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## Rulemaking Hearing Rule(s) Filing Form

*Rulemaking Hearing Rules are rules filed after and as a result of a rulemaking hearing. T.C.A. § 4-5-205*

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

- Amendment  
 New  
 Repeal

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

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

(Place substance of rules and other info here. Statutory authority must be given for each rule change. For information on formatting rules go to <http://state.tn.us/sos/rules/1360/1360.htm>)

1200-34-01	Pain Management Clinics.
1200-34-01-.01	Purpose.
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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) "Substance Abuse Risk Assessment" means the assessment of an individual's unique risk for addiction, abuse, misuse, diversion or another adverse consequence resulting from prescription medication intended to treat pain. Substance abuse risk assessment may be accomplished through a standardized written or orally-delivered questionnaire or through a clinical interview.
- (14) "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.
- (15) "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, one or more of the opioids , 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.

- (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, 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, there is an alternate or substitute medical director meeting the same qualifications as a medical director under 1200-34-01-.09;
  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) use of substance abuse risk assessment tools upon new patient admission and periodic review or re-assessment;
    - (iv) 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;
    - (v) medication counts for any controlled substances prescribed by the clinic to the clinic's patients;
    - (vi) use of patient agreements and periodic review of such agreements;
    - (vii) 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;

(viii) 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, geriatric medicine, rheumatology, hematology, medical oncology, gynecologic oncology, infectious disease, pediatric hematology-oncology, or pediatric rheumatology 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) Completion of forty (40) hours of in-person, live-participatory AMA Category I or AOABOS Category I CME coursework in pain management completed within three (3) years prior to implementation of this rule or prior to serving as medical director for the clinic, whichever event is most recent. The coursework shall address the following 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 address at least one or more of the following topics related to pain management:

- (a) prescribing controlled substances;
- (b) drug screening or testing;
- (c) pharmacological and non-pharmacological pain management;
- (d) completing a pain management focused history and physical examination and maintaining appropriate progress notes;
- (e) comorbidities with pain syndromes; and
- (f) substance abuse and misuse including diversion, prevention of same, and risk assessment for abuse.

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.

\* If a roll-call vote was necessary, the vote by the Agency on these rulemaking hearing rules was as follows:

Board Member	Aye	No	Abstain	Absent	Signature (if required)
N/A					

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Department of Health on 12/01/2011, and is in compliance with the provisions of T.C.A. § 4-5-222.

I further certify the following:

Notice of Rulemaking Hearing filed with the Department of State on: 10/10/11

Rulemaking Hearing(s) Conducted on: (add more dates). 12/01/11

Date: 21 Dec 11

Signature: [Handwritten Signature]

Name of Officer: John J. Dreyzehner, MD, MPH, FACOEM

Title of Officer: Commissioner of Health

Subscribed and sworn to before me on: 12/21/11

Notary Public Signature: Theodora P. Wilkiri

My commission expires on: 11/3/15



All rulemaking hearing rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

[Handwritten Signature]  
Robert E. Cooper, Jr.  
Attorney General and Reporter  
12-21-11

Date

**Department of State Use Only**

Filed with the Department of State on: 12/27/11

Effective on: 3/26/12

[Handwritten Signature]  
Tre Hargett  
Secretary of State

RECEIVED  
2011 DEC 27 AM 11:50  
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PUBLICATIONS

## Public Hearing Comments

One copy of a document containing responses to comments made at the public hearing must accompany the filing pursuant to T.C.A. § 4-5-222. Agencies shall include only their responses to public hearing comments, which can be summarized. No letters of inquiry from parties questioning the rule will be accepted. When no comments are received at the public hearing, the agency need only draft a memorandum stating such and include it with the Rulemaking Hearing Rule filing. Minutes of the meeting will not be accepted. Transcripts are not acceptable.

Several commenters suggested that the definition of pain management clinic as provided both in the statute and the rules (1200-34-01-02) could be interpreted to implicate mental health treatment using benzodiazepines. The department has not made any change to this definition as it comes directly from the statute and appears to restrict the application to those clinics offering "pain management services". Pain management services is defined in the rules as the evaluation, diagnosis or treatment for the prevention, reduction, or cessation of the symptom of pain and thus would not include mental health treatment using benzodiazepines.

A comment was made suggesting that these rules should apply only to those clinics offering exclusively pain management services and should not apply to primary care clinics. The department has not made any change to the definition because, again, this language comes directly from the statute and any amendment or clarification is best left to the discretion of the legislature.

The Tennessee Medical Association commented that there was some confusion as to the definition of "pain management clinic" and whether the determination was based on the patients of each individual or the total of patients in a group practice. The department has not made any change to this definition, for the reasons set out above.

One commenter suggested that benzodiazepines should not be included in the definition of pain management clinic. However, this medication is included in the statute.

One commenter suggested that suboxone should be included in these regulations, inasmuch as suboxone contains opiates. However, the statute specifically excludes suboxone from the list of medications included in the definition of "pain management clinic".

Several commenters expressed concern regarding Rule 1200-34-01-.07 as it related to medication counts. The department has not deleted the language regarding medication counts entirely, as this is an important tool in ensuring appropriate usage of these drugs. The department has, however, deleted the requirement as to medication counts for controlled drugs prescribed by other providers.

Other commenters suggested that medication counts should only be required for Schedule II and III drugs. The department has declined this change, given that benzodiazepines (a Schedule IV drug) are contained within the definition of "pain management clinic". Further, these drugs are a frequent target of abuse and diversion.

One commenter suggested that urine drug screens should only be allowed to be performed by clinical reference laboratories. The department considered this suggestion, but deemed the incremental benefits of such a requirement to be outweighed by the economic and practical burdens it would place on clinics and, by extension, patients.

Another commenter suggested that urine drug screens should not be required at all and that such a requirement only benefits drug testing companies. The department has declined to delete this requirement inasmuch as drug screening is an important tool in monitoring safe and appropriate use of controlled drugs and the option of using a commercial test kit adequately addresses economic concerns.

One commenter suggested that Rule 1200-34-01-.07 should provide for more frequent checks of the controlled substance monitoring database. The department notes that the rule only sets a minimum frequency and more frequent checks are permissible under the rule and within the practitioner's discretion.

Another comment was made stating that neither dispensing issues nor delays in reporting to the controlled substance monitoring database were addressed. The department notes that the definition of "pain management clinic" includes patients to whom the named drugs are either prescribed or dispensed.

The following reflect changes in the rules based on public hearing comments received:

- Deleted requirement of medication counts on controlled drugs prescribed by other prescribers and amended to medication counts only on controlled drugs prescribed by clinic providers;
- Deleted language in urine drug screens definition regarding “naturally-occurring opiates” and amended to “one or more of the opioids”;
- Amended language in medical director training requirements regarding continuing medical education training option;
- Deleted option in medical director training requirements regarding any other subspecialty approved by the Board of Medical Examiners or Board of Osteopathic Examination;
- Clarified language regarding continuing education requirement for all clinic providers.

### Regulatory Flexibility Addendum

Pursuant to T.C.A. §§ 4-5-401 through 4-5-404, prior to initiating the rule making process as described in T.C.A. § 4-5-202(a)(3) and T.C.A. § 4-5-202(a), all agencies shall conduct a review of whether a proposed rule or rule affects small businesses.

## REGULATORY FLEXIBILITY ANALYSIS

### PAIN MANAGEMENT CLINICS; Rule No. 1200-34-01

Pursuant to the Regulatory Flexibility Act of 2007, T.C.A. §§ 4-5-401, *et seq.*, the Department of Health submits the following regulatory flexibility analysis:

#### Regulatory Flexibility Analysis:

(1) The extent to which the rule may overlap, duplicate, or conflict with other federal, state, and local governmental rules:

These rules do not overlap, duplicate or conflict with other rules. These rules effectuate and comport with T.C.A. § 63-1-301 *et seq.*

(2) Clarity, conciseness, and lack of ambiguity in the rule:

These rules are clear, concise and lack ambiguity.

(3) The establishment of flexible compliance and reporting requirements for small businesses:

The rules have established compliance and reporting requirements for all businesses, large or small, that meet the statutory definition of a pain management clinic. The reporting requirements are reasonable and attainable regardless of the size of the business and therefore do not require the establishment of any additional flexibility for small businesses.

(4) The establishment of friendly schedules or deadlines for compliance and reporting requirements for small businesses:

The schedules or deadlines for compliance and reporting requirements are the same for all businesses that meet the statutory definition of a pain management clinic.

(5) The consolidation or simplification of compliance or reporting requirements for small businesses:

The compliance and reporting requirements are the same for small and large businesses because they are established to ensure quality patient care, regardless of the size of the business providing pain management services.

(6) The establishment of performance standards for small businesses as opposed to design or operational standards required in the proposed rule:

These rules do not establish performance standards that are different for small businesses providing pain management services as opposed to larger businesses. The standards established by these rules are designed to ensure quality patient care and patient safety.

(7) The unnecessary creation of entry barriers or other effects that stifle entrepreneurial activity, curb innovation, or increase costs:

These rules do not establish unnecessary barriers that stifle entrepreneurial activity, curb innovation or increase costs.

## ECONOMIC IMPACT STATEMENT

### PAIN MANAGEMENT CLINICS; Rule No. 1200-34-01

- (1) The type or types of small businesses and an identification and estimate of the number of small businesses subject to the proposed rule that would bear the cost of, or directly benefit from the proposed rule:** It is estimated that there are approximately one hundred and fifty (150) pain management clinics currently operating in Tennessee that will need to obtain a certification by January 1, 2012. The number of those that qualify as small businesses, is unknown.
- (2) The projected reporting recordkeeping and other administrative costs required for compliance and the proposed rule, including the type of professional skills necessary for preparation of the report or record:** The recordkeeping costs and other administrative costs associated with compliance with the rules are unknown, but should be commensurate with the costs that any medical office would bear in maintaining patient medical records and billing records as well as ensuring appropriate medical care.
- (3) A statement of the probable effect on impacted small businesses and consumers:** The rules will impact small and large businesses alike by requiring those businesses that constitute a pain management clinic as defined by law, to obtain certification and abide by Commissioner rules.
- (4) A description of any less burdensome, less intrusive or less costly alternative methods of achieving the purpose and objectives of the proposed rule that may exist, and to what extent the alternative means might be less burdensome to small business:** There are not any less burdensome, less intrusive or less costly alternative methods to achieve the purpose and objectives contained in the rules.
- (5) A comparison of the proposed rule with any federal or state counterparts:** These rules are comparable to rules promulgated in Louisiana, Florida, Texas, and Ohio.
- (6) Analysis of the effect of the possible exemption of small businesses from all or any part of the requirements contained in the proposed rule:** Small businesses should not be exempt from any portion of the rules that are geared toward ensuring quality patient care and patient safety. To exempt small businesses from those requirements may dilute the purpose of the law which is to ensure that pain management clinics are prescribing controlled substances based on a medical condition and without leading to patient addiction to the medications.

### **Impact on Local Governments**

Pursuant to T.C.A. §§ 4-5-220 and 4-5-228 “any rule proposed to be promulgated shall state in a simple declarative sentence, without additional comments on the merits of the policy of the rules or regulation, whether the rule or regulation may have a projected impact on local governments.” (See Public Chapter Number 1070 (<http://state.tn.us/sos/acts/106/pub/pc1070.pdf>) of the 2010 Session of the General Assembly)

(Insert statement here)

These rules are not expected to have any impact on local governments.

**Additional Information Required by Joint Government Operations Committee**

All agencies, upon filing a rule, must also submit the following pursuant to TCA 4-5-226(i)(1).

- (A)** A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

Promulgation of these rules is required pursuant to Public Chapter 340 of the 2011 Tennessee General Assembly, as codified in T.C.A. § 63-1-301 et seq. Specifically, T.C.A. § 63-1-303 requires the commissioner of health, in consultation with the board of medical examiners, board of osteopathic examination, board of nursing and the committee on physician assistants, to promulgate rules necessary to implement this part. Pursuant to that part, rules may be adopted to address the following topics, among others: operation of the clinic, personnel requirements of the clinic, training requirements for clinic providers, patient records, standards to ensure quality of patient care, infection control, health and safety standards, certificate application and renewal procedures and requirements, data collection and reporting requirements, inspection and complaint investigations and patient billing procedures.

- (B)** A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

T.C.A. § 63-1-301 et seq

- (C)** Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

Licensees of the Board of Medical Examiners, Board of Osteopathic Examination, Board of Nursing and Committee on Physician Assistants who own, operate, or practice in a pain management clinic.

- (D)** Identification of any opinions of the attorney general and reporter or any judicial ruling that directly relates to the rule;

Attorney General's Opinion No.: 07-116 dated August 8, 2007 regarding Provision of Medical Services by a Certified Nurse Practitioner, Registered Nurse, Advance Practice Nurse, Licensed Practical Nurse or Physician Assistant

- (E)** An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars (\$500,000), whichever is less;

The rules are not expected to have more than a minimal impact.

- (F)** Identification of the appropriate agency representative or representatives, possessing substantial knowledge and understanding of the rule;

Andrea Huddleston  
Department of Health  
Office of General Counsel

- (G)** Identification of the appropriate agency representative or representatives who will explain the rule at a scheduled meeting of the committees;

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Department of Health  
Office of General Counsel

- (H)** Office address, telephone number, and email address of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

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(I) Any additional information relevant to the rule proposed for continuation that the committee requests.

None.