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# Notice of Rulemaking Hearing

*Hearings will be conducted in the manner prescribed by the Uniform Administrative Procedures Act, Tennessee Code Annotated, Section 4-5-204. For questions and copies of the notice, contact the person listed below.*

<b>Agency/Board/Commission:</b>	Department of Health
<b>Division:</b>	Pain Management Clinics
<b>Contact Person:</b>	Andrea Huddleston, Deputy General Counsel
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*Any Individuals with disabilities who wish to participate in these proceedings (to review these filings) and may require aid to facilitate such participation should contact the following at least 10 days prior to the hearing:*

<b>ADA Contact:</b>	ADA Coordinator
<b>Address:</b>	227 French Landing, Heritage Place, Nashville, Tennessee 37243
<b>Phone:</b>	(615) 532-3202 or (Toll Free) 1-800-778-4123
<b>Email:</b>	

**Hearing Location(s)** (for additional locations, copy and paste table)

Address 1:	Poplar Conference Room		
Address 2:	227 French Landing, Heritage Place, Nashville, Tennessee 37243		
City:	Nashville, Tennessee		
Zip:	37243		
Hearing Date :	December 1, 2011		
Hearing Time:	10:00 AM	<input checked="" type="checkbox"/> CST	<input type="checkbox"/> EST

**Additional Hearing Information:**

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**Revision Type (check all that apply):**

- Amendment
- New
- Repeal

Chapter Number	Chapter Title
1200-34-01	Pain Management Clinics
Rule Number	Rule Title
1200-34-01-.01	Purpose
1200-34-01-.02	Definitions
1200-34-01-.03	Certification, Renewal, and Reapplication
1200-34-01-.04	Fees
1200-34-01-.05	Inspections and Investigations
1200-34-01-.06	Notifications

1200-34-01-.07	Medical Director Responsibilities
1200-34-01-.08	Certificate Holder Responsibilities
1200-34-01-.09	Training Requirements
1200-34-01-.10	Civil Penalties

**Rule(s)** (ALL chapters and rules contained in filing must be listed. If needed, copy and paste additional tables to accommodate more than one chapter. Please enter only ONE Rule Number/Rule Title per row.)

1200-34-01	Pain Management Clinics.
1200-34-01-.01	Purpose.
1200-34-01-.02	Definitions.
1200-34-01-.03	Certification, Renewal, and Reapplication.
1200-34-01-.04	Fees.
1200-34-01-.05	Inspections and Investigations.
1200-34-01-.06	Notifications.
1200-34-01-.07	Medical Director Responsibilities.
1200-34-01-.08	Certificate Holder Responsibilities.
1200-34-01-.09	Training Requirements.
1200-34-01-.10	Civil Penalties.

1200-34-01-.01 Purpose.

The rules in this chapter implement the law relative to the certification and regulation of pain management clinics pursuant to T.C.A. § 63-1-301, et seq.

Authority: T.C.A. §§ 63-1-301 through 63-1-311.

1200-34-01-.02 Definitions.

In addition to the definitions contained in T.C.A. § 63-1-301, the following definitions are applicable to this chapter:

- (1) "Applicant" means a person who has submitted or is in the process of submitting an application to operate a pain management clinic;
- (2) "Department" means Department of Health;
- (3) "Commissioner" means Commissioner of Health;
- (4) "Certificate Holder" means the person who holds a certificate as a pain management clinic and is the owner or one of the owners of the clinic;
- (5) "Controlled Substance" means a drug, substance, or immediate precursor identified, defined or listed in title 39, chapter 17, part 4 and title 53, chapter 11;
- (6) "Health Care Provider" means a medical doctor licensed under Title 63, Chapter 6; osteopathic physician licensed under Title 63, Chapter 9; advanced practice nurse licensed under Title 63, Chapter 7, who meets the requirements contained in T.C.A. §63-7-126; or a physician assistant licensed under Title 63, Chapter 19;
- (7) "Medical Director" means an individual licensed as a physician under Title 63, Chapter 6 or Chapter 9 who practices in this State with an unrestricted, unencumbered license and who provides oversight relative to the operations of the pain management clinic;
- (8) "Medical Record" shall have the same meaning as set forth in T.C.A. § 63-1-117;
- (9) "Pain Management Clinic" or "Clinic" shall have the same meaning as set forth in T.C.A. § 63-1-301(5);
- (10) "Pain Management Services" means evaluation, diagnosis, or treatment for the prevention, reduction, or cessation of the symptom of pain through pharmacological, non pharmacological and other approaches;
- (11) "Patient Agreement" means a written document signed by the patient which, at a minimum, addresses patient responsibility for proper use and safeguarding of medications, describes the

clinic's drug screening policy, provides for prescriptions to be filled at only one pharmacy to be identified by the patient and addresses the use of controlled substances prescribed by other providers;

- (12) "Person" means any individual licensed under Title 63 who may own or form an entity providing pain management services, including but not limited to a professional corporation or professional limited liability company pursuant to applicable Tennessee laws and rules;
- (13) "Unencumbered" means an active license that is not suspended or on probation at the time the clinic owner(s) submit a pain management clinic application and that does not have any conditions, restrictions, or limitations.
- (14) "Urine Drug Screen" means urinalysis performed using a commercial test kit in a pain management or other clinic or at a reference laboratory that tests for the presence of at least the controlled substance(s) being prescribed as well as marijuana, naturally occurring opiates, benzodiazepines, cocaine and methamphetamines and may include any additional controlled substances at the discretion of the clinic.

Authority: T.C.A. §§ 63-1-301, 63-1-303, and 63-1-306.

1200-34-01-.03 Certification, Renewal, and Reapplication.

- (1) Certification.
  - (a) Beginning January 1, 2012, in order to obtain a certificate as a pain management clinic, an applicant shall submit the following to the Department:
    - 1. a completed application on a form prescribed by the Department;
    - 2. a completed form prescribed by the Department showing proof of having a medical director who is a physician who practices in Tennessee under an unrestricted and unencumbered license issued pursuant to T.C.A. § 63-6-201 or 63-9-104;
    - 3. proof of having obtained a Drug Enforcement Administration registration for the clinic, if required pursuant to federal laws and rules;
    - 4. proof of Drug Enforcement Administration registrations for the individual health care providers who provide pain management services at the clinic, if required pursuant to federal laws and rules;
    - 5. the results of a criminal background check or criminal background checks for all of the pain management clinic owners (whole or partial owners) to be sent directly from the vendor to the Department;
    - 6. a list of individuals who own, co-own, operate or otherwise provide pain management services in the clinic as an employee or a person with whom the clinic contracts for services;
    - 7. a disclosure of any license denial, restriction, or discipline imposed on an owner, co-owner, operator, individual who provides services at the clinic, employee of the clinic, or person with whom the clinic contracts for services pursuant to T.C.A. § 63-1-309;
    - 8. payment of the application fee and initial certification fee; and
    - 9. any other information requested by the Department.

- (b) An applicant shall submit a separate application for certification for each clinic location regardless of whether the clinic is operated under the same business name, ownership, or management as another clinic.
  - (c) If an applicant does not complete the application process within sixty (60) days after the Department receives the application because the application lacks the required information or fails to meet the prerequisites for certification, then the application will be closed, the application fee will not be refunded, and the applicant shall reapply for certification.
  - (d) Any application that is submitted to the Department may be withdrawn at any time prior to the grant or denial of certification; provided, however, that the application fee will not be refunded.
- (2) Renewal.
- (a) A pain management clinic certificate shall expire two (2) years from the date of issuance. All certificates shall be renewed on or before the last day of the two (2)- year certificate cycle.
  - (b) A certificate holder may renew a current, valid certificate prior to its expiration date by submitting the following to the Department:
    1. a renewal application form prescribed by the Department;
    2. the required renewal fee;
    3. proof of having a medical director who meets the requirements contained in these rules;
    4. an attestation that the clinic is not owned wholly or partly by a person who has been convicted of, pleaded nolo contendere to, or received deferred adjudication for:
      - (i) an offense that constitutes a felony; or
      - (ii) an offense that constitutes a misdemeanor, the facts of which relate to the distribution of illegal prescription drugs or a controlled substance as defined in §39-17-402; and
    5. any other information requested by the Department.
- (3) Late Renewal and Reapplication.
- (a) The pain management clinic may renew its certificate within ninety (90) days after the certificate expiration date with payment of the renewal fee and late renewal penalty fee, and after having completed all of the other requirements for renewal. After the ninety (90)- day grace period, the certificate holder may reapply for a new certificate.

Authority: T.C.A. §§ 63-1-303, 63-1-306, 63-1-307, and 63-1-308.

1200-34-01-.04 Fees.

(1)	Initial certificate fee.....	\$405.00
(2)	Renewal fee.....	\$405.00
(3)	Regulatory fee.....	\$10.00

- (4) The late renewal penalty fee is one hundred dollars (\$100.00) per month for each month or fraction of a month that renewal is late.

Authority: T.C.A. §§ 63-1-303, 63-1-306, and 63-1-308.

#### 1200-34-01-.05 Inspections and Investigations.

- (1) Upon the inspection of a pain management clinic by the boards regulating the health care providers working for or at the clinic, the owners, officers, employees, or authorized representatives of the pain management clinic shall allow board representatives access to the pain management clinic and the records contained therein, including, but not limited to medical records.
- (2) The owners, officers, employees or authorized representatives of the pain management clinic or independent contractors working at the pain management clinic shall provide copies of all documentation, including but not limited to medical records, requested by the board regulating the health care providers working for or at the clinic, in connection with an inspection or investigation of the pain management clinic in accordance with T.C.A. § 63-1-117.

Authority: T.C.A. §§ 63-1-303, 63-1-304, 63-1-305, and 63-1-306.

#### 1200-34-01-.06 Notifications.

- (1) In the event that there is a change in the majority ownership of the clinic, the certificate holder shall notify the Department within ten (10) business days after the change in majority ownership.
- (2) Within ten (10) business days after notification of the change in majority ownership, the certificate holder shall submit a new application for a certificate to the Department.
- (3) In the event that the clinic no longer has a medical director or the medical director no longer meets the requirements contained in the T.C.A. §§63-1-301 et seq. and these rules, the certificate holder shall notify the Department within ten (10) business days of the identity of another physician who will serve as the medical director for the clinic on a form prescribed by the Department. Failure to obtain a new medical director within ten (10) days may result in disciplinary action, including revocation of certificate.
- (4) A certificate holder shall notify the Department within ten (10) business days of the occurrence if any person who owns, co-owns, operates, provides pain management services in the clinic, is an employee of the clinic, or contracts with the clinic to provide services has been denied, held a restricted certificate, or been subject to disciplinary action relative to prescribing, dispensing, administering, supplying or selling a controlled substance.
- (5) In the event that the name of the clinic changes, the certificate holder shall notify the Department of the name change within ten (10) business days after the name change occurs.

Authority: T.C.A. §§ 63-1-303, 63-1-306, and 63-1-309.

#### 1200-34-01-.07 Medical Director Responsibilities.

- (1) Clinic Operation and Personnel.
  - (a) The medical director of a pain management clinic shall:
    1. oversee all of the pain management services provided at the clinic;
    2. be on-site at the clinic at least twenty percent (20%) of the clinic's weekly total number of operating hours;

3. ensure that each supervising physician for each of the health care providers working at the clinic complies with the supervision requirements contained in Tenn. Comp. Rules and Regulations Chapter 0880-03 and Chapter 0880-06, or Rule 1050-02-.15, as applicable. Should the medical director of the clinic serve as a health care provider's supervising physician, the medical director must ensure that he or she complies with Chapter 0880-03 and Chapter 0880-06. or Rule 1050-02-.15, as applicable;
4. ensure that all health care providers employed by or working at the pain management clinic comply with applicable state and federal laws and rules relative to the prescribing of controlled substances in the pain management clinic;
5. ensure the establishment of protocols for the health care providers employed by or working at the pain management clinic as provided in Tenn. Comp. Rules and Regulations Chapter 0880-03 and Chapter 0880-06 and ensure that providers comply with such protocols, as well as any other established policies and procedures;
6. ensure that there is an alternate or substitute medical director in the event that the medical director for the clinic is unable to fulfill his or her duties on a temporary basis because of illness, vacation, or unavailability;
7. establish quality assurance policies and procedures, which, at a minimum, include, but are not limited to:
  - (i) documentation of the background, training, licensure, and certifications for all pain management clinic staff providing patient care;
  - (ii) a written drug screening policy and compliance plan for patients to include random urine drug screening as clinically indicated, but at a minimum, upon each new admission and once every six (6) months thereafter;
  - (iii) evaluating and monitoring the quality and appropriateness of patient care, the methods of improving patient care as well as identifying and correcting deficiencies, and the opportunities to improve the clinic's performance and quality of care;
  - (iv) medication counts for all controlled substances prescribed to each patient, even those controlled substances prescribed by a health care provider other than the providers at the clinic;
  - (v) use of patient agreements and periodic review of such agreements;
  - (vi) health care provider access to and review of patient information contained in the controlled substance monitoring database in accordance with T.C.A. §§ 53-10-301 - 53-10-309, as clinically indicated, but at a minimum upon each new admission and once every six (6) months thereafter;
  - (vii) documentation of requests for records from other health care providers;
8. establish an infection control program to provide a sanitary environment for the prevention, control, and investigation of infections and communicable diseases, including, but not limited to:
  - (i) written infection control policies and procedures;
  - (ii) techniques and systems for identifying, reporting, investigating and controlling infections at the clinic;

- (iii) written policies and procedures relative to the use of aseptic techniques;
  - (iv) training for clinic staff providing direct patient care relative to infection control and aseptic techniques; and
  - (v) a log of incidents related to infectious and communicable diseases and the corrective action taken;
9. establish written policies and procedures for health and safety requirements at the clinic;
  10. ensure compliance with the patient safety standards established by the licensing boards for each health care provider;
  11. establish written policies and procedures to assure patient access to their medical records and continuity of care should the pain management clinic close.
- (2) Records, Reporting Requirements, and Patient Billing Procedures.
- (a) The medical director shall ensure that each health care provider employed by or working at a certified pain management clinic shall maintain complete and accurate medical records of patient consultation, examination, diagnosis, and treatment, which shall include, but not be limited to the following:
    1. patient medical history;
    2. physical examination;
    3. diagnostic, therapeutic, and laboratory results;
    4. evaluations and consultations;
    5. treatment objectives;
    6. documentation of informed consent and discussion of risks and benefits of treatment provided;
    7. treatments and treatment options;
    8. medications prescribed (including date, type, dosage and quantity prescribed);
    9. instructions and agreements;
    10. periodic reviews;
    11. reason for prescribing or dispensing more than a seventy-two (72) hour dose of controlled substances for the treatment of chronic nonmalignant pain;
    12. a notation indicating whether the controlled substance monitoring database had been accessed for a particular patient;
    13. copies of records, reports, or other documentation obtained from other health care providers;
    14. results of urine drug screens to be performed as clinically indicated, but at a minimum upon each new admission and once every six (6) months thereafter.

Authority: T.C.A. §§ 63-1-303, 63-1-306, and 63-1-309.



1200-34-01-.08 Certificate Holder Responsibilities.

- (1) The certificate holder shall ensure that adequate billing records are maintained onsite at the pain management clinic and shall ensure that adequate billing records are maintained for all patients and for all patient visits. Billing records shall be made for all methods of payment. Billing records shall be made available to the Department upon request.

Billing records shall include, but not be limited to the following:

- (a) the amount paid for the co-pay and/or remainder of services;
  - (b) method of payment;
  - (c) date of the delivery of services;
  - (d) date of payment; and
  - (e) description of services.
- (2) The certificate holder shall ensure that patient billing records and patient medical records shall be maintained for seven (7) years from the date of the patient's last treatment at the clinic.
  - (3) The certificate holder shall ensure that all health care providers employed by or working at the pain management clinic are properly licensed and certified at all times.
  - (4) The certificate holder shall ensure the delivery of quality care and quality services at the clinic.
  - (5) The certificate holder shall ensure that there is a medical director at each clinic who meets the requirements contained in laws and rules.
  - (6) The certificate holder shall ensure that all monetary transactions at the pain management clinic shall be in accordance with T.C.A. § 63-1-310 which provides that a pain management clinic may accept only a check, credit card or money order in payment for services provided at the clinic; except that payment may be made in cash for a co-pay, coinsurance or deductible when the remainder of the charge for the services will be submitted to the patient's insurance plan for reimbursement.
  - (7) The certificate holder shall ensure that patients have access to their medical records in the event that the clinic closes.

Authority: T.C.A. §§ 63-1-303, 63-1-306, and 63-1-310.

1200-34-01-.09 Training Requirements.

- (1) Each physician serving as the medical director at a clinic shall meet at least one (1) 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 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 ACGME or AOABOS;
  - (c) Subspecialty certification in pain management, hospice and palliative medicine or geriatric medicine recognized by the ABMS or AOABOS with a certificate of added qualification from the 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; or
  - (f) Any other subspecialty certification recognized by the Board of Medical Examiners and Board of Osteopathic Examination; or
  - (g) Completion of forty (40) hours of in-person, live-participatory AMA Category I or AOABOS Category I CME course in pain management completed within seven (7) years prior to employment or service with the certificate holder that addresses the following subject areas:
    - 1. the goals of treating both short term and ongoing pain treatment;
    - 2. controlled substance prescribing rules, including controlled substance agreements;
    - 3. drug screening or testing, including usefulness and limitations;
    - 4. the use of controlled substances in treating short-term and ongoing pain syndromes, including usefulness and limitations;
    - 5. evidence-based non-controlled pharmacological pain treatments;
    - 6. evidence-based non-pharmacological pain treatments;
    - 7. a complete pain medicine history and physical examination;
    - 8. appropriate progress note keeping;
    - 9. comorbidities with pain disorders, including psychiatric and addictive disorders;
    - 10. substance abuse and misuse including alcohol and diversion, and prevention of same;
    - 11. risk management;
    - 12. medical ethics.
- (2) Each health care provider providing pain management services at a clinic shall complete ten (10) hours in continuing education courses during each health care provider's licensure renewal cycle which shall be a part of the continuing education requirements established by each of the health care provider's respective boards. The ten (10) continuing education hours shall include, but not be limited to, the following topics relative to pain management:
- (a) prescribing controlled substances;
  - (b) drug screening or testing;
  - (c) pharmacological and non-pharmacological pain treatments;
  - (d) completing a physical examination and pain medicine history;
  - (e) maintaining appropriate progress notes;
  - (f) comorbidities with pain disorders; and
  - (g) substance abuse and misuse including alcohol and diversion, and prevention of same.

Authority: T.C.A. §63-1-303 and 63-1-306.

1200-34-01-.10 Civil Penalties.

- (1) With respect to any certified pain management clinic, the Department may, in addition to or in lieu of any other lawful disciplinary action, assess a civil penalty for each separate violation of a statute, rule or Commissioner order in accordance with the following schedule:

Violation	Penalty
T.C.A. § 63-1-134	\$0-\$1,000
T.C.A. § 63-1-306	\$0-\$1,000
T.C.A. § 63-1-309	\$0-\$1,000
T.C.A. § 63-1-310	\$0-\$1,000
Rule 1200-34-01-.06	\$0-\$1,000
Rule 1200-34-01-.08	\$0-\$1,000

- (2) Each day of continued violation may constitute a separate violation.
- (3) In determining the amount of any penalty to be assessed pursuant to this rule, the Department may consider such factors as the following:
- (a) Whether the amount imposed will be a substantial economic deterrent to the violator;
  - (b) The circumstances leading to the violation;
  - (c) The severity of the violation and the risk of harm to the public;
  - (d) The economic benefits gained by the violator as a result of noncompliance;
  - (e) The interest of the public; and
  - (f) The willfulness of the violation.

Authority: T.C.A. §§ 63-1-303 and 63-1-306.

I certify that the information included in this filing is an accurate and complete representation of the intent and scope of rulemaking proposed by the agency.

Date: 10/10/11

Signature: \_\_\_\_\_

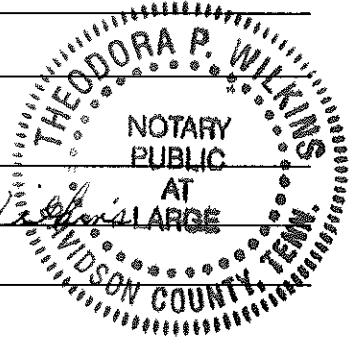
Name of Officer: Andrea Huddleston

Title of Officer: Deputy General Counsel  
Department of Health

Subscribed and sworn to before me on: 10/10/11

Notary Public Signature: Theodora P. Wilkins

My commission expires on: 11/7/11



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Filed with the Department of State on: 10/10/11

Tre Hargett

Tre Hargett  
Secretary of State

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