TRANSMITTAL SHEET FOR NOTICE OF INTENDED ACTION

| Control 540 Departm | ent or Age | ncy Alabama | State Board of Medic | cal Examiners |
|--|--------------|-----------------|-----------------------|--|
| Rule No. <u>540-X-1902</u> Rule Title: <u>Definitions</u> | | | | |
| 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 had directly or indirectly incre of any goods or services it to what degree? | easing the | costs | | NO |
| Is the increase in cost, if a to the public than the harm from the absence of the p | m that migl | nt result | | NO |
| Are all facets of the rulendesigned solely for the puthey have, as their primar protection of the public? | irpose of, a | nd so | | YES |
| ******* | ****** | ***** | ****** | ********** |
| Does the proposed rule have an economic impact? | | | | NO |
| If the proposed rule has a required to be accompani subsection (f) of Section | ed by a fisc | cal note prepar | red in accordance wi | th |
| ************************************** | | ***** | ******* | ********** |
| I certify that the attached compliance with the requ all applicable filing requi Service. | irements o | f Chapter 22, | Title 41, Code of Ala | abama 1975, and that it conforms to ision of the Legislative Reference |
| Signature of certifying of | ficer | 14 | ייעעויי | |
| Date: March 20, 2014 | | | <u>P</u> | THE STREET S |

ALABAMA STATE BOARD OF MEDICAL EXAMINERS

NOTICE OF INTENDED ACTION

AGENCY NAME:

Alabama State Board of Medical Examiners

RULE NO. & TITLE:

540-X-19-.02, Definitions

INTENDED ACTION:

To amend the rule

<u>SUBSTANCE OF PROPOSED ACTION</u>: To amend the definitions of "Dispense" and "Pain Management Services" to provide clarity and to amend the conditions under which a physician is required to register with the Board as a pain management services physician.

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, May 5, 2014. 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. The rule amendment will also be available at the Board's web site, www.albme.org.

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE: May 5, 2014

CONTACT PERSON AT AGENCY: Patricia E. Shaner

Larry D. Dixon, Executive Director

540-X-19-.02 Definitions.

The following definitions shall apply to the rules in this chapter:

- (1) ACUTE PAIN. The normal, predicted, time-limited physiological response to nociceptive stimuli such as injury, trauma or illness.
- (2) APPLICANT. A person who has submitted or who is in the process of submitting a registration under this article.
 - (3) BOARD. The Alabama Board of Medical Examiners.
- (4) CHRONIC NON-MALIGNANT PAIN. Chronic pain that is not associated with active cancer and does not occur at the end of life.
- (5) 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.
- (6) CONTROLLED SUBSTANCE. A drug, substance, or immediate precursor identified, defined, or listed in §§ 20-2-20 to 20-2-32, Code of Alabama 1975, as amended, inclusive.
- any controlled substance, except prepackaged samples and/or starter packs, where such controlled substances are purchased by the physician or osteopath for resale to a patient whether or not a separate charge is made for the controlled substance.

 Prepackaged samples and starter packs shall mean those controlled substances which are packaged and labeled by the manufacturer in individual or small dosage units and which are intended to be distributed to patients for consumption or administration within

a limited period of time. Controlled substances which are consumed by or which are administered to patients while being treated in the physician's office, clinic, hospital or other facility are not considered to be dispensed for the purposes of this rule. Dispensing occurs when a physician or osteopath provides, gives or distributes controlled substances for consumption or administration by patients off the premises of the clinic, hospital or other facility where the physician or osteopath practices, without respect to whether such controlled substances are purchased by an individual physician or osteopath, a professional association or professional corporation, a for-profit or not-for-profit corporation, a hospital, clinic or other medical facility. For purposes of this Chapter, dispensing shall not apply to the dispensing of controlled substances to patients treated in any hospital emergency room provided that (a) the patient has registered for treatment in the hospital emergency room and was treated by the emergency room physician on duty and (b) the controlled substances dispensed are subject to inventory, accounting and security controls and policies of the hospital pharmacy or the emergency room department. For purposes of this definition, a controlled substance is any drug or substance listed in Schedules II through IV of the Alabama Uniform Controlled Substance Act, Code of Ala. 1975, §§20-2-1, et seg. Pursuant to § 20-2-2, Code of Alabama 1975, as amended, to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling or compounding necessary to prepare the substance for that delivery.

(8) HOSPITAL. A health care institution licensed by the Alabama Department of Public Health and has the same definition as provided in Chapter 420-5-7 of the

Alabama Administrative Code. The term shall include any outpatient facility or clinic that is separated from the hospital that is owned, operated, or controlled by the hospital.

- (9) PAIN MANAGEMENT SERVICES. Those medical services that involve the prescription of controlled substances in order to treat chronic non-malignant pain by a physician who treats pain. For the purposes of this rule, the provision of pain management services shall mean:
- (a) A physician practice which advertises or holds itself out to the public as a provider of pain management services; OR
 - (b) A physician practice which dispenses opioids; OR
- (c) A physician practice with greater than fifty percent of the patients being provided pain management services; OR
- (d) A physician practice in which any of the providers of pain management services are rated in the top ten three percent (3%) of practitioners who prescribe controlled substances in Alabama in Schedules II, IIN, III, IIIN and IV, determined by the Alabama Prescription Drug Monitoring Database on an annual basis.
 - (10) PHYSICIAN. A doctor of medicine or an osteopathic physician.
- (11) REGISTRANT. Any physician issued a registration by the Board in its capacity as a certifying board pursuant to § 20-2-2, Code of Alabama 1975, as amended.

Author: Alabama Board of Medical Examiners

Statutory Authority: Code of Alabama § 34-24-53; Act 2013-257

History: Approved for publication: September 18, 2013. Effective Date: December 19, 2013. Amended/Approved for publication: March 19, 2014.