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Emergency Rule Filing Form

Emergency rules are effective from date of filing for a period of up to 180 days.

Agency/Board/Commission:	Department of Health
Division:	Pain Management Clinics
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Rule Type:
X Emergency Rule

Revision Type (check all that apply):
___ Amendment
X New
X Repeal

Statement of Necessity:

The Commissioner of the Tennessee Department of Health is proposing to promulgate emergency rules for the Tennessee Division of Pain Management Clinics pursuant to Tenn. Code Ann. § 4-5-208 (a)(1) and (a)(5) because he finds that "[a]n immediate danger to the public health, safety [and] welfare exists," and no other form of rulemaking authorized by Part 4, Chapter 5 of the Tennessee Code would adequately protect the public in the required timeframe. Emergency rules are required because in Public Chapter 1033 the 109th Tennessee General Assembly set forth a date of July 1, 2017, for the dissolution of the certification system for pain management clinics and the start to the licensure system for pain management clinics. Emergency rulemaking authority is expressly authorized in Tenn. Code Ann. § 63-1-306(k) under the statutes as currently enacted, and will exist at Tenn. Code Ann. § 63-1-306(e) under the statutes as enacted after July 1, 2017.

The proposed rules will repeal the entire existing rule chapter, which relates to the current certification of pain management clinics, and create a new set of rules regarding the process of applying for licensure for pain management clinics which was created by and is required by Public Chapter 1033. These rules will govern the process and requirements involved in applying for the license, as well as direct the Department on requirements to timely inspect the clinic and grant or deny a license. Additionally, pursuant to the new abilities and requirements granted both the Commissioner as regulator and the medical directors as licensees under Public Chapter 1033, these rules will: (1) inform medical directors of their responsibilities under the new licensure structure; (2) clearly outline procedures for licensure discipline and how to obtain an order of compliance thereafter; (3) give guidance for inactivation; (4) create a grace period in which a pain clinic can operate in the unplanned absence of the licensed medical director; (5) list acts or conditions that will result in the Commissioner suspending admissions or treatment at a clinic; and (6) list what evidence must be submitted by unlicensed clinics attempting to avoid a presumption they are operating as an unlicensed pain management clinic.

The proposed rules are necessary following the Legislature's determination that the current statutory authority regarding pain management clinics was insufficient for the task of regulating an area so directly tied to the opioid

epidemic that Tennessee is currently facing. Public Chapter 1033 tasked the Department with promulgating rules in numerous areas which were not previously regulated. The Commissioner is acutely aware of the opioid epidemic and the regulatory requirements placed on the Department by Public Chapter 1033. In a recent study conducted by the Centers for Disease Control and Prevention, it was found that the probability of long-term opioid use increases most sharply after the first five days of taking opioids and then again after the first month of use. Tennessee's vital statistics data indicates that from 2014 to 2015, drug overdose deaths in Tennessee rose by 14%, increasing from 1,263 to 1,451. Furthermore, in 2014, for every drug overdose death, more than 15 nonfatal overdoses were identified in state hospital discharge data. The Commissioner understands that pain management clinics and their regulation play vital roles in ensuring that patients in Tennessee have access to qualified practitioners for needed treatment, while working to lessen the addiction rate in Tennessee.

The Commissioner believes that the proposed rules implement the additional authority and strengthened standards of the new statutory structure intended by the Tennessee General Assembly in a manner that will better protect the public health, safety, and welfare. It is imperative that the Commissioner set forth these rules in order to adequately regulate pain management clinics because of the danger to the public health, safety, and welfare posed by the opioid epidemic.

Public Chapter 1033 sets a date of July 1, 2017 for the promulgation of the new regulatory structure. Beginning July 1, 2017, pursuant to Public Chapter 1033, "no person shall own or operate a pain management clinic unless the medical director obtains a license from the Department." It is imperative that rules be in place to guide the public, the Commissioner and Department, and those practitioners in the field of pain management as to the requirements and processes under the new statutory structure.

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 make sure that **ALL** new rule and repealed rule numbers are listed in the chart below. 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

Chapter Number	**Chapter Title**
1200-34-01	Pain Management Clinics
Rule Number	**Rule Title**
1200-34-01-.01	Definitions
1200-34-01-.02	Licensure Process
1200-34-01-.03	Application Review, Approval, and Denial
1200-34-01-.04	Licensure Renewal
1200-34-01-.05	Exemptions
1200-34-01-.06	Fees
1200-34-01-.07	Licensure Inactivation
1200-34-01-.08	Inspections and Investigations
1200-34-01-.09	Notifications and Reporting
1200-34-01-.10	Medical Director Responsibilities
1200-34-01-.11	Training Requirements
1200-34-01-.12	Licensure Discipline and Civil Penalties
1200-34-01-.13	Commissioner Suspensions of Treatment of New or Existing Patients
1200-34-01-.14	Unlicensed Pain Management Clinics

1200-34-01-.15	Financial Requirement
1200-34-01-.16	Advertising
1200-34-01-.17	Infectious Disease and Building Standards

(Place substance of rules and other info here. Please be sure to include a detailed explanation of the changes being made to the listed rule(s). Statutory authority must be given for each rule change. For information on formatting rules go to http://tn.gov/sos/pub/Rulemaking%20Guidelines_July2014.pdf)

Chapter 1200-34-01
Pain Management Clinics

Emergency Rules

Repeal and Rewrite

Rule Chapter 1200-34-01 Pain Management Clinics is being repealed and rewritten, including the Table of Contents but not the Chapter Title, and shall now read:

1200-34-01-.01 Definitions
1200-34-01-.02 Licensure Process
1200-34-01-.03 Application Review, Approval, and Denial
1200-34-01-.04 Licensure Renewal
1200-34-01-.05 Exemptions
1200-34-01-.06 Fees
1200-34-01-.07 Licensure Inactivation
1200-34-01-.08 Inspections and Investigations
1200-34-01-.09 Notifications and Reporting
1200-34-01-.10 Medical Director Responsibilities
1200-34-01-.11 Training Requirements
1200-34-01-.12 Licensure Discipline and Civil Penalties
1200-34-01-.13 Commissioner Suspensions of Treatment of New or Existing Patients
1200-34-01-.14 Unlicensed Pain Management Clinics
1200-34-01-.15 Financial Requirement
1200-34-01-.16 Advertising
1200-34-01-.17 Infectious Disease and Building Standards

1200-34-01-.01 Definitions

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

(1) "Administrative Office" means the Tennessee Department of Health, Division of Health Related Boards, at which the Pain Management Clinic registry office for administrative support of daily functions is located at 665 Mainstream Drive, Nashville, TN 37243.

(2) "Adjacent" means within 1,000 feet.

(3) "Advisory Panel" means a panel selected by the Commissioner and convened at his or her discretion for advisory purposes and to issue recommendations to the Commissioner.

(4) "Applicant" means a medical doctor licensed under Title 63, Chapter 6 or an osteopathic physician licensed under Title 63, Chapter 9, who has submitted or is in the process of submitting an application for a license to operate a pain management clinic.

(5) "Certificate Holder" means a medical doctor licensed under Title 63, Chapter 6; osteopathic physician licensed under Title 63, Chapter 9; advanced practice registered 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, who practices in this state with an unrestricted, unencumbered license, who was issued a pain management clinic certificate prior to July 1, 2017, and who may continue to operate that certificate as a license under Title 63, Chapter 1 until its expiration.

(6) "Commissioner" means the Commissioner of Health or his designee.

(7) "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.

(8) "Department" means the Tennessee Department of Health.

(9) "Licensee" means any person licensed under Title 63 by one of the Tennessee Department of Health, Division of Health Related Boards.

(10) "Medical Director" means an individual who meets the definitions of Title 63, Chapter 1, Section 301(5) and 301(9), and holds a license to operate a pain management clinic issued by the Department.

(11) "Medical Record" shall have the same meaning as set forth in T.C.A. § 63-2-101.

(12) "Owner" means a medical doctor licensed under Title 63, Chapter 6; osteopathic physician licensed under Title 63, Chapter 9; advanced practice registered 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.

(13) "Pain 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 that prescriptions for controlled substances may only be filled at one pharmacy to be identified by the patient, and addresses the use of controlled substances prescribed by other providers.

(14) "Pain Management Clinic" means a privately-owned clinic, facility, or office in which the majority of patients are prescribed or dispensed opioids, benzodiazepines, barbiturates, or carisoprodol for ninety (90) days or more in a twelve-month period for pain unrelated to cancer or palliative care. For purposes of determining if a clinic, facility, or office qualifies as a pain management clinic, the entire clinic, facility, or office caseload of patients who received medical care services from all medical doctors, osteopathic physicians, advance practice registered nurses, and physician assistants who serve in the clinic, facility, or office shall be counted. Pain Management clinic also means a privately-owned clinic, facility, or office which advertises in any medium for pain management services of any type.

(15) "Substance Use Disorder 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 use disorder risk assessment may be accomplished through a standardized written or orally-delivered questionnaire or through a clinical interview.

(16) "Unencumbered" means an active license that is not suspended or on probation and that does not have any conditions, restrictions, or limitations.

(17) "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, 63-1-306, 63-1-316, and 63-1-318.

1200-34-01-.02 Licensure Process

(1) Before operating or practicing in a pain management clinic as defined in T.C.A. § 63-1-301(8) on or after July 1, 2017, the Medical Director of that clinic must first obtain a Pain Management Clinic License from the Department.

(2) An applicant shall obtain an application from the Administrative Office, respond truthfully and completely to every question or request for information contained in the application, and submit it along with all documentation and fees required by the application and rules to the Administrative Office. When available, this may be accomplished through an online application.

(3) An applicant shall submit all of the following as part of their application:

(a) The initial licensure fee, state regulatory fee, and inspection fee provided in rule 1200-34-01-.05;

(b) Two letters, from a medical doctor licensed under Title 63, Chapter 6 or an osteopathic physician licensed under Title 63, Chapter 9, vouching for the good moral character of the Medical Director;

(c) Proof that the Medical Director meets the statutory requirements defined in T.C.A. § 63-1-301(9) to be a pain management specialist;

(d) The names, and if licensed by the Department, the licensure numbers, of every person with any ownership interest in the pain management clinic for which the applicant seeks licensure and each person's percentage of ownership;

(e) Information regarding the form of business entity the clinic will be established as and whether there is already an existing medical practice at the clinic's proposed location;

(f) The physical mailing address of the clinic for which the applicant seeks licensure;

(g) Identification of any other licenses or applications, including pending or denied applications, for pain management clinics associated with the applicant including as an owner, employee or contractor;

(h) The names, and if licensed by the Department, the licensure numbers, of every employee of the clinic;

(i) The names, and if licensed by the Department, the license numbers of every person with whom the clinic has contracted for services, including persons involved in daily operation of the clinic;

(j) The Drug Enforcement Administration ("DEA") Registration numbers for each individual employed by the clinic or with whom the clinic has contracted who holds a DEA registration;

(k) The result of a criminal background check, submitted to the Administrative Office, directly from the vendor identified in the application, for the following personnel:

1. The Medical Director;

2. Each person with any ownership interest;

3. Each person who holds a DEA registration who will be providing services at that clinic; and

4. Where any disclosure required in 1200-34-01-.02(4)(a)-(d) has yielded an affirmative answer, that employee or individual or company with whom the clinic has contracted who has contact with patients or onsite patient information and/or has management responsibilities;

(l) The name, license number, and address, of every pharmacy in which either the Medical Director or any owner of the clinic has any ownership interest that is greater than one percent (1%), and the percentage of that ownership interest;

(m) Proof that all supervising physicians who are supervising any of the advanced practice registered nurses or physician assistants providing services at the pain management clinic are pain management specialists;

(n) A statement of verification that the Medical Director has read and understood the statutes and rules governing pain management clinics, as well as the Tennessee Chronic Pain Guidelines (http://www.tn.gov/assets/entities/health/attachments/ChronicPainGuidelines.pdf), and the Tennessee Pain Clinic Guidelines (http://www.tn.gov/assets/entities/health/attachments/Pain_Clinic_Guidelines.pdf); and

(o) Any other information requested by the Department.

(4) An applicant shall disclose the circumstances and produce any documentation requested by the Department surrounding any of the following:

(a) Whether any owner has ever been convicted of, pled nolo contendere to, or received deferred adjudication for an offense that constitutes a felony;

(b) Whether any employee, or person with whom the clinic contracts who has contact with patients or onsite patient information and/or has management responsibilities has ever been convicted of any felony;

(c) Whether any owner, employee, or person with whom the clinic contracts who has contact with patients or onsite patient information and/or has management responsibilities is under indictment for any offense involving the sale, diversion, or dispensing of controlled substances under any state or federal law;

(d) Whether any owner, employee, or person with whom the clinic contracts who has contact with patients or onsite patient information and/or has management responsibilities has ever been convicted of any offense involving the sale, diversion, or dispensing of controlled substances under any state or federal law;

(e) Whether any owner, employee, or person with whom the clinic contracts who has contact with patients or onsite patient information and/or has management responsibilities has ever applied for or held any license issued by any jurisdiction, under which that license holder may prescribe, dispense, administer, supply, or sell a controlled substance, which has been restricted, disciplined, or denied;

(f) Whether any owner, employee, or person with whom the clinic contracts who has contact with patients or onsite patient information and/or has management responsibilities has ever been subject to disciplinary action by any licensing entity for conduct that was the result of inappropriately prescribing, dispensing, administering, supplying, or selling a controlled substance;

(g) Loss or restriction of privileges at any hospital or health care facility on the part of the Medical Director;

(h) Whether any owner, medical director, employee or person with whom the clinic contracts who has contact with patients or onsite patient information and/or has management responsibilities is under any board order requiring advocacy from a professional assistance program that monitors for substance abuse;

(i) Whether any owner, employee, or person with whom the clinic contracts who has contact with patients or onsite patient information and/or has management responsibilities has ever had a DEA registration that was surrendered for cause or disciplined.

(5) Where appropriate, the applicant shall cause to be submitted from the DEA, documentation regarding any surrender for cause, revocation, or other discipline of a DEA registration certificate.

(6) Application review and licensure decisions shall be governed by rule 1200-34-01-.03.

(7) An applicant shall submit a separate application for licensure for each clinic location regardless of whether the clinic is operated under the same business name, ownership, or management as another clinic. Each clinic location shall be licensed separately.

Authority: T.C.A. §§ 63-1-301, 63-1-303, 63-1-306, 63-1-309, 63-1-316, and 63-1-401.

1200-34-01-.03 Application Review, Approval, and Denial

(1) Administrative staff shall determine when an application file is complete.

(2) If an applicant does not complete the application process within ninety (90) days after the Department receives the application because the application lacks the required information or fails to meet the prerequisites for licensure, then the application will be closed, the licensure fee will not be refunded, and the applicant shall be required to reapply in order to pursue licensure.

(3) Any applicant who has successfully complied with all requirements governing the licensure process shall then be subject to an inspection of the clinic. The applicant must successfully pass the inspection prior to being eligible for licensure. Upon inspection, if evidence is found that any practice act or any requirement of these rules has been violated, the application may be denied, and the Department may use the evidence in a separate disciplinary matter against any of the licensees involved. Representations in the application which are deemed by the Department to be untrue or incompletely disclosed may also subject the applicant to disciplinary action before his or her licensing board, and may subject the pain management clinic application to denial, and a previously issued pain management clinic license or certificate to revocation or other disciplinary action.

(4) The Department will conduct its eligibility inspection within 90 business days from the date the application is deemed complete by administrative staff. If the applicant does not initially pass the inspection, the Department, at its discretion, may re-inspect the clinic subject to a payment of a re-inspection fee. Such re-inspection may take place beyond the 90 business days from the application completion date.

(5) If the application is denied, or the license is issued with conditions or restrictions, the following shall occur:

(a) A notification of the denial shall be sent from the Administrative Office by certified mail, return receipt requested, which shall contain reasons for the denial, condition, or restriction, as well as the statutory or rule authority for the denial, condition, or restriction.

(b) The notification, when appropriate, shall also contain a statement of the applicant's right to a contested case hearing under the Tennessee Administrative Procedures Act (T.C.A. §4-5-101 et. seq.) to contest the denial, condition, or restriction. An applicant has a right to a contested case hearing only if the denial, condition, or restriction was based upon subjective or discretionary criteria, and only if the request for the contested case hearing is made in writing and received by the Department's Office of General Counsel on or before the thirtieth (30th) day after receipt of the notice by the applicant.

(6) If the Department finds that it has erred in the issuance of a license, the Administrative Office will give written notice by certified mail of its intent to revoke the license. The notice will allow the Medical Director the opportunity to meet the requirements for licensure within thirty (30) days from the date of receipt of the notification. If the Medical Director does not concur with the stated reason and the intent to revoke the license, the Medical Director shall have the right to proceed according to T.C.A. 63-1-316(j).

Authority: T.C.A. §§ 63-1-303, 63-1-304, and 63-1-316.

1200-34-01-.04 Licensure Renewal

(1) Renewal.

(a) A pain management clinic license, unless another time is given at the time of licensure, shall expire two (2) years from the date of issuance. All licenses must be renewed on or before the last day of the two (2) year licensure cycle.

(b) A Medical Director may renew a current, valid license 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 and is a pain management specialist;

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;

5. an attestation that no owner, employee or person with whom the clinic contracts who has contact with patients or onsite patient information and/or has management responsibilities:

   (i) has been convicted of an offense involving the sale, distribution, or dispensing of controlled substances under state or federal law;

   (ii) has been denied, by any jurisdiction, a license under which that person may prescribe, dispense, administer, supply, or sell a controlled substance;

   (iii) has been subject to disciplinary action by any licensing entity for conduct that was the result of inappropriately prescribing, dispensing, administering, supplying, or selling a controlled substance;

6. proof the Medical Director has maintained the status of pain management specialist;

7. any other information requested by the Department.

(2) A clinic whose certificate was renewed before July 1, 2017, shall have its Medical Director apply as a new applicant for licensure under this part, and must meet all requirements for licensure in order to continue operation. In order for the Department to timely process the application and inspect the clinic, the Medical Director must have submitted a complete application as a new applicant a minimum of ninety (90) days before the expiration of the clinic's certificate. For purposes of an expired certificate, there shall be no grace period for operation between expiration of the certificate and the initial licensure date.

(3) Late Renewal and Reapplication.

The pain management clinic may renew its license within sixty (60) days after the license 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 sixty (60) day grace period, the Medical Director may reapply for a new license, but must cease operations until such time as a new license is granted.

Authority: T.C.A. §§ 63-1-303, 63-1-306, 63-1-307, 63-1-308, 63-1-309, and 63-1-316.

1200-34-01-.05 Exemptions

(1) A pain management clinic is not a clinic, facility, or office which provides interventional pain management as defined in § 63-6-244 and whose clinic, facility, or office does not provide chronic non-malignant pain treatment to a majority of the patients of a clinic, facility, or office for ninety (90) days or more in a twelve-month period.

(2) A pain management clinic is not a medical or dental school, an osteopathic medical school, a nursing school, a physician assistant program, or an outpatient clinic associated with any of the foregoing schools or programs, including, but not limited to, clinics that have an agreement to train residents by members of that clinic who are appointed as adjunct faculty of the school or program.

(3) A pain management clinic is not a hospital as defined in § 68-11-201, including any outpatient facility or clinic of a hospital if such outpatient facility or clinic is regulated under title 68.

(4) A pain management clinic is not hospice services as defined in § 68-11-201.

(5) A pain management clinic is not a nursing home as defined in § 68-11-201.

(6) A pain management clinic is not a facility maintained or operated by this state.

(7) A pain management clinic is not a hospital or clinic maintained or operated by the federal government.

Authority: T.C.A. §§ 63-1-301 and 63-1-302.

1200-34-01-.06 Fees

(1) Initial licensure fee.....$1,500.00

(2) Renewal fee.....$1,500.00

(3) State Regulatory fee.....$ 10.00

(4) Inspection fee.....$1,500.00

(5) Re-inspection fee.....$1,000.00

(6) The late renewal penalty fee is five hundred dollars ($500.00) per month for each month or fraction of a month that renewal is late.

(7) The Inspection fee is to be paid with the initial licensure fee upon application, and again biennially within thirty (30) days following the random biennial inspection.

(8) A re-inspection fee shall be assessed and shall be paid by the Medical Director any time an investigator is forced to return to the clinic to complete his or her inspection due to actions or omissions on the part of the Medical Director or anyone working in the pain management clinic. Payment of the re-inspection fee must be remitted to the Department within thirty (30) days of the re-inspection date.

Authority: T.C.A. §§ 63-1-303, 63-1-306, 63-1-308, and 63-1-316.

1200-34-01-.07 Licensure Inactivation

(1) If the Medical Director and/or owners of a pain management clinic determine that the site will close and cease operation, or that the site will no longer provide services that meet the statutory definition of a pain management clinic, the Medical Director must notify the Department. If the Department has not been notified of a closure and appears at the clinic for an inspection or investigation, the Medical Director may be held responsible for the inspection fee or the actual cost of the investigation.

(2) The Medical Director shall notify the Department and inactivate the pain management clinic license as follows:

(a) Obtain from the Administrative Office an official inactivation form;

(b) Complete and submit that form, along with any supporting documentation that may be required by the Administrative Office.

(3) Upon successful completion and submission of the required forms to the administrative office, the Department shall register the pain management clinic license as inactivated. A clinic that has inactivated its license shall not operate as a pain management clinic, and doing so shall subject the practitioners in that clinic to penalties from the Department.

Authority: T.C.A. §§ 63-1-303, 63-1-304, 63-1-305, and 63-1-316.

1200-34-01-.08 Inspections and Investigations

(1) Upon application for licensure as a pain management clinic, the Medical Director shall pay the Inspection fee and permit the Department to conduct an inspection of the clinic which may include, in addition to inspection of the physical site, review of medical records, business records, and any other documents the Department may require.

(2) The Medical Director, owners, officers, employees, authorized representatives of the pain management clinic, and independent contractors working at the pain management clinic shall allow Department representatives access to the pain management clinic and shall provide copies of all documentation, including but not limited to medical records and business records, requested by the Department, in connection with an inspection or investigation of the pain management clinic. The Medical Director shall be responsible for the pain management clinic remitting payment of the biennial inspection fee to the Department within thirty (30) days of the inspection.

(3) Failure or refusal of the Medical Director to grant the Department access to the pain management clinic to perform an audit, inspection, or investigation shall constitute grounds for immediate suspension of the pain management clinic's license as contemplated in T.C.A. § 4-5-320(c).

Authority: T.C.A. §§ 63-1-303, 63-1-304, 63-1-305, and 36-1-316.

1200-34-01-.09 Notifications and Reporting

(1) A pain management clinic license shall not be assignable or transferable. However, the Department recognizes that some circumstances may cause a Medical Director to depart from a clinic. While best practice would be for the new Medical Director to seek licensure from the Department while the current Medical Director is still actively serving at his clinic's licensed location, in the event that the current Medical Director no longer meets the requirements contained in T.C.A. §§63-1-301 et seq. and these rules to be a Medical Director, or departs from a clinic, the Department will allow a grace period during which a clinic may continue to operate provided the following occurs:

(a) The clinic may continue to operate on the current Medical Director's license for a grace period of up to thirty (30) calendar days from the date that the current Medical Director no longer met the requirements contained in T.C.A. §§63-1-301 et seq. and these rules to be a Medical Director, or the date the current Medical Director departs the clinic, provided the clinic notifies the Department, on a form prescribed by the Department, within ten (10) business days of the identity of another pain management specialist who will serve as the interim Medical Director for the clinic;

(b) During this grace period after which the current Medical Director no longer meets the requirements of this part or has departed from the clinic, which shall total no more than thirty (30) calendar days, both the current Medical Director and the interim Medical Director, are liable for any actions or inactions occurring at or caused by the pain management clinic;

(c) The new Medical Director shall submit a completed pain management clinic application immediately upon agreement to assume the duties of medical director at the clinic;

(d) Should the clinic have difficulty obtaining a new medical director, it may apply for a waiver of up to an additional sixty (60) calendar days in which to operate with the interim Medical Director. The waiver form shall be promulgated by the Department. The waiver will only be granted upon good cause shown, demonstrated reasonable efforts to locate and retain a new medical director, and a reasonable belief by the Department that public health will be harmed by not granting the waiver;

(e) Upon expiration of thirty (30) calendar days, or upon the expiration of ninety (90) calendar days if a waiver was applied for and granted, if a new pain management clinic license has not been issued by the Department, the clinic must cease operation. Each day of continued operation would constitute a separate violation for any licensee who continues to work in the clinic; and

(f) Notwithstanding these provisions, if the current Medical Director of a clinic chooses to inactivate the license, the clinic must cease operating as a pain management clinic immediately upon inactivation. Prior to inactivating the license, the Medical Director shall have the responsibility to notify his patients and arrange for continuity of care.

(2) The Medical Director shall notify the Department within thirty (30) days of the occurrence if any of the following occur to any person who owns, is an employee of, or is a person with whom the clinic contracts who has contact with patients or onsite patient information and/or has management responsibilities:

(a) that person has applied for any state or federal license, registration, or certificate that has been denied;

(b) that person has held any state or federal license, registration, or certificate that has been restricted or subject to disciplinary action relative to prescribing, dispensing, administering, supplying or selling a controlled substance; or

(c) that person has been convicted of a felony or any offense involving the sale, diversion, or dispensing of controlled substances under state or federal law related to operation of or work in the clinic.

(3) In the event that the name of the clinic changes, the Medical Director shall notify the Department of the name change within ten (10) business days after the name change occurs.

(4) In addition to the reporting requirements above, the Medical Director shall make an annual report to the Department on a form promulgated for such reporting. The report shall be due to the Department sixty (60) days prior to the pain management clinic's certificate or license anniversary date and shall cover the previous twelve (12) months. The report shall include the following:

(a) Whether the pain management clinic is associated with a hospital;

(b) Whether the pain management clinic is adjacent to a pharmacy;

(c) The names of each physician, physician assistant, and advanced practice registered nurse who worked in the clinic each month during the preceding year along with their license numbers;

(d) The number of patients seen by the clinic for each month in the preceding year;

(e) The number of patients seen in each month who received controlled substances for chronic nonmalignant pain from a practitioner at the clinic;

(f) A list of all drug samples which were dispensed in the preceding year and a copy of the clinic's log pursuant to Title 21 C.F.R. § 1304.11, with regard to those samples;

(g) A list of all owners of the clinic and their percentage of interest in the clinic for each month in the preceding year;

(h) The names of any employees hired or separated within the preceding year as well as the license number of that employee if any are or were licensees; and

(i) A summary of each advertisement paid for in consideration of any kind.

Authority: T.C.A. §§ 63-1-303, 63-1-306, 63-1-309, 63-1-316, 63-1-317, and 63-1-319.

1200-34-01-.10 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, and is a pain management specialist;

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. identify a pain management specialist who has agreed to provide coverage in the event that the Medical Director is unable to fulfill his or her duties on a temporary basis because of illness, vacation, or unavailability. Such coverage may be provided on a temporary, short-term basis and serving in this capacity will not be considered to count against the limit of four (4) pain management clinics at which a pain management specialist may serve as medical director. The Medical Director maintains all responsibility during any period where coverage is provided, but the covering physician shall only share responsibility for those times during which he or she is providing coverage;

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 use disorder 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 pain 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;

(ix) creation of a written process for clinical practice evaluation and evidence of regular appropriate supervisory action based on results of the clinical practice evaluation;

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) creation of written policies that are consistent with the Centers for Disease Control and Prevention's guidelines for minimum prevention for outpatient settings; and

(iii) a log of incidents related to infectious and communicable diseases and the corrective action taken;

9. 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 and physical examination;

2. diagnostic, therapeutic, and laboratory results, evaluations and consultations, and records from other health care providers, as available, or attempts to obtain such;

3. documentation of informed consent and discussion of risks and benefits of treatment provided;

4. treatments, treatment options, and treatment objectives;

5. medications prescribed (including date, type, dosage and quantity prescribed);

6. instructions and agreements;

7. periodic reviews;

8. a notation indicating whether the controlled substance monitoring database had been accessed for a particular patient;

9. 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.

(b) The Medical Director shall ensure adequate medical documentation and shall be responsible for addressing inadequate documentation.

(3) The Medical Director 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.

(4) The Medical Director shall ensure that patient medical records shall be maintained for ten (10) years from the date of the patient's last treatment at the clinic.

(5) The Medical Director shall ensure that patient billing records shall be maintained for seven (7) years from the date of the patient's last treatment at the clinic.

(6) The Medical Director shall ensure that all health care providers employed by or working at the pain management clinic are properly licensed and certified at all times.

(7) The Medical Director shall ensure the delivery of quality care and quality services at the clinic.

(8) The Medical Director 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 or credit card in payment for services provided at the clinic; except that payment may be made in cash or money order 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.

(9) The Medical Director shall ensure that patients have access to their medical records at any time upon request of the patient in keeping with T.C.A. § 63-1-201 et seq. and especially in the event that the clinic closes. The Medical Director shall also ensure that the Department has access to the records upon request.

Authority: T.C.A. §§ 63-1-303, 63-1-306, 63-1-309, and 63-1-310.

1200-34-01-.11 Training Requirements

(1) Each physician serving as the Medical Director or a supervising physician to an advanced practice registered nurse or physician assistant at the clinic shall meet the statutory requirements to be a pain management specialist, and shall complete the requisite continuing education to maintain that status.

(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 medicine:

(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.

(3) Each health care provider providing pain management services at a clinic shall, in addition to the ten (10) hours of continuing education outlined above, thoroughly read the Tennessee Chronic Pain Guidelines and the Tennessee Pain Clinic Guidelines promulgated by the Department.

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

1200-34-01-.12 Licensure Discipline and Civil Penalties

(1) Upon a finding that a pain management clinic is in violation of any provision of the Tennessee Pain Management Clinic Act (T.C.A. §§ 63-1-301 et seq.) or the rules promulgated pursuant thereto, the Commissioner may impose any of the following actions separately or in any combination which is deemed appropriate to the offense:

(a) Private Censure - This is a written action issued to the Medical Director for minor or near infractions. It is informal and advisory in nature and does not constitute a formal disciplinary action.

(b) Reprimand - This is a written action issued on a Medical Director's pain management clinic license for one time and less severe violations. It is a formal, public disciplinary action.

(c) Probation - This is a formal disciplinary action which places a Medical Director's pain management clinic license on close scrutiny for a period of time.

1. This action may be combined with any other formal disciplinary action and include conditions and requirements which must be met before probation can be lifted and/or which restrict or condition the clinic's activities during the probationary period.

2. Once ordered, probation may not be lifted unless and until the Medical Director petitions, pursuant to paragraph (2) of this rule, after the period of initial probation has run and all conditions placed on the probation have been met and the Commissioner is satisfied that a further probationary period is not warranted such that the probation may be lifted.

(d) Licensure Suspension - This is a formal disciplinary action which suspends the right of the Medical Director and his staff to operate the pain management clinic for a fixed period of time. It contemplates the reopening of the practice under the license previously issued at that location.

1. Once ordered, a suspension may not be lifted unless and until the Medical Director petitions, pursuant to paragraph (2) of this rule, after the period of initial suspension has run and:

(i) All conditions placed on the suspension have been met; and

(ii) The Commissioner is satisfied that the Medical Director and his staff are competent to return to practice and that no further period of suspension is warranted such that the suspension should be lifted.

2. The clinic must be completely closed during the period of licensure suspension. If any licensee admits or sees any new or existing patients during the suspension, that shall be considered a violation of the suspension, and the length of suspension shall toll for any time during which the practice was open in violation of the suspension.

(e) Revocation- This is a formal disciplinary action which closes a clinic and terminates the license previously issued to operate that location as a pain management clinic.

(f) Conditions - Any action deemed appropriate by the Commissioner to be required of a disciplined Medical Director and/or clinic in any of the following circumstances:

1. During any period of probation or suspension; or

2. As a prerequisite to the lifting of probation or suspension; or

3. As a stand-alone requirement(s) in any disciplinary order.

(g) Civil penalty - A monetary disciplinary action assessed by the Commissioner pursuant to paragraph (4) of this rule.

(h) Summary Suspension - This is a formal disciplinary action which immediately and entirely suspends the rights of the Medical Director and his staff to operate the pain management clinic until it is lifted or until a final disposition of the matter after a full hearing. This type of suspension may be ordered ex-parte, pursuant to the notice procedures contained in T.C.A. §4-5-320 upon a finding that the public health, safety or welfare imperatively requires emergency action.

(i) Assessment of costs in disciplinary proceedings shall be as set forth in T.C.A. §§ 63-1-144.

(2) Order of Compliance - This procedure is a necessary adjunct to previously issued disciplinary orders and is available only when a petitioner has completely complied with the provisions of a previously issued disciplinary order and wishes or is required to obtain an order reflecting that compliance.

(a) The Commissioner will entertain petitions for an Order of Compliance as a supplement to a previously issued order upon strict compliance with the procedures set forth in subparagraph (b) only when the petitioner can prove compliance with all the terms of the previously issued order and is seeking to have an order issued reflecting that compliance or is seeking to have a suspension or probation lifted.

(b) Procedures

1. The petitioner shall submit a Petition for Order of Compliance, as contained in subparagraph (c), to the Administrative Office that shall contain all of the following:

(i) A copy of the previously issued order; and

(ii) A statement of which provision of subparagraph (a) the petitioner is relying upon as a basis for the requested order; and

(iii) A copy of all documents that prove compliance with all the terms or conditions of the previously issued order. If proof of compliance requires testimony of an individual(s), including that of the petitioner, the petitioner must submit signed, sworn to, and notarized statements from each individual the petitioner intends to rely upon attesting, under oath, to the petitioner's compliance. No documentation or testimony other than that submitted will be considered in making an initial determination on, or a final order in response to, the petition.

2. The administrative staff may make an initial determination on the petition before it is heard by the Commissioner and take one of the following actions:

(i) Certify compliance and have the matter scheduled for presentation to the Commissioner as an uncontested matter; or

(ii) Deny the petition, after consultation with legal staff, if compliance with all of the provisions of the previous order is not proven and notify the petitioner of what provisions remain to be fulfilled and/or what proof of compliance was either not sufficient or not submitted.

3. If the petition is presented to the Commissioner, the petitioner may not submit any additional documentation or testimony other than that contained in the petition as originally submitted.

4. If the Commissioner finds that the petitioner has complied with all the terms of the previous order an Order of Compliance shall be issued.

5. If the petition is denied either initially by staff or after presentation to the Commissioner and the petitioner believes compliance with the order has been sufficiently proven the petitioner may, as authorized by law, file a petition for a declaratory order pursuant to the provisions of T.C.A. § 4-5-223.

(c) Form Petition

Petition for Order of Compliance
Pain Management Clinic

Petitioner's Name: _____
Petitioner's Mailing Address: _____
_____
_____

Petitioner's E-Mail Address: _____
Telephone Number: _____

Attorney for Petitioner: _____
Attorney's Mailing Address: _____
_____
_____

Attorney's E-Mail Address: _____
Telephone Number: _____

The petitioner respectfully represents, as substantiated by the attached documentation that all provisions of the attached disciplinary order have been complied with and I am respectfully requesting: (circle one)

1. An order issued reflecting that compliance; or

2. An order issued reflecting that compliance and lifting a previously ordered suspension or probation.

Note - You must enclose all documents necessary to prove your request including a copy of the original order. If any of the proof you are relying upon to show compliance is the testimony of any individual, including yourself, you must enclose signed statements from every individual you intend to rely upon attesting, under oath, to the compliance. The Committee's consultant, the Disciplinary Coordinator, and legal staff, in their discretion, may require such signed statements to be notarized. No documentation or testimony other than that submitted will be considered in making an initial determination on, or a final order in response to, this petition.

Respectfully submitted this the _ day of _____, 20____.

_____
Petitioner's Signature

(3) Order Modifications - This procedure is not intended to allow anyone under a previously issued disciplinary order, including an unlicensed practice civil penalty order, to modify any findings of fact, conclusions of law, or the reasons for the decision contained in the order. It is also not intended to allow a petition for a lesser disciplinary action, or civil penalty other than the one(s) previously ordered. All such provisions of Commissioner Orders were subject to reconsideration and appeal under the provisions of the Uniform Administrative Procedures Act (T.C.A. §§ 4-5-301, et seq.). This procedure is not available as a substitute for reconsideration and/or appeal and is only available after all reconsideration and appeal rights have been either exhausted or not timely pursued. It is also not available for those who have accepted or been issued a reprimand.

(a) The Commissioner will entertain petitions for modification of the disciplinary portion of previously issued orders upon strict compliance with the procedures set forth in subparagraph (b) only when the petitioner can prove that compliance with any one or more of the conditions or terms of the discipline previously ordered is impossible. For purposes of this rule the term "impossible" does not mean that compliance is inconvenient or impractical for personal, financial, scheduling or other reasons.

(b) Procedures

1. The petitioner shall submit a written and signed Petition for Order Modification on the form contained in subparagraph (c) to the Administrative Office that shall contain all of the following:

   (i) A copy of the previously issued order; and

   (ii) A statement of why the petitioner believes it is impossible to comply with the order as issued; and

   (iii) A copy of all documents that prove that compliance is impossible. If proof of impossibility of compliance requires testimony of an individual(s), including that of the petitioner, the petitioner must submit signed, sworn to, and notarized statements from each individual the petitioner intends to rely upon attesting, under oath, to the reasons why compliance is impossible. No documentation or testimony other than that submitted will be considered in making an initial determination on, or a final order in response to, the petition.

2. The administrative staff may make an initial determination on the petition before the Commissioner hears it and take one of the following actions:

   (i) Certify impossibility of compliance and forward the petition to the Office of General Counsel for review and presentation to the Commissioner; or

   (ii) Deny the petition, after consultation with legal staff, if impossibility of compliance with the provisions of the previous order is not proven and notify the petitioner of what proof of impossibility of compliance was either not sufficient or not submitted.

3. If the petition is presented to the Commissioner, the petitioner may not submit any additional documentation or testimony other than that contained in the petition as originally submitted.

4. If the petition is granted, the Commissioner may issue a new order reflecting the authorized modifications that he deems appropriate and necessary in relation to the violations found in the previous order.

5. If the petition is denied either initially by staff or after presentation to the Commissioner and the petitioner believes impossibility of compliance with the order has been sufficiently proven the petitioner may, as authorized by law, file a petition for a declaratory order pursuant to the provisions of T.C.A. § 4-5-223.

(c) Form Petition

Petition for Order Modification
Pain Management Clinic

Petitioner's Name: _____
Petitioner's Mailing Address: _____
_____

Petitioner's E-Mail Address: _____
Telephone Number: _____

Attorney for Petitioner: _____
Attorney's Mailing Address: _____
_____
_____

Attorney's E-Mail Address: _____
Telephone Number: _____

The petitioner respectfully represents that for the following reasons, as substantiated by the attached documentation, the identified provisions of the attached disciplinary order are impossible for me to comply with:

_____
_____
_____
_____
_____
_____
_____

Note - You must enclose all documents necessary to prove your request including a copy of the original order. If any of the proof you are relying upon to show impossibility is the testimony of any individual, including yourself, you must enclose signed and notarized statements from every individual you intend to rely upon attesting, under oath, to the reasons why compliance is impossible. No documentation or testimony other than that submitted will be considered in making an initial determination on, or a final order in response to, this petition.

Respectfully submitted this the _ day of _____, 20____.

_____
Petitioner's Signature

(4) Civil Penalties

(a) Purpose - The purpose of this paragraph is to set out a schedule designating the minimum and maximum civil penalties which may be assessed pursuant to T.C.A. §§ 63-1-134 and 63-1-316.

(b) Schedule of Civil Penalties

1. A Type A civil penalty may be imposed whenever the Commissioner finds the medical director, an owner, or clinic staff guilty of a willful and knowing violation of the Practice Act, or regulations promulgated pursuant thereto, to such an extent that there is, or is likely to be an imminent, substantial threat to the health, safety and welfare of an individual client or the public or in such a manner as to impact directly on the care of patients or the public.

2. A Type B civil penalty may be imposed whenever the Commissioner finds medical director, an owner, or clinic staff is guilty of a violation of the Practice Act, or regulations promulgated pursuant thereto, which are neither directly detrimental to the patients or public, nor directly impact their care.

(c) Amount of Civil Penalties

1. Type A Civil Penalties shall be assessed in the amount of not less than $500 or more

than $1,000.

2. Type B Civil Penalties may be assessed in the amount of not less than $100 and not more than $500.

(d) Procedures for Assessing Civil Penalties

1. The Department may initiate a civil penalty assessment by filing a Memorandum of Assessment of Civil Penalty. The Department shall state in the memorandum the facts and law upon which it relies in alleging a violation, the proposed amount of the civil penalty and the basis for such penalty. The Department may incorporate the Memorandum of Assessment of Civil Penalty with a Notice of Charges which may be issued attendant thereto.

2. Civil Penalties may also be initiated and assessed by the Commissioner or his designee during consideration of any Notice of Charges. In addition, the Commissioner or his designee may, upon good cause shown, assess a type and amount of civil penalty which was not recommended by the Department.

3. In assessing the civil penalties pursuant to these rules the Commissioner or his designee may consider the following factors:

(i) Whether the amount imposed will be a substantial economic deterrent to the violator;

(ii) The circumstances leading to the violation;

(iii) The severity of the violation and the risk of harm to the public;

(iv) The economic benefits gained by the violator as a result of non-compliance; and,

(v) The interest of the public.

4. All proceedings for the assessment of civil penalties shall be governed by the contested case provisions of Title 4, Chapter 5, Tennessee Code Annotated.

(5) At the conclusion of a hearing, should the Commissioner determine to hold the case under advisement and make a recommendation as to requirements to be met by the pain management clinic in order to avoid suspension, revocation, or other discipline of a license or suspension of admissions, such recommendations shall be a public record and shall be considered formal discipline.

(a) Should the Commissioner make such a recommendation, the clinic must present proof of having met those requirements to the Commissioner for a determination regarding whether they have been satisfactorily met.

(b) Should the Commissioner determine that the recommended requirements have not been met, the Commissioner shall make a finding and record of this determination, and shall impose appropriate formal discipline.

(c) Should the clinic comply with the recommendations, the Commissioner has the authority to impose a lesser sanction as outlined in his recommendation, or no sanction at all, provided however, that both the initial recommendations and final order shall be a public record and shall be considered formal discipline.

Authority: T.C.A. §§ 63-1-303, 63-1-306, and 63-1-316.

1200-34-01-.13 Commissioner Suspensions of Treatment of New or Existing Patients

(1) In cases where the Commissioner determines that the conditions of any pain management clinic are, or

are likely to be, detrimental to the health, safety, or welfare of any patient, the Commissioner may suspend treatment of any new or existing patients in whole or part at the Commissioner's sole discretion, pending a prompt hearing and in accordance with the requirements and provisions set out at T.C.A. § 63-1-318. The Commissioner may also convene an advisory panel, at his discretion, to make recommendations regarding the conditions of any clinic.

(2) The following is a non-exhaustive list of conditions which are, or are likely to be, detrimental to the health, safety, or welfare of a patient:

(a) Where there is gross deviation or a pattern of deviation from the Chronic Pain Guidelines or Pain Clinic Guidelines promulgated by the Department;

(b) Where there is a pattern of negligence or a pattern of noncompliance with normal standards of care;

(c) Where there is dispensing of schedule II or schedule III drugs in violation of T.C.A. § 63-1-313;

(d) Where a provider in the clinic demonstrates active, untreated impairment or substance use disorder.

Authority: T.C.A. §§ 63-1-303 and 63-1-318.

1200-34-01-.14 Unlicensed Pain Management Clinics

(1) When the Department has reason to believe that a health care provider's office is operating as an unlicensed pain management clinic, such health care provider shall produce satisfactory evidence to the Department that the majority of its patient population is not receiving chronic nonmalignant pain treatment to avoid establishment of a rebuttable presumption that the clinic is operating as an unlicensed pain management clinic. For purposes of this determination, patients seen within the preceding twelve (12) months will be considered in determining the percentage of patients receiving chronic non-malignant pain treatment.

(2) Upon request from the Department the health care provider's office shall produce medical records, business records, and any information responsive to the list below, within ten (10) business days. After initial review, the Department may ask for any necessary additional information to be produced within another ten (10) business days from the Department's request for additional information. Evidence which will be required by the Department during this process may, at the discretion of the Department, include:

(a) A complete list of every patient seen at the clinic to include a listing of all dates during the preceding twelve (12) months when that patient was seen or treated;

(b) A complete list of every patient seen at the clinic within the preceding twelve (12) months which delineates each patient's diagnosis as well as what was prescribed to that patient, the drug name, drug strength, number of pills to be dispensed, and number of days of intended use;

(c) A complete list of all the billing codes which were submitted for each patient seen by the clinic as well as copies of the bills with remittances during the preceding twelve (12) months; and

(d) A complete list of every clinic patient seen by the clinic during the preceding twelve (12) months who did not receive chronic non-malignant pain treatment with a description of the type of services that patient did receive.

(3) After being provided any of the patient lists above, should the Department need to review charts of any of the clinic's patients to assist in making its determination, the clinic will be notified of the names and given ten (10) business days to produce those patients' charts.

(4) Should the health care provider's office be unable to provide satisfactory evidence, the Department shall notify the clinic of such determination in writing. The clinic shall be prohibited from admitting any new patients to the practice, and all owners and practitioners who worked at the clinic shall be subject to

revocation of their licenses.

(5) The Commissioner may issue a determination, or at the Commissioner's discretion, may convene an advisory panel to meet regarding whether the clinic was operating as an unlicensed pain management clinic and to make a recommendation to the Commissioner prior to the Commissioner's determination. The Commissioner shall not be bound by the recommendation of the advisory panel.

(6) The Department has discretion to await the Commissioner's determination and the recommendations of the Advisory Panel before proceeding against the health care practitioners at the clinic for providing services in an unlicensed pain management clinic.

Authority: T.C.A. §§ 63-1-311, 63-1-315, and 63-1-317.

1200-34-01-.15 Financial Requirement

(1) Licensed pain management clinics shall be required to hold as surety either bonds or liability insurance in an amount at least double one year's operating expense.

(2) The bond or insurance must remain in force as long as the Medical Director's pain management clinic license is active. Upon notice of cancellation for any reason, the Medical Director shall cease operating, and shall cause all the staff to cease operating, the clinic.

(3) Proof of such surety shall be produced to the Department upon request.

Authority: T.C.A. § 63-1-316.

1200-34-01-.16 Advertising

(1) The vulnerability on the part of some patients concerning pain management services, and the foreseeable consequences of unrestricted advertising by pain clinics, requires that special care be taken in advertising for pain management services.

(2) The following statements, acts, or omissions in the context of advertisements by or for any clinic shall not be permitted:

(a) Any communication, including the use of personal testimonials, attesting to the quality of a service or treatment offered at the clinic, or the competency of those at the clinic rendering the service or treatment, with regard to potential results of any service or treatment that is not reasonably verifiable, if that communication is in exchange for consideration of any form.

(b) Any communication which creates an unjustified expectation concerning the potential results of that treatment.

(c) Failure of the pain management clinic to include all the following in the advertisement:

1. The licensure or certification number of the clinic as well as the official name in which the clinic is licensed;

2. The name of the medical director.

(d) Use of the name of any licensee formerly practicing at or associated with any pain management clinic after thirty (30) days from that licensee's departure, including use of the name on any signage for the office or building.

(e) Stating or implying that a certain licensee provides, or will be providing, all services when any such services are regularly, or will be, performed by another licensee.

(f) Directly or indirectly offering, giving, receiving, or agreeing to receive any fee or other consideration to or from a third party for the referral of a patient in connection with the

performance of professional services.

(3) A copy of every advertisement, whether communicated through electronic or printed media, must be kept in as close to the original communication method as possible for at least two (2) years from the last date of communication and shall be submitted to the Department for review upon request.

(4) The Medical Director is responsible for all advertising content which must also be in compliance with the rules of the Tennessee Board of Medical Examiners.

Authority: T.C.A. §§ 63-1-311 and 63-1-317.

1200-34-01-.17 Infectious Disease and Building Standards

Each pain management clinic shall meet all health and safety standards necessary to protect the health and welfare of patients seeking medical assistance from the clinic.

Authority: T.C.A. §§ 63-1-311 and 63-1-317.

* If a roll-call vote was necessary, the vote by the Agency on these 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 an emergency rule(s), lawfully promulgated and adopted.

Date: 5/9/17

Signature: Mary K Bratton

Name of Officer: Mary Katherine Bratton

Title of Officer: Deputy General Counsel
Department of Health

Subscribed and sworn to before me on: 5-9-17

Notary Public Signature: Suzanne Mechkowski

My commission expires on: My Commission Expires January 26, 2021

SUZANNE MECHKOWSKI NOTARY PUBLIC STATE OF TENNESSEE SUMNER COUNTY

All emergency 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.

Herbert H. Slatery III

Herbert H. Slatery III
Attorney General and Reporter

5/24/2017

Date

Department of State Use Only

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SECRETARY OF STATE
PUBLICATIONS

Filed with the Department of State on: 5/25/17

Effective for: 180 *days

Effective through: 11/21/17

** Emergency rule(s) may be effective for up to 180 days from the date of filing.*

Tre Hargett

Tre Hargett
Secretary of State

REGULATORY FLEXIBILITY ANALYSIS

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

These rules do not overlap, duplicate, or conflict with other federal, state, or local governmental rules.

(2) Clarity, conciseness, and lack of ambiguity in the rule or rules.

These rules exhibit clarity, conciseness, and lack of ambiguity.

(3) The establishment of flexible compliance and/or reporting requirements for small businesses.

The reporting requirements included in these rules are uniform for each licensed clinic upon licensure application and renewal and in an annual report.

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

The reporting requirements are uniform for each licensed clinic. These rules allow for a 30 day grace period and potentially an additional 60 day grace period with waiver for those clinics whose medical director has departed and are struggling to find a new medical director.

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

The rules require reporting upon licensure and renewal and annually during licensure cycles.

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

These rules require each medical director to create his or her own performance, standards for his or her own clinic.

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

These rules do not create unnecessary barriers or stifle entrepreneurial activity or innovation.

STATEMENT OF ECONOMIC IMPACT TO SMALL BUSINESSES

Name of Board, Committee or Council: Pain Management Clinics

1. **Type or types of small business and an identification and estimate of the number of small businesses subject to the proposed rule that would bear the cost of, and/or directly benefit from the proposed rule:**

   These proposed rule amendments will have an impact on all pain management clinic owners and medical directors, in keeping with last year's statutory changes. While the medical directors and owners will be subject to some additional requirements such as greater reporting to the Department of Health, more frequent inspections, and higher licensing fees, these new rules will follow the statutory changes from last session to ensure a safer environment in pain management clinics, serving the public with another step towards lessening the addiction rate in Tennessee.

2. **Projected reporting, recordkeeping and other administrative costs required for compliance with the proposed rule, including the type of professional skills necessary for preparation of the report or record:**

   These proposed rule amendments will require additional annual reporting requirements by the medical director, but these new reporting requirements should have a minimal financial impact on the clinics.

3. **Statement of the probable effect on impacted small businesses and consumers:**

   These proposed rule amendments, following the statutory changes from last session, vest more responsibility and control in the medical director of pain management clinics, and while some of the rules create additional burdens, the new rules should have a positive impact on pain management clinics by creating more specific requirements. Additionally, these new rules will ensure better service to the public and will serve as another step towards lessening the addiction rate in Tennessee.

4. **Description of any less burdensome, less intrusive or less costly alternative methods of achieving the purpose and/or objectives of the proposed rule that may exist, and to what extent, such alternative means might be less burdensome to small business:**

   There are no less burdensome, less intrusive, or less costly alternative methods of achieving the purpose and/or objectives of the proposed rule amendments. These rules are required by Public Chapter 1033, which was signed by the Governor on April 20, 2016.

5. **Comparison of the proposed rule with any federal or state counterparts:**

   Federal: There are no federal regulations for pain management clinics.

   State: Most doctor's offices are not regulated in this manner, but compared to licensed healthcare facilities, these requirements are less burdensome.

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.**

   The proposed rule amendments do not provide for any exemptions for small businesses.

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)

The proposed rule amendments should not have a financial 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 T.C.A. § 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;

Rule Chapter 1200-34-01 [Pain Management Clinics] is being repealed and rewritten.

(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;

Public Chapter 1033, which was signed by the Governor on April 20, 2016.

(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;

These proposed rule amendments will have an impact on all pain management clinic owners and medical directors, in keeping with last year's statutory changes.

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

None.

(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;

These rules should not result in any increase or decrease in state or local government revenues or expenditures.

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

Mary Katherine Bratton, Deputy General Counsel, Department of Health.

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

Mary Katherine Bratton, Deputy General Counsel, Department of Health.

(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

Department of Health, Office of General Counsel, 665 Mainstream Drive, Nashville, Tennessee 37205, (615) 741-1611, Mary.Bratton@tn.gov.

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

None.

RULES
OF
DEPARTMENT OF HEALTH
DIVISION OF PAIN MANAGEMENT CLINICS

CHAPTER 1200-34-01
PAIN MANAGEMENT CLINICS

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~~**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.* ***Administrative History:*** *Emergency rule filed September 30, 2011; effective March 28, 2012. Emergency rule filed September 30, 2011 and effective through March 28, 2012; on March 29, 2012 the emergency rule expired and reverted to its previous status. Permanent rules 1200-34-.01 through .10 filed December 27, 2011; to have been effective March 26, 2012. The Government Operations Committee filed a seven-day stay of effective date of the rules; new effective date April 2, 2012. On March 26, 2012, the Government Operations Committee withdrew its stay; new effective date March 26, 2012.*~~

~~**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.~~

(Rule 1200-34-01-.02, continued)

(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.* ***Administrative History:*** *Emergency rule filed September 30, 2011; effective through March 28, 2012. Emergency rule filed September 30, 2011 and effective through March 28, 2012; on March 29, 2012 the emergency rule expired and reverted to its previous status. Permanent rules 1200-34-.01 through .10 filed December 27, 2011; to have been effective March 26, 2012. The Government Operations Committee filed a seven-day stay of effective date of the rules; new effective date April 2, 2012. On March 26, 2012, the Government Operations Committee withdrew its stay; new effective date March 26, 2012.*

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.

(Rule 1200-34-01-.03, continued)

(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.* ***Administrative History:*** *Emergency rule filed September 30, 2011; effective through March 28, 2012. Emergency rule filed September 30, 2011 and effective through March 28, 2012; on March 29, 2012 the emergency rule expired and reverted to its previous status. Permanent rules 1200-34-.01 through .10 filed December 27, 2011; to have been effective March 26, 2012. The Government Operations Committee filed a seven-day stay of effective date of the rules; new effective date April 2, 2012. On March 26, 2012, the Government Operations Committee withdrew its stay; new effective date March 26, 2012.*

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.* ***Administrative History:*** *Emergency rule filed September 30, 2011; effective through March 28, 2012. Emergency rule filed September 30, 2011 and effective through March 28, 2012; on March 29, 2012 the emergency rule expired and reverted to its previous status. Permanent rules 1200-34-.01 through .10 filed December 27, 2011; to have been effective March 26, 2012. The Government Operations Committee filed a seven-day stay of effective date of the rules; new effective date April 2, 2012. On March 26, 2012, the Government Operations Committee withdrew its stay; new effective date March 26, 2012.*

(Rule 1200-34-01-.03, continued)

~~**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.* ***Administrative History:*** *Emergency rule filed September 30, 2011; effective through March 28, 2012. Emergency rule filed September 30, 2011 and effective through March 28, 2012; on March 29, 2012 the emergency rule expired and reverted to its previous status. Permanent rules 1200-34-.01 through .10 filed December 27, 2011; to have been effective March 26, 2012. The Government Operations Committee filed a seven-day stay of effective date of the rules; new effective date April 2, 2012. On March 26, 2012, the Government Operations Committee withdrew its stay; new effective date March 26, 2012.*~~

~~**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.* ***Administrative History:*** *Emergency rule filed September 30, 2011; effective through March 28, 2012. Emergency rule filed September 30, 2011 and effective through March 28, 2012; on March 29, 2012 the emergency rule expired and reverted to its previous status. Permanent rules 1200-34-.01 through .10 filed December 27, 2011; to have been effective March 26, 2012. The Government Operations Committee filed a seven-day stay of effective date of the rules; new effective date April 2, 2012. On March 26, 2012, the Government Operations Committee withdrew its stay; new effective date March 26, 2012.*~~

~~**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;

(Rule 1200-34-01-.07, continued)

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.* ***Administrative History:*** *Emergency rule filed September 30, 2011; effective through March 28, 2012. Permanent rules 1200-34-.01 through .10 filed December 27, 2011; to have been effective March 26, 2012. The Government Operations Committee filed a seven-day stay of effective date of the rules; new effective date April 2, 2012. On March 26, 2012, the Government Operations Committee withdrew its stay; new effective date March 26, 2012.*

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.

(Rule 1200-34-01-.08, continued)

(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 deductable 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.* ***Administrative History:*** *Emergency rule filed September 30, 2011; effective through March 28, 2012. Emergency rule filed September 30, 2011 and effective through March 28, 2012; on March 29, 2012 the emergency rule expired and reverted to its previous status. Permanent rules 1200-34-.01 through .10 filed December 27, 2011; to have been effective March 26, 2012. The Government Operations Committee filed a seven-day stay of effective date of the rules; new effective date April 2, 2012. On March 26, 2012, the Government Operations Committee withdrew its stay; new effective date March 26, 2012.*

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.* ***Administrative History:*** *Emergency rule filed September 30, 2011; effective through March 28, 2012. Emergency rule filed September 30, 2011 and effective through March 28, 2012; on March 29, 2012 the emergency rule expired and reverted to its previous status. Permanent rules 1200-34-.01 through .10 filed December 27, 2011; to have been effective March 26, 2012. The Government Operations Committee filed a seven-day stay of effective date of the rules; new effective date April 2, 2012. On March 26, 2012, the Government Operations Committee withdrew its stay; new effective date March 26, 2012.*

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:

(Rule 1200-34-01-.10, continued)

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.* ***Administrative History:*** *Emergency rule filed September 30, 2011; effective through March 28, 2012. Emergency rule filed September 30, 2011 and effective through March 28, 2012; on March 29, 2012 the emergency rule expired and reverted to its previous status. Permanent rules 1200-34-.01 through .10 filed December 27, 2011; to have been effective March 26, 2012. The Government Operations Committee filed a seven-day stay of effective date of the rules; new effective date April 2, 2012. On March 26, 2012, the Government Operations Committee withdrew its stay; new effective date March 26, 2012.*

1200-34-01-.01 Definitions

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

(1) "Administrative Office" means the Tennessee Department of Health, Division of Health Related Boards, at which the Pain Management Clinic registry office for administrative support of daily functions is located at 665 Mainstream Drive, Nashville, TN 37243.

(2) "Adjacent" means within 1,000 feet.

(3) "Advisory Panel" means a panel selected by the Commissioner and convened at his or her discretion for advisory purposes and to issue recommendations to the Commissioner.

(4) "Applicant" means a medical doctor licensed under Title 63, Chapter 6 or an osteopathic

(Rule 1200-34-01-.10, continued)

physician licensed under Title 63, Chapter 9, who has submitted or is in the process of submitting an application for a license to operate a pain management clinic.

(5) "Certificate Holder" means a medical doctor licensed under Title 63, Chapter 6; osteopathic physician licensed under Title 63, Chapter 9; advanced practice registered 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, who practices in this state with an unrestricted, unencumbered license, who was issued a pain management clinic certificate prior to July 1, 2017, and who may continue to operate that certificate as a license under Title 63, Chapter 1 until its expiration.

(6) "Commissioner" means the Commissioner of Health or his designee.

(7) "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.

(8) "Department" means the Tennessee Department of Health.

(9) "Licensee" means any person licensed under Title 63 by one of the Tennessee Department of Health, Division of Health Related Boards.

(10) "Medical Director" means an individual who meets the definitions of Title 63, Chapter 1, Section 301(5) and 301(9), and holds a license to operate a pain management clinic issued by the Department.

(11) "Medical Record" shall have the same meaning as set forth in T.C.A. § 63-2-101.

(12) "Owner" means a medical doctor licensed under Title 63, Chapter 6; osteopathic physician licensed under Title 63, Chapter 9; advanced practice registered 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.

(13) "Pain 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 that prescriptions for controlled substances may only be filled at one pharmacy to be identified by the patient, and addresses the use of controlled substances prescribed by other providers.

(14) "Pain Management Clinic" means a privately-owned clinic, facility, or office in which the majority of patients are prescribed or dispensed opioids, benzodiazepines, barbiturates, or carisoprodol for ninety (90) days or more in a twelve-month period for pain unrelated to cancer or palliative care. For purposes of determining if a clinic, facility, or office qualifies as a pain management clinic, the entire clinic, facility, or office caseload of patients who received medical care services from all medical doctors, osteopathic physicians, advance practice registered nurses, and physician assistants who serve in the clinic, facility, or office shall be counted. Pain Management clinic also means a privately-owned clinic, facility, or office which advertises in any medium for pain management services of any type.

(15) "Substance Use Disorder 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 use disorder risk assessment may be accomplished through a standardized written or orally-delivered questionnaire or through a clinical interview.

(16) "Unencumbered" means an active license that is not suspended or on probation and that does not have any conditions, restrictions, or limitations.

(Rule 1200-34-01-.10, continued)

(17) "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, 63-1-306, 63-1-316, and 63-1-318.

1200-34-01-.02 Licensure Process

(1) Before operating or practicing in a pain management clinic as defined in T.C.A. § 63-1-301(8) on or after July 1, 2017, the Medical Director of that clinic must first obtain a Pain Management Clinic License from the Department.

(2) An applicant shall obtain an application from the Administrative Office, respond truthfully and completely to every question or request for information contained in the application, and submit it along with all documentation and fees required by the application and rules to the Administrative Office. When available, this may be accomplished through an online application.

(3) An applicant shall submit all of the following as part of their application:

(a) The initial licensure fee, state regulatory fee, and inspection fee provided in rule 1200-34-01-.05;

(b) Two letters, from a medical doctor licensed under Title 63, Chapter 6 or an osteopathic physician licensed under Title 63, Chapter 9, vouching for the good moral character of the Medical Director;

(c) Proof that the Medical Director meets the statutory requirements defined in T.C.A. § 63-1-301(9) to be a pain management specialist;

(d) The names, and if licensed by the Department, the licensure numbers, of every person with any ownership interest in the pain management clinic for which the applicant seeks licensure and each person's percentage of ownership;

(e) Information regarding the form of business entity the clinic will be established as and whether there is already an existing medical practice at the clinic's proposed location;

(f) The physical mailing address of the clinic for which the applicant seeks licensure;

(g) Identification of any other licenses or applications, including pending or denied applications, for pain management clinics associated with the applicant including as an owner, employee or contractor;

(h) The names, and if licensed by the Department, the licensure numbers, of every employee of the clinic;

(i) The names, and if licensed by the Department, the license numbers of every person with whom the clinic has contracted for services, including persons involved in daily operation of the clinic;

(j) The Drug Enforcement Administration ("DEA") Registration numbers for each individual employed by the clinic or with whom the clinic has contracted who holds a DEA registration;

(Rule 1200-34-01-.10, continued)

(k) The result of a criminal background check, submitted to the Administrative Office, directly from the vendor identified in the application, for the following personnel:

1. The Medical Director;

2. Each person with any ownership interest;

3. Each person who holds a DEA registration who will be providing services at that clinic; and

4. Where any disclosure required in 1200-34-01-.02(4)(a)-(d) has yielded an affirmative answer, that employee or individual or company with whom the clinic has contracted who has contact with patients or onsite patient information and/or has management responsibilities;

(l) The name, license number, and address, of every pharmacy in which either the Medical Director or any owner of the clinic has any ownership interest that is greater than one percent (1%), and the percentage of that ownership interest;

(m) Proof that all supervising physicians who are supervising any of the advanced practice registered nurses or physician assistants providing services at the pain management clinic are pain management specialists;

(n) A statement of verification that the Medical Director has read and understood the statutes and rules governing pain management clinics, as well as the Tennessee Chronic Pain Guidelines (http://www.tn.gov/assets/entities/health/attachments/ChronicPainGuidelines.pdf), and the Tennessee Pain Clinic Guidelines (http://www.tn.gov/assets/entities/health/attachments/Pain_Clinic_Guidelines.pdf); and

(o) Any other information requested by the Department.

(4) An applicant shall disclose the circumstances and produce any documentation requested by the Department surrounding any of the following:

(a) Whether any owner has ever been convicted of, pled nolo contendere to, or received deferred adjudication for an offense that constitutes a felony;

(b) Whether any employee, or person with whom the clinic contracts who has contact with patients or onsite patient information and/or has management responsibilities has ever been convicted of any felony;

(c) Whether any owner, employee, or person with whom the clinic contracts who has contact with patients or onsite patient information and/or has management responsibilities is under indictment for any offense involving the sale, diversion, or dispensing of controlled substances under any state or federal law;

(d) Whether any owner, employee, or person with whom the clinic contracts who has contact with patients or onsite patient information and/or has management responsibilities has ever been convicted of any offense involving the sale, diversion, or dispensing of controlled substances under any state or federal law;

(e) Whether any owner, employee, or person with whom the clinic contracts who has contact with patients or onsite patient information and/or has management responsibilities has ever applied for or held any license issued by any jurisdiction, under which that license holder may prescribe, dispense, administer, supply, or sell a controlled substance, which

(Rule 1200-34-01-.10, continued)

has been restricted, disciplined, or denied;

(f) Whether any owner, employee, or person with whom the clinic contracts who has contact with patients or onsite patient information and/or has management responsibilities has ever been subject to disciplinary action by any licensing entity for conduct that was the result of inappropriately prescribing, dispensing, administering, supplying, or selling a controlled substance;

(g) Loss or restriction of privileges at any hospital or health care facility on the part of the Medical Director;

(h) Whether any owner, medical director, employee or person with whom the clinic contracts who has contact with patients or onsite patient information and/or has management responsibilities is under any board order requiring advocacy from a professional assistance program that monitors for substance abuse;

(i) Whether any owner, employee, or person with whom the clinic contracts who has contact with patients or onsite patient information and/or has management responsibilities has ever had a DEA registration that was surrendered for cause or disciplined.

(5) Where appropriate, the applicant shall cause to be submitted from the DEA, documentation regarding any surrender for cause, revocation, or other discipline of a DEA registration certificate.

(6) Application review and licensure decisions shall be governed by rule 1200-34-01-.03.

(7) An applicant shall submit a separate application for licensure for each clinic location regardless of whether the clinic is operated under the same business name, ownership, or management as another clinic. Each clinic location shall be licensed separately.

Authority: T.C.A. §§ 63-1-301, 63-1-303, 63-1-306, 63-1-309, 63-1-316, and 63-1-401.

1200-34-01-.03 Application Review, Approval, and Denial

(1) Administrative staff shall determine when an application file is complete.

(2) If an applicant does not complete the application process within ninety (90) days after the Department receives the application because the application lacks the required information or fails to meet the prerequisites for licensure, then the application will be closed, the licensure fee will not be refunded, and the applicant shall be required to reapply in order to pursue licensure.

(3) Any applicant who has successfully complied with all requirements governing the licensure process shall then be subject to an inspection of the clinic. The applicant must successfully pass the inspection prior to being eligible for licensure. Upon inspection, if evidence is found that any practice act or any requirement of these rules has been violated, the application may be denied, and the Department may use the evidence in a separate disciplinary matter against any of the licensees involved. Representations in the application which are deemed by the Department to be untrue or incompletely disclosed may also subject the applicant to disciplinary action before his or her licensing board, and may subject the pain management clinic application to denial, and a previously issued pain management clinic license or certificate to revocation or other disciplinary action.

(4) The Department will conduct its eligibility inspection within 90 business days from the date the application is deemed complete by administrative staff. If the applicant does not initially pass the inspection, the Department, at its discretion, may re-inspect the clinic subject to a payment of a re-inspection fee. Such re-inspection may take place beyond the 90 business days from the application completion date.

(Rule 1200-34-01-.10, continued)

(5) If the application is denied, or the license is issued with conditions or restrictions, the following shall occur:

(a) A notification of the denial shall be sent from the Administrative Office by certified mail, return receipt requested, which shall contain reasons for the denial, condition, or restriction, as well as the statutory or rule authority for the denial, condition, or restriction.

(b) The notification, when appropriate, shall also contain a statement of the applicant's right to a contested case hearing under the Tennessee Administrative Procedures Act (T.C.A. §4-5-101 et. seq.) to contest the denial, condition, or restriction. An applicant has a right to a contested case hearing only if the denial, condition, or restriction was based upon subjective or discretionary criteria, and only if the request for the contested case hearing is made in writing and received by the Department's Office of General Counsel on or before the thirtieth (30th) day after receipt of the notice by the applicant.

(6) If the Department finds that it has erred in the issuance of a license, the Administrative Office will give written notice by certified mail of its intent to revoke the license. The notice will allow the Medical Director the opportunity to meet the requirements for licensure within thirty (30) days from the date of receipt of the notification. If the Medical Director does not concur with the stated reason and the intent to revoke the license, the Medical Director shall have the right to proceed according to T.C.A. 63-1-316(j).

Authority: T.C.A. §§ 63-1-303, 63-1-304, and 63-1-316.

1200-34-01-.04 Licensure Renewal

(1) Renewal.

(a) A pain management clinic license, unless another time is given at the time of licensure, shall expire two (2) years from the date of issuance. All licenses must be renewed on or before the last day of the two (2) year licensure cycle.

(b) A Medical Director may renew a current, valid license 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 and is a pain management specialist;

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;

5. an attestation that no owner, employee or person with whom the clinic contracts who has contact with patients or onsite patient information and/or has management responsibilities;

(i) has been convicted of an offense involving the sale, distribution, or dispensing of controlled substances under state or federal law;

(ii) has been denied, by any jurisdiction, a license under which that person may prescribe, dispense, administer, supply, or sell a controlled substance;

(iii) has been subject to disciplinary action by any licensing entity for conduct that was the result of inappropriately prescribing, dispensing, administering, supplying, or selling a controlled substance;

6. proof the Medical Director has maintained the status of pain management specialist;

7. any other information requested by the Department.

(2) A clinic whose certificate was renewed before July 1, 2017, shall have its Medical Director apply as a new applicant for licensure under this part, and must meet all requirements for licensure in order to continue operation. In order for the Department to timely process the application and inspect the clinic, the Medical Director must have submitted a complete application as a new applicant a minimum of ninety (90) days before the expiration of the clinic's certificate. For purposes of an expired certificate, there shall be no grace period for operation between expiration of the certificate and the initial licensure date.

(3) Late Renewal and Reapplication.

The pain management clinic may renew its license within sixty (60) days after the license 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 sixty (60) day grace period, the Medical Director may reapply for a new license, but must cease operations until such time as a new license is granted.

Authority: T.C.A. §§ 63-1-303, 63-1-306, 63-1-307, 63-1-308, 63-1-309, and 63-1-316.

1200-34-01-.05 Exemptions

(1) A pain management clinic is not a clinic, facility, or office which provides interventional pain management as defined in § 63-6-244 and whose clinic, facility, or office does not provide chronic non-malignant pain treatment to a majority of the patients of a clinic, facility, or office for ninety (90) days or more in a twelve-month period.

(2) A pain management clinic is not a medical or dental school, an osteopathic medical school, a nursing school, a physician assistant program, or an outpatient clinic associated with any of the foregoing schools or programs, including, but not limited to, clinics that have an agreement to train residents by members of that clinic who are appointed as adjunct faculty of the school or program.

(3) A pain management clinic is not a hospital as defined in § 68-11-201, including any outpatient facility or clinic of a hospital if such outpatient facility or clinic is regulated under title 68.

(4) A pain management clinic is not hospice services as defined in § 68-11-201.

(5) A pain management clinic is not a nursing home as defined in § 68-11-201.

(6) A pain management clinic is not a facility maintained or operated by this state.

(Rule 1200-34-01-.10, continued)

(7) A pain management clinic is not a hospital or clinic maintained or operated by the federal government.

Authority: T.C.A. §§ 63-1-301 and 63-1-302.

1200-34-01-.06 Fees

(1) Initial licensure fee.....$1,500.00

(2) Renewal fee.....$1,500.00

(3) State Regulatory fee.....$ 10.00

(4) Inspection fee.....$1,500.00

(5) Re-inspection fee.....$1,000.00

(6) The late renewal penalty fee is five hundred dollars ($500.00) per month for each month or fraction of a month that renewal is late.

(7) The Inspection fee is to be paid with the initial licensure fee upon application, and again biennially within thirty (30) days following the random biennial inspection.

(8) A re-inspection fee shall be assessed and shall be paid by the Medical Director any time an investigator is forced to return to the clinic to complete his or her inspection due to actions or omissions on the part of the Medical Director or anyone working in the pain management clinic. Payment of the re-inspection fee must be remitted to the Department within thirty (30) days of the re-inspection date.

Authority: T.C.A. §§ 63-1-303, 63-1-306, 63-1-308, and 63-1-316.

1200-34-01-.07 Licensure Inactivation

(1) If the Medical Director and/or owners of a pain management clinic determine that the site will close and cease operation, or that the site will no longer provide services that meet the statutory definition of a pain management clinic, the Medical Director must notify the Department. If the Department has not been notified of a closure and appears at the clinic for an inspection or investigation, the Medical Director may be held responsible for the inspection fee or the actual cost of the investigation.

(2) The Medical Director shall notify the Department and inactivate the pain management clinic license as follows:

(a) Obtain from the Administrative Office an official inactivation form;

(b) Complete and submit that form, along with any supporting documentation that may be required by the Administrative Office.

(3) Upon successful completion and submission of the required forms to the administrative office, the Department shall register the pain management clinic license as inactivated. A clinic that has inactivated its license shall not operate as a pain management clinic, and doing so shall subject the practitioners in that clinic to penalties from the Department.

Authority: T.C.A. §§ 63-1-303, 63-1-304, 63-1-305, and 63-1-316.

(Rule 1200-34-01-.10, continued)

1200-34-01-.08 Inspections and Investigations

(1) Upon application for licensure as a pain management clinic, the Medical Director shall pay the Inspection fee and permit the Department to conduct an inspection of the clinic which may include, in addition to inspection of the physical site, review of medical records, business records, and any other documents the Department may require.

(2) The Medical Director, owners, officers, employees, authorized representatives of the pain management clinic, and independent contractors working at the pain management clinic shall allow Department representatives access to the pain management clinic and shall provide copies of all documentation, including but not limited to medical records and business records, requested by the Department, in connection with an inspection or investigation of the pain management clinic. The Medical Director shall be responsible for the pain management clinic remitting payment of the biennial inspection fee to the Department within thirty (30) days of the inspection.

(3) Failure or refusal of the Medical Director to grant the Department access to the pain management clinic to perform an audit, inspection, or investigation shall constitute grounds for immediate suspension of the pain management clinic's license as contemplated in T.C.A. § 4-5-320(c).

Authority: T.C.A. §§ 63-1-303, 63-1-304, 63-1-305, and 36-1-316.

1200-34-01-.09 Notifications and Reporting

(1) A pain management clinic license shall not be assignable or transferable. However, the Department recognizes that some circumstances may cause a Medical Director to depart from a clinic. While best practice would be for the new Medical Director to seek licensure from the Department while the current Medical Director is still actively serving at his clinic's licensed location, in the event that the current Medical Director no longer meets the requirements contained in T.C.A. §§ 63-1-301 et seq. and these rules to be a Medical Director, or departs from a clinic, the Department will allow a grace period during which a clinic may continue to operate provided the following occurs:

(a) The clinic may continue to operate on the current Medical Director's license for a grace period of up to thirty (30) calendar days from the date that the current Medical Director no longer met the requirements contained in T.C.A. §§ 63-1-301 et seq. and these rules to be a Medical Director, or the date the current Medical Director departs the clinic, provided the clinic notifies the Department, on a form prescribed by the Department, within ten (10) business days of the identity of another pain management specialist who will serve as the interim Medical Director for the clinic;

(b) During this grace period after which the current Medical Director no longer meets the requirements of this part or has departed from the clinic, which shall total no more than thirty (30) calendar days, both the current Medical Director and the interim Medical Director, are liable for any actions or inactions occurring at or caused by the pain management clinic;

(c) The new Medical Director shall submit a completed pain management clinic application immediately upon agreement to assume the duties of medical director at the clinic;

(d) Should the clinic have difficulty obtaining a new medical director, it may apply for a waiver of up to an additional sixty (60) calendar days in which to operate with the interim Medical Director. The waiver form shall be promulgated by the Department. The waiver will only be granted upon good cause shown, demonstrated reasonable efforts to locate and retain a new medical director, and a reasonable belief by the Department that public health will be harmed by not granting the waiver;

(Rule 1200-34-01-.10, continued)

(e) Upon expiration of thirty (30) calendar days, or upon the expiration of ninety (90) calendar days if a waiver was applied for and granted, if a new pain management clinic license has not been issued by the Department, the clinic must cease operation. Each day of continued operation would constitute a separate violation for any licensee who continues to work in the clinic; and

(f) Notwithstanding these provisions, if the current Medical Director of a clinic chooses to inactivate the license, the clinic must cease operating as a pain management clinic immediately upon inactivation. Prior to inactivating the license, the Medical Director shall have the responsibility to notify his patients and arrange for continuity of care.

(2) The Medical Director shall notify the Department within thirty (30) days of the occurrence if any of the following occur to any person who owns, is an employee of, or is a person with whom the clinic contracts who has contact with patients or onsite patient information and/or has management responsibilities:

(a) that person has applied for any state or federal license, registration, or certificate that has been denied;

(b) that person has held any state or federal license, registration, or certificate that has been restricted or subject to disciplinary action relative to prescribing, dispensing, administering, supplying or selling a controlled substance; or

(c) that person has been convicted of a felony or any offense involving the sale, diversion, or dispensing of controlled substances under state or federal law related to operation of or work in the clinic.

(3) In the event that the name of the clinic changes, the Medical Director shall notify the Department of the name change within ten (10) business days after the name change occurs.

(4) In addition to the reporting requirements above, the Medical Director shall make an annual report to the Department on a form promulgated for such reporting. The report shall be due to the Department sixty (60) days prior to the pain management clinic's certificate or license anniversary date and shall cover the previous twelve (12) months. The report shall include the following:

(a) Whether the pain management clinic is associated with a hospital;

(b) Whether the pain management clinic is adjacent to a pharmacy;

(c) The names of each physician, physician assistant, and advanced practice registered nurse who worked in the clinic each month during the preceding year along with their license numbers;

(d) The number of patients seen by the clinic for each month in the preceding year;

(e) The number of patients seen in each month who received controlled substances for chronic nonmalignant pain from a practitioner at the clinic;

(f) A list of all drug samples which were dispensed in the preceding year and a copy of the clinic's log pursuant to Title 21 C.F.R. § 1304.11, with regard to those samples;

(g) A list of all owners of the clinic and their percentage of interest in the clinic for each month in the preceding year;

(h) The names of any employees hired or separated within the preceding year as well as the license number of that employee if any are or were licensees; and

(Rule 1200-34-01-.10, continued)

(i) A summary of each advertisement paid for in consideration of any kind.

Authority: T.C.A. §§ 63-1-303, 63-1-306, 63-1-309, 63-1-316, 63-1-317, and 63-1-319.

1200-34-01-.10 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, and is a pain management specialist;

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. identify a pain management specialist who has agreed to provide coverage in the event that the Medical Director is unable to fulfill his or her duties on a temporary basis because of illness, vacation, or unavailability. Such coverage may be provided on a temporary, short-term basis and serving in this capacity will not be considered to count against the limit of four (4) pain management clinics at which a pain management specialist may serve as medical director. The Medical Director maintains all responsibility during any period where coverage is provided, but the covering physician shall only share responsibility for those times during which he or she is providing coverage;

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 use disorder risk assessment tools upon new patient admission and periodic review or re-assessment;

(Rule 1200-34-01-.10, continued)

(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 pain 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;

(ix) creation of a written process for clinical practice evaluation and evidence of regular appropriate supervisory action based on results of the clinical practice evaluation;

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) creation of written policies that are consistent with the Centers for Disease Control and Prevention's guidelines for minimum prevention for outpatient settings; and

(iii) a log of incidents related to infectious and communicable diseases and the corrective action taken;

9. 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 and physical examination;

2. diagnostic, therapeutic, and laboratory results, evaluations and consultations, and records from other health care providers, as available, or attempts to obtain such;

3. documentation of informed consent and discussion of risks and benefits of treatment provided;

4. treatments, treatment options, and treatment objectives;

(Rule 1200-34-01-.10, continued)

5. medications prescribed (including date, type, dosage and quantity prescribed);

6. instructions and agreements;

7. periodic reviews;

8. a notation indicating whether the controlled substance monitoring database had been accessed for a particular patient;

9. 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.

(b) The Medical Director shall ensure adequate medical documentation and shall be responsible for addressing inadequate documentation.

(3) The Medical Director 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.

(4) The Medical Director shall ensure that patient medical records shall be maintained for ten (10) years from the date of the patient's last treatment at the clinic.

(5) The Medical Director shall ensure that patient billing records shall be maintained for seven (7) years from the date of the patient's last treatment at the clinic.

(6) The Medical Director shall ensure that all health care providers employed by or working at the pain management clinic are properly licensed and certified at all times.

(7) The Medical Director shall ensure the delivery of quality care and quality services at the clinic.

(8) The Medical Director 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 or credit card in payment for services provided at the clinic; except that payment may be made in cash or money order 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.

(9) The Medical Director shall ensure that patients have access to their medical records at any time upon request of the patient in keeping with T.C.A. § 63-1-201 et seq. and especially in the event that the clinic closes. The Medical Director shall also ensure that the Department has access to the records upon request.

Authority: T.C.A. §§ 63-1-303, 63-1-306, 63-1-309, and 63-1-310.

(Rule 1200-34-01-.10, continued)

1200-34-01-.11 Training Requirements

(1) Each physician serving as the Medical Director or a supervising physician to an advanced practice registered nurse or physician assistant at the clinic shall meet the statutory requirements to be a pain management specialist, and shall complete the requisite continuing education to maintain that status.

(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 medicine:

(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.

(3) Each health care provider providing pain management services at a clinic shall, in addition to the ten (10) hours of continuing education outlined above, thoroughly read the Tennessee Chronic Pain Guidelines and the Tennessee Pain Clinic Guidelines promulgated by the Department.

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

1200-34-01-.12 Licensure Discipline and Civil Penalties

(1) Upon a finding that a pain management clinic is in violation of any provision of the Tennessee Pain Management Clinic Act (T.C.A. §§ 63-1-301 et seq.) or the rules promulgated pursuant thereto, the Commissioner may impose any of the following actions separately or in any combination which is deemed appropriate to the offense:

(a) Private Censure - This is a written action issued to the Medical Director for minor or near infractions. It is informal and advisory in nature and does not constitute a formal disciplinary action.

(b) Reprimand - This is a written action issued on a Medical Director's pain management clinic license for one time and less severe violations. It is a formal, public disciplinary action.

(c) Probation - This is a formal disciplinary action which places a Medical Director's pain management clinic license on close scrutiny for a period of time.

1. This action may be combined with any other formal disciplinary action and include conditions and requirements which must be met before probation can be lifted and/or which restrict or condition the clinic's activities during the probationary period.

2. Once ordered, probation may not be lifted unless and until the Medical Director petitions, pursuant to paragraph (2) of this rule, after the period of initial probation has run and all conditions placed on the probation have been met and the Commissioner is satisfied that a further probationary period is not warranted such that the probation may be lifted.

(d) Licensure Suspension - This is a formal disciplinary action which suspends the right of the Medical Director and his staff to operate the pain management clinic for a fixed period of time. It contemplates the reopening of the practice under the license previously issued at that location.

1. Once ordered, a suspension may not be lifted unless and until the Medical Director petitions, pursuant to paragraph (2) of this rule, after the period of initial suspension has run and:

(i) All conditions placed on the suspension have been met; and

(ii) The Commissioner is satisfied that the Medical Director and his staff are competent to return to practice and that no further period of suspension is warranted such that the suspension should be lifted.

2. The clinic must be completely closed during the period of licensure suspension. If any licensee admits or sees any new or existing patients during the suspension, that shall be considered a violation of the suspension, and the length of suspension shall toll for any time during which the practice was open in violation of the suspension.

(e) Revocation- This is a formal disciplinary action which closes a clinic and terminates the license previously issued to operate that location as a pain management clinic.

(f) Conditions - Any action deemed appropriate by the Commissioner to be required of a disciplined Medical Director and/or clinic in any of the following circumstances:

1. During any period of probation or suspension; or

2. As a prerequisite to the lifting of probation or suspension; or

3. As a stand-alone requirement(s) in any disciplinary order.

(g) Civil penalty - A monetary disciplinary action assessed by the Commissioner pursuant to paragraph (4) of this rule.

(h) Summary Suspension - This is a formal disciplinary action which immediately and entirely suspends the rights of the Medical Director and his staff to operate the pain management clinic until it is lifted or until a final disposition of the matter after a full hearing. This type of suspension may be ordered ex-parte, pursuant to the notice procedures contained in T.C.A. §4-5-320 upon a finding that the public health, safety or welfare imperatively requires emergency action.

(i) Assessment of costs in disciplinary proceedings shall be as set forth in T.C.A. §§ 63-1-144.

(2) Order of Compliance - This procedure is a necessary adjunct to previously issued disciplinary orders and is available only when a petitioner has completely complied with the provisions of a previously issued disciplinary order and wishes or is required to obtain an order reflecting that

(Rule 1200-34-01-.10, continued)

compliance.

(a) The Commissioner will entertain petitions for an Order of Compliance as a supplement to a previously issued order upon strict compliance with the procedures set forth in subparagraph (b) only when the petitioner can prove compliance with all the terms of the previously issued order and is seeking to have an order issued reflecting that compliance or is seeking to have a suspension or probation lifted.

(b) Procedures

1. The petitioner shall submit a Petition for Order of Compliance, as contained in subparagraph (c), to the Administrative Office that shall contain all of the following:

(i) A copy of the previously issued order; and

(ii) A statement of which provision of subparagraph (a) the petitioner is relying upon as a basis for the requested order; and

(iii) A copy of all documents that prove compliance with all the terms or conditions of the previously issued order. If proof of compliance requires testimony of an individual(s), including that of the petitioner, the petitioner must submit signed, sworn to, and notarized statements from each individual the petitioner intends to rely upon attesting, under oath, to the petitioner's compliance. No documentation or testimony other than that submitted will be considered in making an initial determination on, or a final order in response to, the petition.

2. The administrative staff may make an initial determination on the petition before it is heard by the Commissioner and take one of the following actions:

(i) Certify compliance and have the matter scheduled for presentation to the Commissioner as an uncontested matter; or

(ii) Deny the petition, after consultation with legal staff, if compliance with all of the provisions of the previous order is not proven and notify the petitioner of what provisions remain to be fulfilled and/or what proof of compliance was either not sufficient or not submitted.

3. If the petition is presented to the Commissioner, the petitioner may not submit any additional documentation or testimony other than that contained in the petition as originally submitted.

4. If the Commissioner finds that the petitioner has complied with all the terms of the previous order an Order of Compliance shall be issued.

5. If the petition is denied either initially by staff or after presentation to the Commissioner and the petitioner believes compliance with the order has been sufficiently proven the petitioner may, as authorized by law, file a petition for a declaratory order pursuant to the provisions of T.C.A. § 4-5-223.

(c) Form Petition

Petition for Order of Compliance
Pain Management Clinic

(Rule 1200-34-01-.10, continued)

Petitioner's Name: _____
Petitioner's Mailing Address: _____
_____
_____
Petitioner's E-Mail Address: _____
Telephone Number: _____

Attorney for Petitioner: _____
Attorney's Mailing Address: _____
_____
_____
Attorney's E-Mail Address: _____
Telephone Number: _____

The petitioner respectfully represents, as substantiated by the attached documentation that all provisions of the attached disciplinary order have been complied with and I am respectfully requesting: (circle one)

1. An order issued reflecting that compliance; or

2. An order issued reflecting that compliance and lifting a previously ordered suspension or probation.

Note - You must enclose all documents necessary to prove your request including a copy of the original order. If any of the proof you are relying upon to show compliance is the testimony of any individual, including yourself, you must enclose signed statements from every individual you intend to rely upon attesting, under oath, to the compliance. The Committee's consultant, the Disciplinary Coordinator, and legal staff, in their discretion, may require such signed statements to be notarized. No documentation or testimony other than that submitted will be considered in making an initial determination on, or a final order in response to, this petition.

Respectfully submitted this the ____ day of _____, 20____.

_____
Petitioner's Signature

(3) Order Modifications - This procedure is not intended to allow anyone under a previously issued disciplinary order, including an unlicensed practice civil penalty order, to modify any findings of fact, conclusions of law, or the reasons for the decision contained in the order. It is also not intended to allow a petition for a lesser disciplinary action, or civil penalty other than the one(s) previously ordered. All such provisions of Commissioner Orders were subject to reconsideration and appeal under the provisions of the Uniform Administrative Procedures Act (T.C.A. §§ 4-5-301, et seq.). This procedure is not available as a substitute for reconsideration and/or appeal and is only available after all reconsideration and appeal rights have been either exhausted or not timely pursued. It is also not available for those who have accepted or been issued a reprimand.

(a) The Commissioner will entertain petitions for modification of the disciplinary portion of previously issued orders upon strict compliance with the procedures set forth in subparagraph (b) only when the petitioner can prove that compliance with any one or more of the conditions or terms of the discipline previously ordered is impossible. For purposes of this rule the term "impossible" does not mean that compliance is inconvenient or impractical for personal, financial, scheduling or other reasons.

(b) Procedures

1. The petitioner shall submit a written and signed Petition for Order Modification on the form contained in subparagraph (c) to the Administrative Office that shall contain all of the following:

   (i) A copy of the previously issued order; and

   (ii) A statement of why the petitioner believes it is impossible to comply with the order as issued; and

   (iii) A copy of all documents that prove that compliance is impossible. If proof of impossibility of compliance requires testimony of an individual(s), including that of the petitioner, the petitioner must submit signed, sworn to, and notarized statements from each individual the petitioner intends to rely upon attesting, under oath, to the reasons why compliance is impossible. No documentation or testimony other than that submitted will be considered in making an initial determination on, or a final order in response to, the petition.

2. The administrative staff may make an initial determination on the petition before the Commissioner hears it and take one of the following actions:

   (i) Certify impossibility of compliance and forward the petition to the Office of General Counsel for review and presentation to the Commissioner; or

   (ii) Deny the petition, after consultation with legal staff, if impossibility of compliance with the provisions of the previous order is not proven and notify the petitioner of what proof of impossibility of compliance was either not sufficient or not submitted.

3. If the petition is presented to the Commissioner, the petitioner may not submit any additional documentation or testimony other than that contained in the petition as originally submitted.

4. If the petition is granted, the Commissioner may issue a new order reflecting the authorized modifications that he deems appropriate and necessary in relation to the violations found in the previous order.

5. If the petition is denied either initially by staff or after presentation to the Commissioner and the petitioner believes impossibility of compliance with the order has been sufficiently proven the petitioner may, as authorized by law, file a petition for a declaratory order pursuant to the provisions of T.C.A. § 4-5-223.

(c) Form Petition

Petition for Order Modification
Pain Management Clinic

Petitioner's Name: _____
Petitioner's Mailing Address: _____
_____
_____
Petitioner's E-Mail Address: _____
Telephone Number: _____

(Rule 1200-34-01-.10, continued)

Attorney for Petitioner: _____
Attorney's Mailing Address: _____
_____
_____
Attorney's E-Mail Address: _____
Telephone Number: _____

The petitioner respectfully represents that for the following reasons, as substantiated by the attached documentation, the identified provisions of the attached disciplinary order are impossible for me to comply with:

_____
_____
_____
_____
_____
_____
_____

Note - You must enclose all documents necessary to prove your request including a copy of the original order. If any of the proof you are relying upon to show impossibility is the testimony of any individual, including yourself, you must enclose signed and notarized statements from every individual you intend to rely upon attesting, under oath, to the reasons why compliance is impossible. No documentation or testimony other than that submitted will be considered in making an initial determination on, or a final order in response to, this petition.

Respectfully submitted this the day of , 20 .

_____
Petitioner's Signature

(4) Civil Penalties

(a) Purpose - The purpose of this paragraph is to set out a schedule designating the minimum and maximum civil penalties which may be assessed pursuant to T.C.A. §§ 63-1-134 and 63-1-316.

(b) Schedule of Civil Penalties

1. A Type A civil penalty may be imposed whenever the Commissioner finds the medical director, an owner, or clinic staff guilty of a willful and knowing violation of the Practice Act, or regulations promulgated pursuant thereto, to such an extent that there is, or is likely to be an imminent, substantial threat to the health, safety and welfare of an individual client or the public or in such a manner as to impact directly on the care of patients or the public.

2. A Type B civil penalty may be imposed whenever the Commissioner finds medical director, an owner, or clinic staff is guilty of a violation of the Practice Act, or regulations promulgated pursuant thereto, which are neither directly detrimental to the patients or public, nor directly impact their care.

(c) Amount of Civil Penalties

1. Type A Civil Penalties shall be assessed in the amount of not less than $500 or

(Rule 1200-34-01-.10, continued)

more than $1,000.

2. Type B Civil Penalties may be assessed in the amount of not less than $100 and not more than $500.

(d) Procedures for Assessing Civil Penalties

1. The Department may initiate a civil penalty assessment by filing a Memorandum of Assessment of Civil Penalty. The Department shall state in the memorandum the facts and law upon which it relies in alleging a violation, the proposed amount of the civil penalty and the basis for such penalty. The Department may incorporate the Memorandum of Assessment of Civil Penalty with a Notice of Charges which may be issued attendant thereto.

2. Civil Penalties may also be initiated and assessed by the Commissioner or his designee during consideration of any Notice of Charges. In addition, the Commissioner or his designee may, upon good cause shown, assess a type and amount of civil penalty which was not recommended by the Department.

3. In assessing the civil penalties pursuant to these rules the Commissioner or his designee may consider the following factors:

(i) Whether the amount imposed will be a substantial economic deterrent to the violator;

(ii) The circumstances leading to the violation;

(iii) The severity of the violation and the risk of harm to the public;

(iv) The economic benefits gained by the violator as a result of non-compliance; and,

(v) The interest of the public.

4. All proceedings for the assessment of civil penalties shall be governed by the contested case provisions of Title 4, Chapter 5, Tennessee Code Annotated.

(5) At the conclusion of a hearing, should the Commissioner determine to hold the case under advisement and make a recommendation as to requirements to be met by the pain management clinic in order to avoid suspension, revocation, or other discipline of a license or suspension of admissions, such recommendations shall be a public record and shall be considered formal discipline.

(a) Should the Commissioner make such a recommendation, the clinic must present proof of having met those requirements to the Commissioner for a determination regarding whether they have been satisfactorily met.

(b) Should the Commissioner determine that the recommended requirements have not been met, the Commissioner shall make a finding and record of this determination, and shall impose appropriate formal discipline.

(c) Should the clinic comply with the recommendations, the Commissioner has the authority to impose a lesser sanction as outlined in his recommendation, or no sanction at all, provided however, that both the initial recommendations and final order shall be a public record and shall be considered formal discipline.

(Rule 1200-34-01-.10, continued)
Authority: T.C.A. §§ 63-1-303, 63-1-306, and 63-1-316.

1200-34-01-.13 Commissioner Suspensions of Treatment of New or Existing Patients

(1) In cases where the Commissioner determines that the conditions of any pain management clinic are, or are likely to be, detrimental to the health, safety, or welfare of any patient, the Commissioner may suspend treatment of any new or existing patients in whole or part at the Commissioner's sole discretion, pending a prompt hearing and in accordance with the requirements and provisions set out at T.C.A. § 63-1-318. The Commissioner may also convene an advisory panel, at his discretion, to make recommendations regarding the conditions of any clinic.

(2) The following is a non-exhaustive list of conditions which are, or are likely to be, detrimental to the health, safety, or welfare of a patient:

(a) Where there is gross deviation or a pattern of deviation from the Chronic Pain Guidelines or Pain Clinic Guidelines promulgated by the Department;

(b) Where there is a pattern of negligence or a pattern of noncompliance with normal standards of care;

(c) Where there is dispensing of schedule II or schedule III drugs in violation of T.C.A. § 63-1-313;

(d) Where a provider in the clinic demonstrates active, untreated impairment or substance use disorder.

Authority: T.C.A. §§ 63-1-303 and 63-1-318.

1200-34-01-.14 Unlicensed Pain Management Clinics

(1) When the Department has reason to believe that a health care provider's office is operating as an unlicensed pain management clinic, such health care provider shall produce satisfactory evidence to the Department that the majority of its patient population is not receiving chronic nonmalignant pain treatment to avoid establishment of a rebuttable presumption that the clinic is operating as an unlicensed pain management clinic. For purposes of this determination, patients seen within the preceding twelve (12) months will be considered in determining the percentage of patients receiving chronic non-malignant pain treatment.

(2) Upon request from the Department the health care provider's office shall produce medical records, business records, and any information responsive to the list below, within ten (10) business days. After initial review, the Department may ask for any necessary additional information to be produced within another ten (10) business days from the Department's request for additional information. Evidence which will be required by the Department during this process may, at the discretion of the Department, include:

(a) A complete list of every patient seen at the clinic to include a listing of all dates during the preceding twelve (12) months when that patient was seen or treated;

(b) A complete list of every patient seen at the clinic within the preceding twelve (12) months which delineates each patient's diagnosis as well as what was prescribed to that patient, the drug name, drug strength, number of pills to be dispensed, and number of days of intended use;

(c) A complete list of all the billing codes which were submitted for each patient seen by the clinic as well as copies of the bills with remittances during the preceding twelve (12)

(Rule 1200-34-01-.10, continued)

months; and

(d) A complete list of every clinic patient seen by the clinic during the preceding twelve (12) months who did not receive chronic non-malignant pain treatment with a description of the type of services that patient did receive.

(3) After being provided any of the patient lists above, should the Department need to review charts of any of the clinic's patients to assist in making its determination, the clinic will be notified of the names and given ten (10) business days to produce those patients' charts.

(4) Should the health care provider's office be unable to provide satisfactory evidence, the Department shall notify the clinic of such determination in writing. The clinic shall be prohibited from admitting any new patients to the practice, and all owners and practitioners who worked at the clinic shall be subject to revocation of their licenses.

(5) The Commissioner may issue a determination, or at the Commissioner's discretion, may convene an advisory panel to meet regarding whether the clinic was operating as an unlicensed pain management clinic and to make a recommendation to the Commissioner prior to the Commissioner's determination. The Commissioner shall not be bound by the recommendation of the advisory panel.

(6) The Department has discretion to await the Commissioner's determination and the recommendations of the Advisory Panel before proceeding against the health care practitioners at the clinic for providing services in an unlicensed pain management clinic.

Authority: T.C.A. §§ 63-1-311, 63-1-315, and 63-1-317.

1200-34-01-.15 Financial Requirement

(1) Licensed pain management clinics shall be required to hold as surety either bonds or liability insurance in an amount at least double one year's operating expense.

(2) The bond or insurance must remain in force as long as the Medical Director's pain management clinic license is active. Upon notice of cancellation for any reason, the Medical Director shall cease operating, and shall cause all the staff to cease operating, the clinic.

(3) Proof of such surety shall be produced to the Department upon request.

Authority: T.C.A. § 63-1-316.

1200-34-01-.16 Advertising

(1) The vulnerability on the part of some patients concerning pain management services, and the foreseeable consequences of unrestricted advertising by pain clinics, requires that special care be taken in advertising for pain management services.

(2) The following statements, acts, or omissions in the context of advertisements by or for any clinic shall not be permitted:

(a) Any communication, including the use of personal testimonials, attesting to the quality of a service or treatment offered at the clinic, or the competency of those at the clinic rendering the service or treatment, with regard to potential results of any service or treatment that is not reasonably verifiable, if that communication is in exchange for consideration of any form.

(b) Any communication which creates an unjustified expectation concerning the potential

(Rule 1200-34-01-.10, continued)

results of that treatment.

(c) Failure of the pain management clinic to include all the following in the advertisement:

1. The licensure or certification number of the clinic as well as the official name in which the clinic is licensed;

2. The name of the medical director.

(d) Use of the name of any licensee formerly practicing at or associated with any pain management clinic after thirty (30) days from that licensee's departure, including use of the name on any signage for the office or building.

(e) Stating or implying that a certain licensee provides, or will be providing, all services when any such services are regularly, or will be, performed by another licensee.

(f) Directly or indirectly offering, giving, receiving, or agreeing to receive any fee or other consideration to or from a third party for the referral of a patient in connection with the performance of professional services.

(3) A copy of every advertisement, whether communicated through electronic or printed media, must be kept in as close to the original communication method as possible for at least two (2) years from the last date of communication and shall be submitted to the Department for review upon request.

(4) The Medical Director is responsible for all advertising content which must also be in compliance with the rules of the Tennessee Board of Medical Examiners.

Authority: T.C.A. §§ 63-1-311 and 63-1-317.

1200-34-01-.17 Infectious Disease and Building Standards

Each pain management clinic shall meet all health and safety standards necessary to protect the health and welfare of patients seeking medical assistance from the clinic.

Authority: T.C.A. §§ 63-1-311 and 63-1-317.