ALABAMA BOARD OF MEDICAL EXAMINERS ADMINISTRATIVE CODE

CHAPTER 540-X-19 PAIN MANAGEMENT SEVICES

TABLE OF CONTENTS

540-X-1901 540-X-1902 540-X-1903 540-X-1904	Preamble Definitions Pain Management Registration Required Ownership And Operation
540-X-1905	Medical Director
540-X-1906	Inspections
540-X-1907	Investigations
540-X-1908	Disciplinary Action And Sanctions
540-X-1909	Requirements For The Use Of Controlled Substances For The Treatment Of Pain (REPEALED)
540-X-1910	Conduct Of Hearings
540-x-19-AA	Appendix A Application For Alabama Pain Management Registration
540-X-19-AB	Appendix B Application For Renewal Of Alabama Pain Management Registration

540-X-19-.01 Preamble.

The Board finds that the diversion, abuse, and misuse of controlled substances constitute a serious threat to the health, safety and welfare of the citizens of the state of Alabama. To assist in preventing diversion, abuse and misuse of controlled substances, the Board is authorized by law to regulate physicians who provide pain management services, including requiring registration with the Board, suspending registrations for pain management services when there is an immediate danger to the public health, and sanctioning, disciplining or placing conditions upon physicians providing pain management services in a manner other than that prescribed in these rules. These rules do not apply to the treatment of acute pain, and physicians are encouraged to be involved in the appropriate care of acute pain. Author: Alabama Board of Medical Examiners Statutory Authority: Code of Ala. 1975, §§34-24-53; Act 2013-257. History: New Rule: Filed November 14, 2013; effective December 29, 2013.

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 Ala. 1975, as amended, inclusive.

(7) DISPENSE. To provide, distribute or give to a patient for the patient's use 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 seq.

(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 in which any of the providers of pain management services are rated in the top 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 Ala. 1975, as amended.

(12) UNRESTRICTED. When referring to a license to practice medicine, an Alabama Controlled Substances Certificate (ACSC), or a Drug Enforcement Administration (DEA) registration, a license, certificate, or registration which is unencumbered by any restriction or condition or which is otherwise not subject to current discipline, and which has not been revoked, suspended, placed on probation, or voluntarily surrendered while under investigation within the past five (5) years. Author: Alabama Board of Medical Examiners Statutory Authority: Code of Ala. 1975, \$\$34-24-53; Act 2013-257. History: New Rule: Filed November 14, 2013; effective December 29, 2013. Amended: Filed May 22, 2014; effective June 26, 2014. Amended: Filed June 19, 2019; effective August 3, 2019.

540-X-19-.03 Pain Management Registration Required.

(1) Beginning January 1, 2014, and continuing every year thereafter, all physicians who provide pain management services must obtain a pain management registration from the Board.

(2) All physicians who otherwise meet the criteria established by the Board shall obtain a pain management registration from the Board.

(3) To obtain a pain management registration, a physician applicant shall submit the following to the Board:

(a) A completed application on a form prescribed by the Board.

(b) Proof of a current Drug Enforcement Administration (DEA) registration.

(c) Proof of an Alabama Controlled Substance Certificate (ACSC).

(d) Proof of a current registration with the Alabama Prescription Drug Monitoring Program (PDMP).

(e) A list of all registrants who own, co-own, operate or provide pain management services in the physician applicant's practice location.

(f) The disclosure of any controlled substances certificate or registration denial, restriction or discipline imposed on the registrant, or any disciplinary act against any medical license of the registrant.

(g) Payment of the initial registration fee as set forth below in these rules under paragraph (6).

(h) A certification listing the current name of the physician who serves as the medical director.

(i) Any other information requested by the Board related to the qualifications for providing pain management services.

Medical Examiners

(4) The physician applicant shall provide the Board with a physical address for each location where he or she provides pain management services and a list of all physicians who work at the practice location, including the name of the physician who will serve as the medical director. If the applicant's practice location is a hospital, the applicant is not required to provide the names of physicians at the hospital other than the name of the medical director.

(5) Exemptions. The provisions of this rule shall not apply to any of the following:

(a) A hospice program as defined by and licensed by the Alabama Department of Public Health, or any physician while performing work or providing pain management services for that program.

(b) A facility maintained or operated by the United States or any of its departments, offices or agencies, or any physicians while performing work for that facility.

(c) In addition, the Board shall provide individual, entity and any categorical exemptions as, in its discretion, it deems appropriate.

(d) Any physician who is not included in subparagraphs (a) and (b) above may petition the Board for an exemption from the requirements of this rule for working at a particular entity. The Board shall have the sole discretion in determining whether the requested exemption shall be granted or denied.

(6) Fees.

(a) Initial Application Fee. All applicants for pain management registration shall submit an initial application fee in the amount of One Hundred Dollars (\$100.00).

(b) Renewal Fee. All applicants for renewal of their pain management registration shall submit renewal fee in the amount of One Hundred Dollars (\$100.00).

(7) Miscellaneous.

(a) If an applicant does not complete the initial application process within 90 days of his or her first submission to the Board, the application shall be closed, the application fee shall not be refunded, and the applicant shall be required to reapply for registration.

(b) An application which is submitted to the Board may be withdrawn at any time prior to the granting or denial of registration; however that application fee shall not be refunded.

Chapter 540-X-19

(8) Renewal.

(a) A registration by a physician under this rule shall expire on December 31 of each year.

(b) A registrant may renew a current registration prior to its expiration date by submitting the following to the Board:

1. A completed renewal application form prescribed by the Board,

2. The required renewal fee,

3. A certification that each location at which the applicant provides pain management services has a medical director,

4. If the practice location is not a hospital, an attestation that the practice location is not owned wholly or partly by a person who has been convicted of or pled nolo contendere to any of the following:

(i) A felony.

(ii) An offense that constitutes a misdemeanor, the facts of which relate to the distribution or illegal prescribing of any controlled substance.

(iii) Any applicant who has been convicted of a crime described in paragraph 4 may request an interview before the Board, after which the Board, in its discretion, may approve or deny the registration.

5. Any other information requested by the Board.

(9) Grounds for Denial of Registration

(a) The Board may deny issuance or renewal of a pain management registration to any applicant who:

1. Fails to meet any of the requirements set forth in Code of Ala. 1975, §§34-24-600, et seq., or Alabama Administrative Code Rule 540-X-19-.01, et seq.;

2. Furnishes false, misleading, untruthful, or fraudulent information in connection with the application;

3. Discloses, or fails to disclose, any controlled substances certificate or registration denial, restriction, or discipline imposed on the applicant, or any disciplinary act against any medical license of the applicant; 4. At the time of the application, is under any state or federal restriction, probation, discipline, investigation, or indictment related to the provision of medical services or fraud; or

5. Is seeking to provide pain management services at a practice location where two or more licensees have committed violations under <u>Code of Ala. 1975</u>, §§34-24-600, et seq., <u>Code of Ala. 1975</u>, §34-24-360, or Code of Ala. 1975, §§20-2-50 through 20-2-78, inclusive.

(b) An applicant who is denied a pain management registration under this section may petition the Board for reconsideration of the application. Any petition must be filed within thirty (30) days of denial of the registration. Upon receipt of the petition, the Board shall issue the registration or set a hearing thereon. The hearing shall be considered a contested case and shall be governed by the rules on reinstatement hearings in accordance with Alabama Administrative Rule 540-X-6-.02(1) (b) (3).

Author: Alabama Board of Medical Examiners Statutory Authority: Code of Ala. 1975, §§34-24-53, 34-24-600 through 34-24-610. History: New Rule: Filed November 14, 2013; effective December 29, 2013. Amended: Filed June 19, 2014; effective July 24, 2014. Amended: Filed September 17, 2015; effective October 22, 2015. Amended: Filed April 16, 2019; effective May 31, 2019.

540-X-19-.04 Ownership And Operation.

(1) All registrants must provide pain management services at a location owned and operated by one of the following:

(a) One or more physicians licensed to practice medicine in Alabama.

(b) A business entity registered with the Alabama Secretary of State's Office.

(c) A governmental entity or body, or political subdivision, or any combination thereof, including state universities and schools.

(2) In order to be registered, a physician shall certify that each practice location is under the direction of a medical director.

(3) Every registrant providing pain management services is required to register with the Alabama Department of Public Health (ADPH) in order to obtain access to the Alabama Prescription Drug Monitoring Program (PDMP) maintained by the ADPH. **Author:** Alabama Board of Medical Examiners Statutory Authority: Code of Ala. 1975, §§34-24-53; Act 2013-257. History: New Rule: Filed November 14, 2013; effective December 29, 2013. Amended: Filed June 19, 2019; effective August 3, 2019.

540-X-19-.05 Medical Director.

(1) A Medical Director shall be a physician who must meet all of the requirements stated in this rule.

(2) A Medical Director shall possess an active, unrestricted license to practice medicine or osteopathy in Alabama.

(3) A Medical Director shall possess an active, unrestricted Alabama Controlled Substances Certificate (ACSC).

(4) A Medical Director shall possess an active, unrestricted Drug Enforcement Administration (DEA) registration.

(5) Each physician serving as a Medical Director at a practice location shall meet at least one of the following requirements.

(a) Successful completion of a residency program in physical medicine and rehabilitation, anesthesiology, addiction medicine, neurology, neurosurgery, family practice, preventive medicine, internal medicine, surgery, orthopedics, or psychiatry approved by the Accreditation Council for Graduate Medical Education (ACGME) or the American Osteopathic Association Bureau of Osteopathic Specialists (AOABOS).

(b) Board certification in physical medicine and rehabilitation, anesthesiology, addiction medicine, neurology, neurosurgery, family practice, preventive medicine, internal medicine, surgery, orthopedics, or psychiatry approved by the American Board of Medical Specialties (ABMS) or the American Osteopathic Association Bureau of Osteopathic Specialties (AOABOS).

(c) Specialty certification in pain management, pain medicine, hospice and palliative medicine, geriatric medicine, rheumatology, hematology, medical oncology, gynecologic oncology, infectious disease, pediatric hematology-oncology, or pediatric rheumatology recognized by the American Board of Medical Specialties (ABMS) or the American Osteopathic Association Bureau of Osteopathic Specialists.

(d) Board certification by the American Board of Pain Medicine.

(e) Board certification by the American Board of Interventional Pain Physicians.

Medical Examiners

(f) At least one of the following:

1. Completion of 40 in-person, live participatory AMA PRA Category 1 Credit or AOA Category 1-A credits in the area of pain management completed within three years of implementation of these rules or prior to serving as a medical director for the practice location, whichever is more recent.

2. Completion of a Board approved course of medical education in the area of prescribing controlled substances completed within three years of implementation of these rules or prior to serving as medical director for the practice location, whichever is more recent, and completion of 40 in-person, live participatory AMA PRA Category 1 Credit or AOA Category 1-A credits in the area of pain management within three years of commencement of service as medical director.

(6) The Medical Director shall have a current registration with the Alabama Department of Public Health Prescription Drug Monitoring Program (PDMP).

Author: Alabama Board of Medical Examiners Statutory Authority: <u>Code of Ala. 1975</u>, §§34-24-53; Act 2013-257. History: New Rule: Filed November 14, 2013; effective December 29, 2013. Amended: Filed December 16, 2015; effective January 30, 2016. Amended: Filed June 19, 2019; effective August 3, 2019.

540-X-19-.06 Inspections.

(1) The medical records and documents of every physician registered under these rules shall be open to inspection to the extent authorized by Code of Ala. 1975, \$34-24-608 and the Administrative Rules of the Board as set out below.

(2) All inspections of physician records undertaken by the Board may be conducted without prior notice to physician, clinic or its staff.

(3) Physicians registered under these rules shall make all records, notes, and files of the registrant open to inspection. In carrying out the intent of these rules, the Board shall have all of the power and authority it currently possesses in its current capacity under §§34-24-363 to 34-24-365, <u>Code of Ala. 1975</u>, as amended, inclusive, and all of the power and authority therein may be applied under these rules for purposes of pain management services registration and enforcement.

(4) If the Board finds that danger to the public health, safety, or welfare requires emergency suspension of a registration and

states in writing its reason for that finding, it may proceed without hearing or upon any abbreviated hearing that it finds practicable to suspend the registration under these rules. The suspension shall become effective immediately, unless otherwise stated therein. The suspension may be effective for a period of not longer than 120 days and shall not be renewable. The Board shall not suspend the same registration for the same or substantially similar emergency within one calendar year from its first suspension unless the Board clearly establishes that it could not reasonably be foreseen during the initial 120-day period that such emergency would continue or would likely reoccur during the next nine months. When such summary suspension is ordered, a formal suspension or revocation proceeding under § 34-24-361, Code of Alabama 1975, as amended, or \S 20-2-53, Code of Alabama 1975, as amended, shall also be promptly instituted and acted upon. Author: Alabama Board of Medical Examiners Statutory Authority: Code of Ala. 1975, §§34-24-53; Act 2013-257. History: New Rule: Filed November 14, 2013; effective December 29, 2013. Amended: Filed May 22, 2014; effective June 26, 2014.

540-X-19-.07 Investigations.

(1) The Board or its agents, on the Board's own motion or in response to a written complaint, may investigate known or suspected violations of §§34-24-600, et seq., <u>Code of Ala. 1975</u>, as amended, and may issue subpoenas.

(2) In addition to the powers granted under §§34-24-600, et seq., <u>Code of Ala. 1975</u>, as amended, the Board or its agents are further authorized to conduct any investigation pursuant to its authority in §34-24-361, <u>Code of Ala. 1975</u>, as amended, including but not limited to, the conducting of formal interviews with a physician, the filing of a written administrative complaint and the request for the temporary emergency suspension of the license of a physician by the Medical Licensure Commission of Alabama. **Author:** Alabama Board of Medical Examiners **Statutory Authority:** <u>Code of Ala. 1975</u>, §§34-24-53; Act 2013-257.

History: New Rule: Filed November 14, 2013; effective December 29, 2013. Amended: Filed May 22, 2014; effective June 26, 2014.

540-X-19-.08 Disciplinary Action And Sanctions.

(1) A violation of \$\$34-24-600, et seq., Code of Ala. 1975, as amended, as set out below in paragraphs (2) and (3) of this rule is grounds for disciplinary action and sanctions against a registrant as provided in this rule.

(2) Any violation of §§ 34-24-600, et seq., <u>Code of Ala. 1975</u>, as amended, or a rule adopted under those sections, shall be

Medical Examiners

prosecuted against and in the name of the registrant or registrants participating in the alleged violation.

(3) In addition to the requirements, sanctions and punishment of an ACSC provided by §§20-2-50 through 20-2-58, <u>Code of Ala. 1975</u>, as amended, the Board may impose the following sanctions:

(a) The failure of a physician who provides pain management services as defined in these rules, to obtain a pain management registration from the Board, shall be punishable by a fine up to Ten Thousand Dollars (\$10,000) per violation, or the revocation of the registration, or both, whenever the physician shall be found guilty on the basis of substantial evidence.

(b) A violation of any other requirements under §§34-24-600, et seq., including a medical director, shall be punishable by a fine up to One Thousand Dollars (\$1,000) per violation, or the revocation of the registration, or both, whenever the physician charged shall be found guilty on the basis of substantial evidence. Specific violations under this paragraph include:

1. Making a fraudulent or untrue statement in applying for a pain management registration.

2. Aiding and abetting the providing of pain management services by a physician who has not obtained a pain management registration from the Board.

3. Failure to register with the Alabama Prescription Drug Monitoring Program in obtaining a pain management registration from the Board

(c) If a practice location has two or more physicians who commit a violation under \$\$34-24-600, et seq., <u>Code of Ala.</u> <u>1975</u>, as amended, within one year, the Board shall report the violations to the appropriate licensing agency or agencies that regulate the practice location.

Author: Alabama Board of Medical Examiners Statutory Authority: <u>Code of Ala. 1975</u>, §§34-24-53; Act 2013-257. History: New Rule: Filed November 14, 2013; effective December 29, 2013. Amended: Filed May 22, 2014; effective June 26, 2014.

540-X-19-.09 Requirements For The Use Of Controlled Substances For The Treatment Of Pain (REPEALED).

Author: Alabama Board of Medical Examiners Statutory Authority: Code of Ala. 1975, §§34-24-53; Act 2013-257. History: New Rule: Filed November 14, 2013; effective December 29, 2013. Repealed: Published July 31, 2023; effective September 14, 2023.

540-X-19-.10 Conduct Of Hearings.

Except when §§20-2-50 through 20-2-58, Code of Ala. 1975, as amended, and Board Rules 540-X-4-.01 through 540-X-4-.07 are in conflict and shall take precedence, hearings related to Pain Management Services and Registrants as set out in this Chapter, are to be governed and conducted in accordance with Board Rules 540-X-6-.03 (Hearing Officer); 540-X-6-.04 (Conduct of Hearings in Contested Cases); and 540-X-6-.05 (Miscellaneous Provisions). Author: Alabama Board of Medical Examiners Statutory Authority: Code of Ala. 1975, §§34-24-53; Act 2013-257. History: New Rule: Filed November 14, 2013; effective December 29, 2013.

540-X-19-AA Appendix A Application For Alabama Pain Management Registration.

ALABAMA BOARD OF MEDICAL EXAMINERS P.O.Box 946 - Montgomery, Alabama 36101 • 848 Washington Avenue - 36104

Application for Alabama Pain Management Registration

Separate registration required for each location where pain management services are provided

Registration Fees: \$100.00 for first location; no additional charge for each additional location

Under Alabama law, this document is a public record and will be provided upon request

Name

AL License Number Alabama Controlled Substances Certificate Number Expiration Date DEA Number: DEA Expiration Date: DEA "X" Number (if applicable) Expiration Date

1 Are you registered with PDMP? [] Yes [] No (Upload copy of PDMP registration receipt)

2 Have you ever had a controlled substance registration certificate denied, restricted or disciplined? [] Yes [] No You answered yes, please provide a summary of each action including the year, state and description of each action.

3 Have you ever had a disciplinary action taken against your medical license in Alabama or any other state? [] Yes [] No You answered yes, please provide an explanation of the action, including the year, state and description of each action.

Please provide the following information for the above location where you provide pain management services:

Facility Name
Facility Physical Address:
The facility is owned or operated by:
A business entity qualifying under Ala. Code § 34-25-605(a)(2)
Name of business entity
List all persons or entities having an interest in the facility
Upload a copy of the articles of formation as filed with the Alabama
Secretary of State.
You answered no, please provide the following information
A physician licensed to practice medicine in Alabama

Chapter 540-X-19

List all Owners, Operators of the facility A governmental entity or body, or political subdivision, or any combination thereof, including state universities and schools. Full Name of Medical Director:

Please identify with supporting documentation, the criteria under which the listed medical directory qualifies to serve as the medical director, which can be found at Ala. Admin. Code 540-X-19-.05

Upload Supporting Documentation

List all physicians providing pain management services at this location: I swear (affirm) that the information set forth on this application for Alabama Pain Management Registration form is true and correct to the best of my knowledge, information and belief. I also understand that the Board of Medical Examiners may conduct an on-site inspection of my records at any time.

I understand and agree that by typing my name, I am providing an electronic signature that has the same legal effect as a written signature pursuant to Ala. Code §§ 8-1A-2 and 8-1A-7. I attest that the foregoing information has been provided by me and is true and correct to the best of my knowledge, information and belief.

Knowingly providing false information to the Alabama Board of Medical Examiners or Medical Licensure Commission of Alabama could result in disciplinary action.

Author: Alabama Board of Medical Examiners Statutory Authority: Code of Ala. 1975, §\$20-2-250, et. seq.; Act 2013-223. History: New Rule: Filed November 14, 2013; effective December 29, 2013. Amended: Filed June 19, 2014; effective July 24, 2014. Amended: Filed September 17, 2015; effective October 22, 2015. Amended: Filed August 23, 2018; effective October 7, 2018. 540-X-19-AB Appendix B Application For Renewal Of Alabama Pain Management Registration.

20XX Application for Renewal of Alabama Pain Management Registration Deadline: December 31, 20XX

Under Alabama law, this document is a public record and if requested it will be provided in its entirety.

Licensee's Name Primary License Number Location Name Location Address

> 1. Do you provide pain management services at a hospital? Yes No In the past year, have either you or the owner(s) of each location where you provide pain management services been convicted of or pled nolo contendere to a felony or an offense that constitutes a misdemeanor, the facts of which relate to the distribution or illegal prescribing of any controlled substance?* Yes No (If yes, please include a detailed explanation)

*Any applicant who has been convicted of a crime described in this paragraph may request an interview before the Board, after which the Board, in its discretion, may approve or deny the registration.

2. Does the location listed above at which the above licensee provides pain management services have a medical director as required by Board Rule 540-X-19-.04? Yes No

I understand and agree that by typing my name, I am providing an electronic signature that has the same legal effect as a written signature pursuant to Ala. Code §§ 8-1A-2 and 8-1A-7. I attest that the foregoing information has been provided by me and is true and correct to the best of my knowledge, information and belief.

Knowingly providing false information to the Alabama Board of Medical Examiners could result in disciplinary action.

Author: Alabama Board of Medical Examiners Statutory Authority: Code of Ala. 1975, §§34-24-53. History: New Rule: Filed November 14, 2013; effective December 29, 2013. Amended: Filed August 21, 2014; effective September 25, 2014. Amended: Filed September 17, 2015; effective October 22, 2015. Amended: Filed July 20, 2017; effective September 3, 2017.