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 Alabama § 34-24-53; Act 2013-257  
**History:** Approved for publication: September 18, 2013. Effective Date: December 19, 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 Alabama 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, IIN 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
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 fees 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.

(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 Fees. 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 a renewal fee in the amount of One Hundred Dollars ($100.00).

(7) Miscellaneous.

(a) An applicant practicing in more than one location shall submit a separate registration fee in the amount of Ten Dollars ($10.00) for each location.

(b) 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 fees shall not be refunded, and the applicant shall be required to reapply for registration.

(c) An application which is submitted to the Board may be withdrawn at any time prior to the granting or denial of registration; however the application fees shall not be refunded.

(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 fees,

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.

**Author:** Alabama Board of Medical Examiners  
**Statutory Authority:** Code of Alabama § 34-24-53, Act 2013-257  

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 who shall be a physician who possesses a current, unrestricted license to practice medicine or osteopathy in
Alabama.

(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 Alabama § 34-24-53, Act 2013-257  
**History:** Approved for publication: September 18, 2013. Effective Date: December 19, 2013.

540-X-19-.05 Training Requirements.

(1) Each physician serving as the 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.

(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.

(2) The Medical Director shall be physically on site for a minimum of ten percent of the clinic’s operating hours.

Author: Alabama Board of Medical Examiners
History: Approved for publication: September 18, 2013. Effective Date: December 19, 2013.

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 Ala. Code § 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, Code of Alabama 1975, 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 § 20-2-53, Code of Alabama 1975,
as amended, shall also be promptly instituted and acted upon.

Author: Alabama Board of Medical Examiners  

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., Code of Alabama 1975, as amended, and may issue subpoenas.

(2) In addition to the powers granted under §§ 34-24-600, et seq., Code of Alabama 1975, as amended, the Board or its agents are further authorized to conduct any investigation pursuant to its authority in § 34-24-361, Code of Alabama 1975, 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  

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

(1) A violation of §§ 34-24-600, et seq., Code of Alabama 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., Code of Alabama 1975, as amended, or a rule adopted under those sections, shall be 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, Code of Alabama 1975, 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., Code of Alabama 1975, 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:** Code of Alabama § 34-24-53, Act 2013-257  
**History:** Approved for publication: September 18, 2013. Effective Date: December 19, 2013. Amended (scrivener’s errors)/Approved for publication: March 19, 2014. Effective Date: June 26, 2014.

540-X-19-.09 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 ________________

1 Please also see Board Rule 540-X-4-.08
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.

Author: Alabama Board of Medical Examiners
540-X-19-.10 Conduct of Hearings. Except when §§ 20-2-50 through 20-2-58, Code of Alabama 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
History: Approved for publication: September 18, 2013. Effective Date: December 19, 2013.
Application for Alabama Pain Management Registration

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

Name: ____________________________ AL License #: __________________________

Address: ____________________________  __________________________

Street  City  State  Zip

Telephone: ________________ Fax: ________________ Email: ________________

DEA Number: ________________ DEA Expiration Date: ________________

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

2. Have you ever had a controlled substance registration certificate denied, restricted or disciplined? [ ] Yes [ ] No
   If yes, attach 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
   If yes, attach 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: (Attach additional pages if necessary)

Facility Name: __________________________

Physical Address: __________________________

Street  City  State  Zip

Owners, Co-Owners, Operators: __________________________

Full Name of Medical Director: __________________________

Full names of 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.

Signature of Physician: __________________________  Date: __________________________
Application for Renewal of Alabama Pain Management Registration

Name: ___________________________ AL License #: ___________________________

Address: ___________________________ ___________________________ ___________________________
    Street                        City                        State                        Zip

Telephone: ___________________________ Fax: ___________________________ Email: ___________________________

DEA Number: ___________________________ DEA Expiration Date: ___________________________

1. Do you provide pain management services at a hospital? [ ] Yes [ ] No
   
   If yes, continue to number 2 below.
   
   If no, complete the following attestation:
   
   I hereby attest that neither I nor the owner(s) of each of the locations where I provide pain
   management services has, in the past year, 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*.

   Signature of Physician: ___________________________ Date: __________________

   *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. I hereby certify that each location at which I provide pain management services has a
   medical director as required by Board Rule 540-X-19-.04. Additionally, I swear (affirm) that
   the information set forth on this application for renewal of Alabama Pain Management
   Registration 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.

   Signature of Physician: ___________________________ Date: __________________