GEORGIA COMPOSITE MEDICAL BOARD

EXECUTIVE DIRECTOR
LaSharn Hughes, MBA

BOARD CHAIRPERSON
Richard Weil, MD

2 Peachtree Street, N.W., 36th Floor • Atlanta, Georgia 30303 • Tel: 404.656.3923 • http://www.medicalboard.georgia.gov
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GEORGIA COMPOSITE MEDICAL BOARD
NOTICE OF INTENT TO AMEND AND ADOPT RULES

TO ALL INTERESTED PARTIES:

Notice is hereby given by the Georgia Composite Medical Board that it intends to post a new **Rule Chapter 360-8 "Pain Clinics**." An exact copy of Rule is attached to this Notice.

This notice, together with an exact copy of the proposed rules and a synopsis of the proposed rules are being emailed to all persons who have requested, in writing, that they be placed on the mailing list. A copy of this notice, an exact copy of the proposed rules and a synopsis of the proposed rules may be reviewed during normal business hours of 8:00 a.m. to 5:00 p.m., Monday through Friday, except official State holidays, at the office of the Georgia Composite Medical Board, 2 Peachtree Street, N.W., 36th Floor, Atlanta, Georgia 30303.

Any interested person who will be affected by these rules may present his or her comments to the Board no later than **October 25, 2013** or make comments at the public hearing. Comments may be directed to Diane Atkinson, Georgia Composite Medical Board, 2 Peachtree Street, N.W., 36th Floor, Atlanta, Georgia 30303-3465 or may be received by the Board by e-mail at matkinson@dch.ga.gov. .

A public hearing is scheduled to begin at **10:30 a.m**. on **November 8, 2013** at the 36th Floor Board Room, 2 Peachtree Street, N.W., Atlanta, Georgia 30303, to provide the public an opportunity to comment upon and provide input into the proposed rules.

The Board voted to adopt this Notice of Intent on **September 13, 2013** meeting. The Board will consider at its meeting on **November 8, 2013** at **10:30 a.m**. the comments from the public hearing whether the formulation and adoption of these proposed rule amendments imposes excessive regulatory costs on any license or entity and whether any cost to comply with the proposed rule amendments could be reduced by a less expensive alternative that accomplishes the objectives of the statutes which are the basis of the proposed rule. Additionally at its meeting on **November 8, 2013**, the Board will consider whether it is legal or feasible in meeting the objectives of the applicable laws to adopt or implement differing actions for businesses as listed in O.C.G.A. § 50-13-4(3)(A)(B)(C)(D).

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The authority for promulgation of these rules is O.C.G.A. Secs. 43-34-5, 43-34-8, 43-34-9, 43-34-281 43-34-282, 43-34-283, 43-34-284, 43-34-285(8), 43-34-286, 43-34-287, 43-34-288, and 43-34-289 the specific statutes cited in the proposed rules.

This Notice is adopted and posted in compliance with O.C.G.A. § 50-13-4 of the Georgia Administrative Procedures Act. A synopsis of the proposed rules and an economic impact statement are attached to this Notice.

Date: September 20, 2013

Signed: _____
LaSharn Hughes, MBA
Executive Director
Georgia Composite Medical Board

ECONOMIC IMPACT AND SYNOPSIS FOR NEW CHAPTER 360-8
Pain Clinics

ECONOMIC IMPACT:

The attached rules are promulgated under the authority of the Medical Practice Act, Title 43, Chapter 34. The Composite State Board of Medical Examiners licenses and regulates nine professions. The formulation and adoption of this rule does not impose excessive regulatory cost on any licensee and any cost to comply with the proposed rule cannot be reduced by a less expensive alternative that fully accomplishes the objectives of Article 2 of Chapter 34 of Title 43 of the Official Code of Georgia Annotated. Additionally, it is not legal or feasible to meet the objectives of the Article 2 of Chapter 34 of Title 43 of the Official Code of Georgia Annotated to adopt or implement differing actions for businesses listed at O.C.G.A. § 50-13-4(a)(3)(A), (B), (C) and (D).

RULE SYNOPSIS:

Rule 360-8 Pain Clinics

Purpose/Main Feature: The purpose of this rule is to implement House Bill 178 which allows for licensure of pain clinics.

O.C.G.A. Secs. 43-34-5, 43-34-8, 43-34-9, 43-34-281 43-34-282, 43-34-283, 43-34-284, 43-34-285(8), 43-34-286, 43-34-287, 43-34-288, and 43-34-289

Pain Management Clinics
Chapter 360-8

The purpose of these rules is to establish standards for licensure of pain management clinics.

360-8-.01 Definitions

(1) 'Annual patient population' means persons seen by a clinic or practice in a 12 month calendar year but shall not include persons that are patients of a nursing home, home health agency or hospice licensed pursuant to Chapter 7 of Title 31.

(2) 'Board' means the Georgia Composite Medical Board created by Code Section 98 43-34-2.

(3) 'Chronic pain' means physical pain treated for a period of 90 days or more in a year but shall not include perioperative pain, which shall mean pain immediately preceding and immediately following a surgical procedure, when such perioperative pain is being treated in connection with a surgical procedure by a licensed health care professional acting within the scope of his or her license.

(4) 'License' means a valid and current certificate of registration issued by the board pursuant to this article which shall give the person to whom it is issued authority to engage in the practice prescribed thereon.

(5) 'Licensee' means any person holding a license under this article.

(6) 'Medical treatment' and 'medical services' means the treatment of chronic pain.

(7) 'Nonterminal condition' means a medical condition which is reversible, where there is a reasonable hope of recovery, and where the patient's medical prognosis is a life expectancy of two years or more.

(8) 'Pain management clinic' means a medical practice advertising 'treatment of pain' or utilizing 'pain' in the name of the clinic or a medical practice or clinic with greater than 50 percent of its annual patient population being treated for chronic pain for nonterminal conditions by the use of Schedule II or III controlled substances. This term shall not include any clinic or practice owned, in whole or in part, or operated by a hospital licensed pursuant to Chapter 7 of Title 31 or by a health system or any ambulatory surgical center, skilled nursing facility, hospice, or home health agency licensed pursuant to Chapter 7 of Title 31.

(9) 'Person' means a natural person.

(10) 'Physician' means a person who possesses a current, unrestricted license to practice medicine in the State of Georgia pursuant to Article 2 of this chapter; who, during the course of his or her practice, has not been denied the privilege of prescribing, dispensing,

administering, supplying, or selling any controlled substance; and who has not, during the course of his or her practice, had board action taken against his or her medical license as a result of dependency on drugs or alcohol.

(11) No pain management clinic shall provide medical treatment or services, ***as defined by the board***, unless a physician, a physician assistant authorized to prescribe controlled substances under an approved job description, or an advanced practice registered nurse authorized to prescribe controlled substances pursuant to a physician protocol is on-site at the pain management clinic.

O.C.G.A Sections 43-34-281, 43-34-282

Rule 360-8-.02 Standards of Operation

(1) Each location of a clinic where a physician practices pain management must be licensed.

(2) A new pain management clinic license must be obtained if there is a change in ownership or a change in location.

(3) No pain management clinic shall provide medical treatment or services unless a physician, a physician assistant authorized to prescribe controlled substances under an approved job description, or an advanced practice registered nurse authorized to prescribe controlled substances pursuant to a physician protocol is on-site at the pain management clinic.

(4) No licensed physician can own a pain management clinic or practice in a pain management clinic if the physician has been denied the privilege of prescribing, dispensing, administering, supplying or selling any controlled substance, or has had board action against his or her medical license as a result of dependency on alcohol or drugs.

(5) No person can own a pain management clinic, and no physician can practice in a pain management clinic, if he or she has been convicted of a felony. For purposes of this rule, the term "convicted of a felony" shall include a conviction of an offense which if committed in this state would be deemed a felony under either state or federal law, without regard to its designation elsewhere. As used in this paragraph, the term "conviction" shall include a finding or verdict of guilt, a plea of guilty resulting in first offender status, or a plea of nolo contendere in a criminal proceeding, regardless of whether the adjudication of guilt or sentence is withheld or not entered thereon.

(6) The owner of the clinic and the physicians practicing in the clinic shall be responsible for compliance with all the laws and rules and regulations regulating the practice of medicine and the laws and rules and regulations pertaining to the controlled substances.

(7) The license issued by the Board shall be displayed in a conspicuous place.

(8) All pain management clinics that dispense controlled substances or dangerous drugs shall be registered with the Georgia State Board of Pharmacy as required by Chapter 4 of Title 26.

(9) Each physician owning or practicing in a pain management clinic must register with the Georgia Prescription Monitoring Program. See link www.gdna.ga.gov

(10) The Board shall have the power to reprimand, cancel, suspend, revoke, or otherwise restrict any license or permit issued by the Board.

(11) Any person who operates a pain management clinic in the State of Georgia without a license shall be guilty of a felony.

O.C.G.A. Sections 43-34-5, 43-34-8, 43-34-282, 43-34-283, 43-34-284, 43-34-286, and 43-34-288.

360-8-.02 Pain Management Clinic License Requirements

(1) Effective July 1, 2013, all pain management clinics must hold a license issued by the Board to operate in this state, and must be owned by physicians holding current licenses to practice in this state.

(a) A pain management clinic who can present satisfactory evidence to the Board of being in existence on June 30, 2013, may also qualify for a licenses at each location if it is jointly owned by one or more Georgia licensed physicians and one or more Georgia licensed physician assistants or Georgia licensed advanced practice registered nurses. However, the non-physician owners must meet all the qualifications for licensure except being a licensed physician.

(b) A pain management clinic who can present satisfactory evidence to the Board of being in existence on June 30, 2013, may also qualify for a license at ONE location even though it is not wholly owned by Georgia licensed physicians. However, the owners must meet all the qualifications for licensure except being a licensed physician.

(2) All applicants for licensure as pain management clinic must submit an application on a form approved by the Board for each location and a non-refundable application fee for each application, and must submit the following:

(a) An affidavit from each owner that each owner is a United States citizen, a legal permanent resident of the United States, or that he/she is a qualified alien or non-immigrant under the Federal Immigration and Nationality Act. If the applicant is not a U.S. citizen, he/she must submit documentation that will determine his/her qualified alien status. The Board participates in the **DHS-USCIS SAVE** (Systematic Alien Verification for Entitlements or "SAVE") program for the purpose of verifying citizenship and immigration status information of non-citizens. If the applicant is a qualified alien or non-immigrant under the Federal Immigration and Nationality Act, he/she must provide the alien number issued by the Department of Homeland Security or other federal immigration agency.

(b) A secure and verifiable document from each owner.

(c) Proof that each licensed owner who holds a license to practice healthcare in this state and each physician , physician assistant and advanced practice registered nurse who practices at the clinic are in good standing with the Board or their respective licensing board.

(d) Each owner, principal, manager, agent, officer, and licensed health care practitioner must pass a criminal background check and further investigation, at the Board's discretion.

(e) Each owner must submit an affidavit of ownership and current photograph.

(f) A National Practitioner Data Bank and Health Integrity and Protection Dank Report is required for all health care providers owning or practicing in the pain management clinic.

(g) A copy of the current Drug Enforcement Administration (DEA) card for all owners and all health care providers practicing in the pain management clinic that holds such license.

(3) Pain management clinic applications are valid for six month from initial receipt.

(4) The Board may require the owner and/or physician(s) practicing at the pain management clinic to appear for a personal interview before the Licensure Committee of the Board.

(5) The physical location of the applicant pain management clinic may be inspected before the application is considered. In addition, if a license is granted, the pain management clinic may be inspected at the Board's discretion at any time. The pain management clinic must have the necessary medical equipment to provide the medical treatment or service offered and must comply with sanitation standards.

(6) An application may be denied for any of the reasons authorized by law, or the Board may grant a license with restrictions.

O.C.G.A. Sections 43-34-5, 43-34-8, 43-34-282, 43-34-283, 43-34-284, 43-34-286, and 43-34-288.

360-8-.04 Denial of Licensure

(1) The Board may deny a license for a pain management clinic for any of the reasons set forth in O.C.G.A. Sections 43-34-8, 43-34-283 and/or 43-34-284.

(2) If the Board intends to deny the license, the applicant shall be allowed to appear before the board, if the applicant so requests, prior to the board making a final decision regarding the issuance of the license.

O.C.G.A. Sections 43-34-5, 43-34-8, 43-34-9, 43-34-282, 43-34-283, 43-34-284, 43-34-286, and 43-34-288.

360-8-.05 Notifications to the Board

The licensee shall notify the Board **within ten business days** upon the occurrence of any of the following:

(1) Permanent closing of a licensed pain management clinic;

(2) Change of ownership, management, or location of a licensed pain management clinic; the license is non-transferrable so the license immediately becomes void and inactive upon a change in ownership or location.

(3) Change of the physicians, physician assistants, and advanced practice nurses practicing in a licensed pain management clinic;

(4) Any theft or loss of drugs or devices of a licensed pain management clinic;

(5) Any known conviction of any employee of a licensed pain management clinic of any state or federal drug laws;

(6) Any known conviction based upon charges of fraud of any employee of a licensed pain management clinic; or

(7) Disasters, accidents, theft, destruction, or loss of records of a licensed pain management clinic required to be maintained by state or federal law or the rules of the board.

(8) If there is a death of a patient due to medication.

(9) Any malpractice settlements or disciplinary actions imposed against the owners or physicians practicing in the clinic

(10) Impairment of any physician, physician assistant or advanced practice registered nurse practicing in the clinic.

(11) Revocation of the license of another pain management clinic in this or other states owned by the same owners.

(12) Notification if the DEA of an owner of physician, physician assistant or advanced practice registered nurse is revoked or surrendered.

O.C.G.A. Sections 43-34-5, 43-34-283, and 43-34-285(8).

Rule 360-8-.06. Renewals and Continuing Education

(1) All active licenses must be renewed every two years. This may be done via the internet or through mail. A pain management clinic may not operate after the expiration date of the license. A license must be renewed biennially by June 30th of odd numbered years, and the licensee must establish satisfaction of Board-approved continuing education requirements to be eligible for renewal.

(2) Licensees have the right to obtain a late renewal of their licenses during the three (3) month period immediately following the expiration date. During this period, the penalty for late renewal applies. A pain management clinic may not operate after the expiration date of the license.

(3) The Board shall administratively revoke any license not renewed prior to the expiration of the late renewal period. Such revocation removes all rights and privileges to operate a pain management clinic in this State. A license that is so revoked may only be reinstated in the sole discretion of the Board. Revocation for failure to renew may be reported to the public and to other state licensing boards, and will be reported as a revocation for failure to renew. Revocation for failure to renew is not considered a disciplinary revocation. However, the license may only be reinstated through application.

(4) The fee for renewals and late renewals shall be designated in the fee schedule.

(5) All physicians owning and/or practicing in a pain management clinic must biennially document competence to the Board for purposes of renewal by providing one of the following:

(a) evidence of having obtained during the preceding two (2) years, twenty (20) hours of continuing medical education ("CME") pertaining to pain management or palliative medicine. Such CME must be an AMA/AOA PRA Category I CME, a board approved CME program, or any federally approved CME. The CME obtained pursuant to this rule may count towards the CME required for individual physician license renewal; or

(b) evidence of current certification or eligibility for certification in pain management or palliative medicine as approved by the Board. The Board recognizes certifications in pain medicine or palliative medicine by the American Board of Medical Specialties or the American Osteopathic Association, the American Board of Pain Medicine and the American Board of Interventional Pain Physicians.

O.C.G.A. Sections 43-34-5, 43-34-11, 43-34-283 and 43-34-287.

360-8-.07 Exemptions

Licensure under this Chapter shall not be required for any clinic or practice owned, in whole or in part, or operated by a hospital licensed pursuant to Chapter 7 of Title 31 or by a health system or any ambulatory surgical center, skilled nursing facility, hospice, or home health agency licensed pursuant to Chapter 7 of Title 31.

O.C.G.A. Sections 43-34-5, 43-34-282, and 43-34-283.

360-8-.08 Annual Reporting by Hospital Clinics

By March 1st of each year, every hospital that operates an outpatient clinic at its main facility or at any satellite facility with greater than 50 percent of such clinic's annual patient population being treated for chronic pain for non-terminal conditions by the use of Schedule II or III controlled substances shall submit a form approved by the Board to notify the Board of such clinic. Such notification shall identify the address of the outpatient clinic and the name or names of the physicians practicing at such clinic.

O.C.G.A. Sections 43-34-5, 43-34-282, and 43-34-289.

360-8-.09 Disciplinary Actions.
The Board can take disciplinary action including revocation against a licensed pain management clinic upon a finding that the owner or a physician practicing in the clinic has engaged in conduct identified in O.C.G.A. Section 43-34-8 as a ground for disciplinary action or as provided in O.C.G.A. Section 43-34-284.

360-8-.11 Reinstatement
(1) A license which is revoked for failure to renew may be reinstated upon the discretion of the Board upon receipt of a reinstatement application and fee.

(2) Applicants for reinstatement must be owned by a physician. If the clinic's original license was issued under the grandfather clause, the clinic must now meet the requirements of 360-8-.02, "Pain Management Clinic License Requirements."

(3) The Board may also require the applicant to meet with the Board or a committee of the Board.

(4) Each owner, principal, manager, agent, officer, and licensed health care practitioner must pass a criminal background check and further investigation, at the Board's discretion.

(5) This provision of this rule shall not be construed to limit the ability of the Board to impose sanctions for continuing to practice with an expired license.

(6) Reinstatement of the license is within the discretion of the Board.

(7) The Board may deny reinstatement if it determines that the granting or renewing of such license would not be in the public interest.

(8) The denial of reinstatement is not a contested case, but the applicant shall be entitled to an appearance before the Board.

O.C.G.A. Section 43-34-287