- 1 SB113
- 2 147608-3
- 3 By Senators Ward, Reed, Allen, Whatley, Scofield, Taylor,
- 4 Brewbaker, Glover, Waggoner, Marsh, Fielding, McGill, and
- 5 Bussman
- 6 RFD: Judiciary
- 7 First Read: 05-FEB-13

1	147608-3:n:02/05/2013:MCS/tj LRS2013-424R2
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8	SYNOPSIS: This bill provides for the Alabama Pain
9	Management Act.
10	This bill would provide additional powers
11	for the Alabama Board of Medical Examiners
12	regarding regulating pain management clinics and
13	physicians.
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15	A BILL
16	TO BE ENTITLED
17	AN ACT
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19	To add a new Article 11 consisting of Sections
20	34-24-1001, 34-24-1002, 34-24-1003, 34-24-1004, 34-24-1005,
21	34-24-1006, 34-24-1007, 34-24-1008, 34-24-1009, 34-24-1010,
22	and 34-24-1011, to Chapter 24 of Title 34 of the Code of
23	Alabama 1975, relating to doctors of medicine, doctors of
24	osteopathy and all licensees of the Alabama Board of Medical
25	Examiners and the Medical Licensure Commission of Alabama so
26	as to provide for additional powers of the board relating to
27	pain management; to provide for the "Alabama Pain Management

1 Act"; to safeguard the public health, safety, and welfare by 2 requiring the registration and regulation of pain management clinics and physicians working at these clinics; to provide 3 for the renewal of pain management registrations; to provide for sanctions and punishments for the violation of the act; to 5 6 provide the board with the authority to close pain management 7 clinics when they pose an immediate danger to public health, safety, or welfare; to provide for reports by and to the 8 9 board; to establish minimum standards for pain management 10 medical records; to provide for related matters and for other 11 purposes.

12 BE IT ENACTED BY THE LEGISLATURE OF ALABAMA:

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Section 1. A new Article 11 is added to Chapter 24,

Title 34, Code of Alabama 1975, as follows:

ARTICLE 11. Alabama Pain Management Act Section 34-24-1001. Short title.

This article shall be known as and may be cited as the "Alabama Pain Management Act."

Section 34-24-1002. Legislative findings.

The Legislature finds that the diversion, abuse, and misuse of prescription medications classified as controlled substances under the Alabama Uniform Controlled Substances Act constitute a serious threat to the health, safety, and welfare of the citizens of the State of Alabama. The Legislature further finds that the registration of all pain management clinics, as defined in this article, and physicians working at these clinics, will assist the Alabama Board of Medical

Examiners in preventing the diversion, abuse, and misuse of controlled substances by regulating these registrants. The Legislature further finds that it is in the best interests of the public safety to give the Board of Medical Examiners the authority it needs to suspend the registration of these clinics and physicians working at these clinics when the public health, safety, or welfare requires immediate action.

Section 34-24-1003.

- (a) Authority. The Alabama Board of Medical Examiners shall have the jurisdiction and authority necessary to carry out the provisions and intent of this article.
- (b) Intent. The article is intended to require certain entities and physicians to register under the provisions of this article, and to provide to the Alabama Board of Medical Examiners the following powers and duties with respect to all registrants of the Board of Medical Examiners, in addition to its existing authority as a certifying board pursuant to the Alabama Uniform Controlled Substances Act:
- (1) To adopt, amend, and repeal such rules and regulations in accordance with the Alabama Pain Management Act for the proper administration and enforcement of this article.
- (2) To establish rules regarding the registration of all pain management clinics and physicians working at those clinics.
  - (3) To set reasonable registration and renewal fees.

1 (4) To renew registrations and set renewal and 2 expiration dates and other deadlines.

- (5) To initiate investigations for the purposes of discovering violations of this article.
  - (6) To administer oaths, subpoena witnesses and documents, including medical records, and take testimony in all matters relating to the board's duties.
    - (7) To conduct investigative interviews.
  - (8) To inspect and regulate pain management clinics and regulate physicians working at these clinics and require these physicians to produce certain documents.
  - (9) To access and obtain information and data from the Alabama Prescription Drug Monitoring Program (PDMP) to discover and investigate patterns of prescribing which endanger the health, safety, and welfare of patients and the public.
  - (10) To revoke, suspend, reprimand, place on probation, issue terms and conditions, limit practice, fine, require additional training, or otherwise sanction pain management clinics and physicians working at these clinics.
  - (11) To immediately close pain management clinics and suspend the clinics' registrations, and immediately suspend registrations from physicians working at these clinics when they pose an immediate danger to the public health, safety, and welfare.
  - (c) The board shall have the necessary power and authority to provide funds under this article and to contract

with any nonprofit or for profit entities, or any individuals, for the purpose of fighting conversion, abuse, and misuse of controlled substances, as set forth in this article, and for the purpose of providing educational activities for

practitioners concerning this article, without being bound by any law that requires competitive bidding.

Section 34-24-1004. Definitions.

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- (a) Unless otherwise indicated from the context, the terms set out below as used in this article shall have the following meanings:
- (1) ADMINISTER. The direct application of a controlled substance, whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject by:
- a. A practitioner, or, in his or her presence, his or her authorized agent.
  - b. The patient or research subject at the direction and in the presence of the practitioner.
- (2) APPLICANT. A person or entity that has submitted or that is in the process of submitting a registration under this article.
  - (3) BOARD. The Alabama Board of Medical Examiners.
- (4) CHRONIC PAIN. Pain unrelated to cancer which persists beyond the usual course of disease or injury that is the cause of the pain for more than 90 days.

1 (5) CONTROLLED SUBSTANCE. A drug, substance, or
2 immediate precursor identified, defined, or listed in Sections
3 20-2-20 to 20-2-32, inclusive.

- (6) DISPENSE. 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.
- which advertises or holds itself out to the public as treating pain; or any practice of medicine or osteopathy which advertises or holds itself out to the public as treating pain and utilizes doctors of medicine or osteopathy and controlled substances; or any business entity, including sole proprietorship, that meets parameters established in rules adopted by the board; or, any practice of medicine or osteopathy which meets parameters established in rules adopted by the board.
- (8) PHYSICIAN. A doctor of medicine or a doctor of osteopathy.
- (9) REGISTRANT. Any person or entity issued a registration by the board in its capacity as a certifying board pursuant to this article.

Section 34-24-1005. Annual registration.

(a) Initial requirements. Beginning January 1, 2014, and continuing each year thereafter, all pain management

- clinics, and all physicians practicing in pain management clinics, shall register with the board.
- 3 (b) To register, a physician applicant shall submit 4 the following to the board:
- 5 (1) A completed application on a form prescribed by 6 the board.
- 7 (2) Proof of a current Drug Enforcement 8 Administration registration.

- 9 (3) Proof of an Alabama Controlled Substances
  10 Certificate.
  - (4) Proof of a current registration with the Alabama Prescription Drug Monitoring Program (PDMP).
  - applicant shall submit a complete set of fingerprints to the board. The board shall submit the fingerprints provided by each applicant for registration to practice in a pain management clinic to the Alabama Bureau of Investigation (ABI). The fingerprints shall be forwarded by the ABI to the Federal Bureau of Investigation (FBI) for a national criminal history record check. Costs associated with conducting a criminal history background check shall be borne by the applicant. The board shall keep information received pursuant to this section confidential, except that such information received and relied upon in denying the registration of a physician to practice in a pain management clinic in this state may be disclosed as may be necessary to support the denial.

1 (6) A list of all registrants who own, co-own,
2 operate, or provide pain management services in the clinic.

- (7) The disclosure of any controlled substances certificate or registration denial, restriction, or discipline imposed on any registrant who practices pain medicine in a pain management clinic.
  - (8) Payment of the initial registration fee as set forth in this section and in the rules of the Alabama Board of Medical Examiners.
    - (9) Any other information requested by the board.
  - (c) To register a clinic, an applicant shall provide information as set forth in rules promulgated by the board.
  - (d) Exemptions. The provisions of this article shall not apply to any of the following:
  - (1) A hospice program licensed by the Alabama Department of Public Health, or any physicians while performing work for that program.
  - (2) 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.
  - (3) Any facility that is not included in subdivisions (1) and (2) may petition the board for an exemption from the requirements of this section for itself and the physicians working at that facility. The board shall have the sole discretion in determining whether the requested exemption shall be granted or denied.
    - (e) Fees.

- 1 (1) Initial registration fee: An amount set by the 2 board in its rules not to exceed three hundred dollars (\$300).
- 3 (2) Renewal fee. An amount set by the board in its 4 rules not to exceed three hundred dollars (\$300).
  - (f) Miscellaneous.

- (1) A physician applicant practicing in more than one location shall submit a separate registration fee for each practice location to which this article applies, regardless of whether the clinic is operated under the same business name, ownership, or management as another clinic.
- (2) If a clinic or physician applicant does not complete the initial application process within 90 days of his or her first submission to the board, then the application shall be closed, the application fee shall not be refunded, and the applicant shall be required to reapply for registration.
- (3) An application which is submitted to the board may be withdrawn at any time prior to the granting or denial of registration; provided, however, that the application fee shall not be refunded.
  - (q) Renewal.
- (1) A registration by a clinic or a physician under this article shall expire on December 31 of each year.
- (2) A registrant may renew a current registration prior to its expiration date by submitting the following to the board:

- 1 a. A renewal application form prescribed by the
- 2 board.

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- 3 b. The required renewal fee.
- c. Proof that the clinic has a medical director who meets the requirements in Section 34-24-1006(b).
  - d. An attestation that the clinic is not owned wholly or partly by a person who has been convicted of or pled nolo contendre to any of the following:
    - 1. A felony.
  - 2. An offense that constitutes a misdemeanor, the facts of which relate to the distribution or illegal prescription of any controlled substance.
  - 3. Any applicant who has been convicted of a crime described in paragraph d. may request an interview before the board, after which the board may, in its discretion, approve or deny the registration.
    - e. Any other information requested by the board. Section 34-24-1006. Ownership and operation.
  - (a) Each pain management clinic shall be owned and operated by one of the following:
  - (1) One or more physicians licensed to practice medicine in Alabama.
  - (2) A business entity registered with the Secretary of State. All clinics under this category shall produce the names and addresses of all individuals listed on the entity's Certification of Formation, and any amendments thereto, filed with the Secretary of State. The clinic shall provide a list

- of all directors and officers, with complete and up-to-date contact information for each, who shall be responsible for the operation of the clinic.
  - (b) Each clinic shall be 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. The medical director shall have the following responsibilities:
- 9 (1) Oversee all medical services provided at the clinic.

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- (2) Be responsible for ensuring compliance with requirements established in rules adopted by the board.
- (3) Ensure that all physicians employed at the clinic have registered with the Alabama Prescription Drug Monitoring Program (PDMP).
- (4) Ensure that the PDMP is utilized by all physicians at the clinic as part of the clinic's quality assurance program.
- (c) Every registrant practicing in a clinic is required to obtain access to the Alabama Prescription Drug Monitoring Program (PDMP) maintained by the Alabama Department of Public Health.

Section 34-24-1007. Training requirements.

(a) Each physician serving as the medical director at a clinic shall meet at least one of the following requirements:

(1) 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).

- (2) 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 ACGME or AOABOS.
- (3) Speciality certification in pain management, 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 or AOABOS with a certificate of added qualification from the Bureau of Osteopathic Specialists.
- (4) Board certification by the American Board of Pain Medicine.
- (5) Board certification by the American Board of Interventional Pain Physicians.
  - (6) At least one of the following:
- a. Completion of 40 in-person, live participatory

  AMA PRA Category 1 Credits or AOABOS Category 1 credits work

  in the area of pain management completed within three years of

implementation of this article or prior to serving as a
medical director for the clinic, whichever of them is most
recent.

b. Completion of a board approved course of medical education in the area of prescribing controlled substances completed within three years of implementation of this article or prior to serving as medical director for the clinic, whichever of them is most recent, and completion of 40 in-person, live participatory AMA PRA Category 1 Credits or AOABOS Category 1 credits work in the area of pain management within three years of commencement of service as medical director.

Section 34-24-1008. Inspections.

- (a) Every pain management clinic registered under this article shall be open to inspection to the extent authorized in this section by employees and agents of the Board of Medical Examiners under rules as shall be promulgated by the board. Physicians registered under this article shall make all records, notes, and files open for inspection under the rules as shall be promulgated by the board.
- (b) All inspections undertaken by the Board of Medical Examiners may be conducted without prior notice to the clinic and its staff. Notwithstanding the foregoing, the board may prescribe by rule exceptions to this section where consideration of public health or safety make advance disclosure of inspection dates and times reasonable. In addition, scheduling inspection of pain management clinics by

the board at regular, periodic intervals which may be predictable shall not be a violation of this section.

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(c) If the board finds that danger to the public health, safety, or welfare requires emergency suspension of a registration and states in writing in its reason for that finding, it may proceed without hearing or upon any abbreviated hearing that it finds practicable to suspend the registration of a clinic or any physician working at that clinic. 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 a 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 Section 34-24-361 or Section 20-2-53, shall also be promptly instituted and acted upon.

Section 34-24-1009. Investigations.

(a) The board or its agents may, on its own motion or in response to a written complaint, investigate any evidence which appears to show that a clinic, a physician registrant, or a physician practicing in a clinic in the State

of Alabama is or may be guilty of any violation of this article.

(b) In addition to the powers granted under this article, the board or its agents are further authorized to conduct any investigations pursuant to its authority in Section 34-24-361, including, but not limited to, the conducting of formal interviews with a physician, the filing of a written administrative complaint, and the temporary emergency suspension of the license of a physician without a hearing in the case of imminent and immediate danger to patients or the public.

Section 34-24-1010. Complaints.

The board may investigate a complaint alleging a violation of this article or a rule adopted under this article.

Section 34-24-1011. Disciplinary action and sanctions.

- (a) A violation of this article or a rule adopted under this article is grounds for disciplinary action and sanctions against a registrant as provided in this section.
- (b) A violation of this article may be enforced in the same manner as any other violation of Sections 20-2-50 to 20-2-58, inclusive.
- (c) Any violation of this article or a rule adopted under this article shall be prosecuted against and in the name of the registrant or registrants participating in the alleged violation.

1 (d) In addition to the requirements, sanctions, and 2 punishment provided by Section 20-2-50 to 20-2-58, inclusive, 3 the board may impose the following sanctions:

- (1) The failure to annually register a pain management clinic as defined in Section 34-24-1004(9) and as established in rules adopted by the board shall be punishable by a fine up to ten thousand dollars (\$10,000) per violation, or the revocation of the clinic's registration, or both.
- (2) The failure of a physician who is practicing at a clinic, or who otherwise has an obligation under law to annually register pursuant to the requirements of this article, shall be punishable by a fine up to ten thousand dollars (\$10,000) per violation or the revocation of the registrant's registration, or both.

Section 2. Nothing in this act shall be construed to limit the ability of the Board of Medical Examiners to exercise authority existing prior to the passage of this act.

Section 3. The provisions of this act are severable. If any part of this act is declared invalid or unconstitutional, that declaration shall not affect the part which remains.

Section 4. This act shall become effective immediately following its passage and approval by the Governor, or its otherwise becoming law.