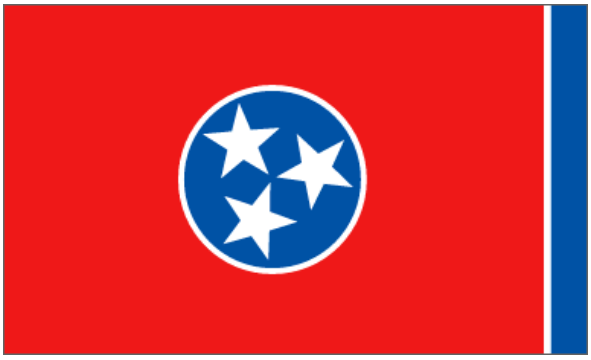
Prescribing and Dispensing Profile

Tennessee



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NAMSDL
National Alliance for Model State Drug Laws

Schedule II Prescribing Limitations (not related to pain clinics)

Schedule II substances may only be dispensed on the written prescription of a practitioner

- May be dispensed on the oral prescription of a practitioner in emergency situations
  - Must be promptly reduced to writing

Schedule II prescriptions may not be refilled

Schedule III, IV and V Prescribing Limitations (not related to pain clinics)

Schedule III and IV substances may only be dispensed on the written or oral prescription of a practitioner

Schedule V substances may not be distributed or dispensed for other than a medical purpose

Schedule III and IV prescriptions may not be filled or refilled more than six months after originally issued or refilled more than five times unless renewed by the practitioner

Miscellaneous Prescribing/Dispensing Requirements

No prescription for opioids or benzodiazepines may be dispensed in quantities greater than a 30 day supply

Any prescribers of opioids, benzodiazepines, barbiturates, or carisoprodol, either alone, concurrently, or sequentially with any other opioids, benzodiazepines, barbiturates, or carisoprodol who are in chronic, long term drug therapy for 90 days or more shall consider mandatory drug testing

If a pharmacist becomes aware that a prescriber has died, a prescription issued by the prescriber may continue to be dispensed based on the pharmacist's professional judgment and in accordance with the following:

- If the prescription is a new prescription that has not previously been dispensed, it may be dispensed within 90 days of the date on which the prescriber has died
- If the prescription has previously been dispensed and has valid authorization to be refilled, the refills may be dispensed but not for a period of more than 90 days from the date on which the prescriber died for Schedule III – V drugs and 180 days for non-scheduled drugs
- Does not apply to Schedule II drugs

Physicians who elect to dispense medication for remuneration must comply with all federal regulations related to dispensing of controlled substances

Prescriptions must contain the following information:

- Name of prescriber
- Name and strength of drug prescribed
- Quantity
- Directions for use
- Date issued

Prescribing/Dispensing Limitations for Dentists

Dentists may dispense, prescribe, or otherwise distribute Schedule II – V controlled substances to patients with whom they have an established dentist/patient relationship

- Dentist/patient relationship means that the dentist has provided dental treatment to the patient on at least one occasion within the preceding year or exists by having a documented knowledge of the specific patient history

Prescribing/Dispensing Limitations for Optometrists

The practice of optometry includes the administration and prescribing of pharmaceutical agents rational to the diagnosis and treatment of conditions or diseases of the eye or eyelid

Optometrists who meet the requirements may be certified to administer and prescribe pharmaceutical agents for treatment

Pain Clinic/Pain Management Regulations

Pain management clinic means:

- A privately-owned clinic, facility, or office in which any health care provider licensed in Tennessee provides chronic non-malignant pain treatment to a majority of its patients for 90 days or more in a twelve month period
  - The caseload of patients who received medical treatment from all medical doctors, osteopathic physicians, advanced practice nurses, and physician assistants who serve in the clinic, facility, or office shall be counted
- Also means a privately-owned clinic, facility, or office which advertises in any medium for pain management services of any type
- Does not include any clinic, facility, or office which provides interventional pain management and whose clinic, facility, or office does not provide chronic non-malignant pain treatment to a majority of its patients
- Does not include any clinic, facility, or office that is wholly owned and operated by a physician multi-specialty practice in which one or more board-eligible or board-certified medical specialists who have also completed fellowships in pain medicine, or who are also board-certified in pain medicine perform the pain management services for chronic pain patients

Health care practitioners must notify the board responsible for their licensure within ten days of starting or ending work at any pain management clinic

Pain management clinics must have a medical director who is a physician that practices in Tennessee

- Medical director must meet one of the following qualifications:
  - 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
  - Board certification in physical medicine and rehabilitation, anesthesiology, addiction medicine, neurology, neurosurgery, family practice, preventive medicine, internal medicine, surgery, orthopedics or psychiatry

Pain Clinic/Pain Management Regulations, cont'd.

- 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 with a certificate of added qualification from the Bureau of Osteopathic Specialists
- Board certification by the American Board of Pain Medicine
- Board certification by the American Board of Interventional Pain Physicians
- Completion of 40 hours of in-person, live participatory AMA Category I continuing medical education in pain management completed within three years prior to serving as medical director for the clinic

- Medical director can serve as director for no more than four pain management clinics
- Medical director shall:
  - Oversee all of the pain management services provided at the clinic
  - Be on site at least 20% of the clinic's weekly total number of operating hours
  - Ensure that each supervising physician for each of the health care providers working at the clinic complies with the supervising requirements
  - Ensure that health care providers comply with federal and state law regarding the prescribing of controlled substances
  - Ensure the establishment of protocols for health care providers and ensure compliance with said protocols
  - Ensure that there is an alternate medical director available in the event the medical director is unable to fulfill his duties for a time
  - Establish quality assurance policies and procedures, which, at a minimum, include, but are not limited to:
    - Documentation of the background, training, licensure, and certifications for all pain management clinic staff providing patient care
    - Written drug screening policy and compliance plan for patients to include random drug screening as clinically indicated, but at a minimum upon each new admission and once every six months thereafter
    - Use of substance abuse risk assessment tools upon each new patient admission and periodic review or re-assessment
    - 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
    - Medication counts for any controlled substance prescribed
    - Use of patient agreements and periodic reviews of such agreements
    - Health care provider access and review of patient PMP information, as clinically indicated, but at a minimum upon each new admission and once every six months thereafter
    - Documentation of requests for records from other health care providers
  - Establish an infection control program
  - Establish written policies and procedures for health and safety requirements at the clinic
  - Ensure compliance with the patient safety standards

Pain Clinic/Pain Management Regulations, cont'd.

- Ensure that health care providers maintain complete and accurate patient records which shall include, but not be limited to, the following:
  - Patient medical history
  - Physical examination
  - Diagnostic, therapeutic, and laboratory results
  - Evaluations and consultations
  - Treatment objectives
  - Documentation of informed consent and discussion of risks and benefits
  - Treatments and treatment options
  - Medications prescribed
  - Instructions and agreements
  - Periodic reviews
  - Reason for prescribing or dispensing more than a 72 hour dose of controlled substances for the treatment of chronic non-malignant pain
  - Notation indicating whether the PMP had been accessed for the particular patient
  - Copies of records, reports, or other documentation from other health care providers
  - Results of drug screens

If any practitioner prescribes controlled substances for the treatment of chronic non-malignant pain, the practitioner must document in the patient's record the reason for prescribing that quantity

No pain management clinic or practitioner working at a pain management clinic shall be permitted to dispense controlled substances

- May provide, without charge, a sample of a Schedule IV or V controlled substance in a quantity limited to an amount that is adequate to treat the patient for a maximum of 72 hours or a sample of a non-narcotic Schedule V substance in a quantity limited to an amount adequate to treat the patient for a maximum of 14 days

Authority of physician to prescribe controlled substances for the treatment of pain

- It is the position of the medical board that controlled substances may be prescribed for the treatment of pain and other related symptoms after a reasonably based medical diagnosis has been made, in adequate doses, and for appropriate lengths of time, which may be as long as the pain or related symptoms persist
- Board recognizes that pain, including intractable pain, and many other related symptoms are subjective complaints and that the appropriateness and adequacy of drug and dose will vary from individual to individual
  - Practitioner is expected to exercise sound medical judgment in treating pain and related symptoms with dangerous drugs and controlled substances
- Intractable pain means a pain state in which the cause of the pain cannot be removed or otherwise treated and which in the generally accepted course of medical practice no relief or cure of the cause of the pain is possible or none has been found after reasonable efforts
- No physician is required to provide treatment to patients with intractable pain with opiate medications but when refusing to do so shall inform the patient that there are physicians whose primary practice is in the treatment of severe, chronic, intractable pain with methods including the use of opiates and shall make referral to such a physician if the patient requests it

Pain Clinic/Pain Management Regulations, cont'd.

- If the physician provides medical care to patients with intractable pain, with or without the use of opiate medications, to the extent that those patients become the focus of the physician's practice, the physician must be prepared to document specialized medical education in pain management sufficient to bring the physician within the current standard of care in the field which shall include education in the causes, different and recommended modalities for treatment, chemical dependency, and the psychosocial aspects of severe, chronic intractable pain

Guidelines regarding the prescribing, administering, ordering, or dispensing of pain medications and other drugs

- The treatment of pain, including intractable pain, with dangerous drugs and controlled substances is a legitimate medical purpose when done in the usual course of professional practice
- Medical history and physical exam by the physician, including an assessment and consideration of the pain, physical, and psychological function, any history and potential for substance abuse, coexisting diseases and conditions, and the presence of a recognized medical indication for the use of a dangerous drug or controlled substance
- Treatment plan tailored to the individual needs of the patient by which treatment progress and success can be evaluated with stated objectives such as pain relief and/or improved physical and psychosocial function
  - Treatment plan shall consider pertinent medical history and physical exam as well as the need for further testing, consultations, referrals, or use of other treatment modalities
- Discussion of the risks and benefits of the use of controlled substances with the patient
- Periodic review of the care by the physician at reasonable intervals in regard to progress toward reaching treatment goals which takes into consideration the medications prescribed as well as any new information about the etiology of the pain
- Complete and accurate medical records must be kept

Training or Education Requirements or Recommendations for Practitioners who Prescribe or Dispense Controlled Substances

Optometrists who are therapeutically certified must complete at least two hours of continuing education in prescribing practices

All optometrists holding a current Tennessee license must complete two hours of continuing education related to controlled substance prescribing, which must include instruction in the Department's treatment guidelines on opioids, benzodiazepines, barbiturates, and carisoprodol and may include topics such as medicine addiction, risk management tools, and other topics approved by the Board

All prescribers who hold a current federal DEA license and who prescribe controlled substances shall be required to complete a minimum of two hours of continuing education related to controlled substances prescribing

- Continuing education must include instruction in the department's treatment guidelines on opioids, benzodiazepines, barbiturates, and carisoprodol and may include other topics such as medicine addiction, risk management tools, and other topics

Training or Education Requirements or Recommendations for Practitioners who Prescribe or Dispense Controlled Substances, cont'd.

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 address one or more of the following topics related to pain management:

- Prescribing controlled substances
- Drug screening
- Pharmacological and non-pharmacological pain management
- Completing a pain management focused history and physical examination and maintaining appropriate progress notes
- Comorbidities with pain syndromes
- Substance abuse and misuse including diversion, prevention of same, and risk assessment for abuse

Medical Marijuana or Controlled Substances Therapeutic Research Program Provisions

No specific statutes or regulations identified.

PMP Requirements for Mandatory Registration and Access

All prescribers with DEA numbers who prescribe controlled substances and dispensers in practice providing direct care to patients in Tennessee for more than 15 calendar days per year shall be registered with the PMP

- New licensees shall have up to 30 calendar days after notification to register with the database

Prescribers are required to check the PMP before prescribing or dispensing certain controlled substances at the beginning of a new episode of treatment and at least annually when the controlled substance remains part of the patient's treatment

- Controlled substances that trigger the requirement to query the PMP include all opioids and benzodiazepines

The medical director of a pain management clinic shall establish quality assurance policies and procedures which include health care provider access to and review of patient PMP information as clinically indicated but, at a minimum, upon each new admission and once every six months thereafter

Non-residential opioid treatment facilities shall implement a screening process for prospective service recipients that includes verification of other prescribed medications through the PMP

- The facility shall check the PMP:
  - Upon admission of the service recipient,
  - At least every six months to determine if controlled substances other than methadone are being prescribed for the service recipient
  - Prior to the initial administration of methadone or other treatment in an opioid treatment program
  - After any positive drug test for prescription medication
  - Prior to requesting any take-home or dosing exceptions and shall submit this report to the SOTA with the exception request

PMP Requirements for Mandatory Registration and Access, cont'd.

Dispensers must check the PMP prior to dispensing a controlled substance if the dispenser is aware or reasonably certain that a person is attempting to obtain a Schedule II – V controlled substance for fraudulent, illegal, or medically inappropriate purposes

Patient Referral to Treatment

No specific statutes or regulations identified.

Board Guidelines

Tennessee Chronic Pain Guidelines, Department of Health, September, 2014

Prior to initiating opioid therapy for chronic non-malignant pain

- Key principles:
  - A patient having been prescribed opioids by a previous provider is not, in and of itself, a reason to continue opioids
  - Reasonable non-opioid treatments should be tried before opioids are initiated
  - All newly pregnant women should have a drug test administered by the appropriate women's health provider
  - The provider should discuss a birth control plan to prevent unintended pregnancies with every woman of child-bearing age who has reproductive capacity when opioids are initiated
  - Patient's medical history, physical examination, laboratory tests, imaging results, electro-physiologic testing, and other elements supporting the plan of care, should be documented in the medical record prior to initiating opioid therapy
  - Chronic pain shall not be treated by the use of controlled substances through the use of telemedicine
- Initial evaluation – steps prior to initiating trial of opioid therapy:
  - Specific evaluation and history of the patient's pain condition should be obtained
    - Exam should include the nature and intensity of the pain, past and current treatments for pain, any co-occurring disorders, and the effect of the pain on the patient's life functioning, including, but not limited to, work, relationships, recreation, and sleep
  - The presence of important co-morbid medical conditions should be assessed, including the age of the patient and certain medical conditions
  - An initial, condition-appropriate physical examination of the patient should be conducted as well as a system review
  - The possible presence of co-occurring mental health disorders should be considered
    - Screening should occur for disorders such as depression, anxiety, and current or past substance abuse and, if present, these should be addressed in the creation of a treatment plan
  - Review of prior records directly related to the patient's chronic pain condition is encouraged
  - Women of child-bearing age who have reproductive capacity should be asked about possible pregnancy at each visit and, for those who wish to avoid unintended pregnancy, use of long-acting reversible contraceptives should be discussed, or referral to appropriate high-risk obstetrician made

Board Guidelines, cont'd.

- There should be the establishment of a current diagnosis that justifies the need for opioid medications
- Assessment for risk of abuse:
  - Prescriber shall assess the patient's risk for misuse, abuse, diversion, and addiction using a validated risk assessment tool
  - Prescriber should obtain a drug test
  - Based on the combined information of the validated risk assessment results, the PMP results, and the drug test results and past records, an initial assessment should be made about the patient's risk of misuse, abuse, or diversion and the prescribing of opioids shall take the risk assessment information into consideration in the prescribing of opioids and patient's treatment plan
- Goals for treatment:
  - Primary goal should be clinically significant improvement in function
  - Treatment plan is expected to include other treatments or modalities beyond opioids, both pharmacological and non-pharmacological
  - Patient should be counseled that the goal of chronic opioid therapy is to increase function and reduce pain, not eliminate pain

Initiating opioid therapy for chronic non-malignant pain

- Key principles:
  - Patient should be prescribed a maximum of four doses of a short-acting opioid per day
    - If provider deems it necessary to do otherwise, s/he shall clearly document the medical reasons for this decision
  - Providers who are not pain medicine specialists shall not prescribe methadone for a chronic pain condition
  - Prescribers shall not prescribe buprenorphine in the form of oral or sublingual buprenorphine for chronic pain condition
  - Benzodiazepines should be generally avoided in combination with chronic opioid therapy
    - When the opioid dose reaches 120mg MEDD and the benzodiazepines are being used for mental health purposes, the provider shall refer to a mental health professional to assess necessity of benzodiazepine medication
  - Buprenorphine/naloxone combinations shall be avoided for the treatment of chronic pain
  - If treatment deviates from recommended guidelines, the reasons shall be documented in the medical record
- Upon initiating opioid therapy:
  - The initiating of opioids should be presented to the patient as a therapeutic trial
  - The lowest dose of opioids should be given to an opioid-naïve patient and then titrated to effect
  - Informed consent must be obtained before initiating opioid therapy
    - Informed consent documents typically cover: potential risks and anticipated benefits of opioid therapy, potential side effects, likelihood of physical dependence, risks of over-sedation, pregnancy, risk of impaired motor skills, risk of addiction and death

Board Guidelines, cont'd.

- Written treatment agreement should be used with the patient
  - Treatment agreements typically cover:
    - Reasons for which opioid therapy might be discontinued
    - The practice policy on early refills
    - Policy on lost prescriptions and medications
    - Expectation for safe storage of medications
    - Use of one pharmacy
    - Expectations about periodic drug testing
    - Expectation that female patients will tell provider if she wishes to avoid unintended pregnancy and if she becomes pregnant
- Providers shall continually monitor the patient for signs of abuse, misuse, or diversion
  - An unannounced drug test should be done twice a year at a minimum

Ongoing opioid therapy for chronic, non-malignant pain

- Key principles:
  - All chronic opioid therapy should be handled by a single provider or practice and all prescriptions should be filled in a single pharmacy, unless the provider is informed and agrees that the patient can go to another pharmacy for a specific reason
  - Opioids should be used at the lowest effective dose
  - Provider should not use more than one short-acting opiate concurrently
  - Documentation of the 5 A's (analgesia, activities of daily living, adverse side effects, aberrant drug-taking behaviors, and affect) at the initiation of chronic opioid therapy and at follow up visits should be included in the medical record
- Ongoing therapy:
  - Patients on opioid doses of 120mg MEDD or greater should be referred to a pain specialist for a consultation and/or management
    - If a provider cannot make the required consultation as outlined above, then s/he shall clearly document why not
  - An ongoing risk assessment should be made about a patient's risk of misuse, abuse or diversion of medications
    - The prescribing of opioids, if medically indicated, shall take this risk assessment information into account on an ongoing basis and adjustments to the patient's treatment should occur in a timely manner based on this information
  - Emergency department physicians should keep the specialist and the primary care provider informed about changes in a patient's condition and any emergent incidents or conditions
  - Opioids are to be discontinued when the risks, side effects, lack of efficacy or presence of medication or aberrant behavior outweigh the benefits
  - Appropriate documentation of PMP query should be included in the medical record