Guidelines~~Requirements. The Board requires the following ~~has adopted the following guidelines~~ when ~~evaluating~~ a physician evaluates the use of controlled substances for pain control:

(a) Evaluation of the Patient. A ~~complete~~ 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 ~~also~~ 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 ~~physical~~

~~and psychosocial~~ 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 ~~each~~the patient. ~~Other~~Alternative non-opioid treatment modalities or a rehabilitation program may be necessary and should be considered. ~~depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.~~

(c) Informed Consent and Agreement for Treatment. The physician ~~should~~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. ~~The patient should receive prescriptions from one physician and one pharmacy where possible. If the patient is determined to be at high risk for medication abuse or to have a history of substance abuse, the physician may employ the use of a w~~Written agreements between physician and patient outlining patient responsibilities should be utilized for all patients with chronic pain, and should include~~ing~~:

1. ~~urine/serum medication levels~~ Drug screening with appropriate confirmation~~when requested~~;

2. ~~number and frequency of all prescription refills~~ A prescription refill policy; and

3. ~~r~~Reasons for which drug therapy may be discontinued (~~i.e.~~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 ~~should~~shall review the course of treatment and any new information about the etiology of the pain. ~~Continuation or modification of therapy should depend on the physician's evaluation of progress toward stated treatment objectives, such as improvement in patient's pain intensity and improved physical and/or psychosocial function, *i.e.*, ability to work, need of health care resources, activities of daily living and quality of social life. If treatment goals are not~~

~~being achieved, despite medication adjustments, the physician should reevaluate the appropriateness of continued treatment.~~ The physician ~~should~~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 ~~should~~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.

Records ~~should~~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. ~~Physicians are referred to *the Physicians Manual of the U.S. Drug Enforcement Administration* and applicable state regulations for rules governing controlled substances.~~

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

(a) Acute Pain. ~~Acute pain is t~~The normal, predicted, ~~physiological~~time-limited physiological response to nociceptive stimuli ~~an adverse chemical, thermal or mechanical stimulus and is associated with~~ such as ~~surgery~~injury, trauma ~~and acute~~or illness. ~~It is generally time-limited and is responsive to opioid therapy, among other therapies.~~

(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. ~~Addiction may also be referred to by terms such as "drug dependence" and "psychological dependence."~~ Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction.

~~(c) Analgesic Tolerance. Analgesic tolerance is the need to increase the dose of opioid to achieve the same level of analgesia. Analgesic tolerance may or may not be evident during opioid treatment and does not equate with addiction.~~

(~~d~~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.

~~(e) Pain. An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.~~

~~(f) Physical Dependence. Physical dependence on a controlled substance is a physiologic state of neuro-adaptation which is characterized by the emergence of a withdrawal syndrome if drug use is stopped or decreased abruptly, or if an antagonist is administered. Physical dependence is an expected result of opioid use. Physical dependence, by itself, does not equate with addiction.~~

~~(g) Pseudoaddiction. Pattern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction.~~

(~~h~~d) Substance Abuse. Substance abuse is ~~the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed~~ a maladaptive pattern of substance use manifested by recurrent and significant adverse consequences related to the repeated use of substances.

(ie) Tolerance. Tolerance is ~~a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect, or a reduced effect is observed with a constant dose~~ 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.

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