

Tennessee Chronic Pain Guidelines

Clinical Practice Guidelines for
Outpatient Management of
Chronic Non-Malignant Pain



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Edition
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TENNESSEE CLINICAL PRACTICE GUIDELINES FOR OUTPATIENT MANAGEMENT OF CHRONIC NON-MALIGNANT PAIN

The purpose of these guidelines is to define appropriate treatment of chronic pain, which is defined as pain lasting longer than 90 days. The goal is to foster timely and appropriate treatment for pain, which improves both the ability to function and quality of life. These guidelines are intended to be used to support clinicians in their treatment of patients with chronic pain with reference to the prescribing of opioid medications. Optimal treatment of chronic pain is a multidisciplinary process that includes many therapies which do not always involve opioid pain medications.

The method used to formulate these guidelines included a review of national expert panel recommendations and state practice guidelines, multiple listening sessions with clinicians in Tennessee, oversight by a multidisciplinary steering committee and recommendations from an advisory committee with strong representation by clinicians with specialty training in pain medicine. Draft clinical guidelines were also circulated to a broader group of professional associations within Tennessee, including but not limited to mental health and substance abuse and workers' compensation programs.

Pain Medicine is the medical specialty dedicated to the prevention, and treatment of people with chronic pain. While most Physicians, Advanced Practice Nurses, and Physicians Assistants have training and experience in the management of chronic pain, Pain Medicine Specialists have fellowship training from ABMS, AOA, or additional training in pain medicine sufficient to obtain ABPM diplomat status. Current protocols regarding the delineation of prescribing authority to and supervision of Advanced Practice Nurses with certificate of fitness for prescribing and Physicians Assistants for prescribing to treat chronic pain continue to apply. Pain Medicine Specialists often deal with patients being treated with more than 120 milligram morphine equivalent daily dose (MEDD) because they are at least eleven times more likely to suffer an adverse effect including overdose death. Pain Medicine Specialist is defined by [T.C.A. § 63-1-301 \(8\)](#). These guidelines address when to consult with or refer to a Pain Specialist for care of a chronic pain patient.

The importance of management of chronic pain is apparent by the following facts:

- In 2022, Tennessee ranked 6th in per capita prescription opioid dispensing rate in the US. [Opioid Dispensing Rate Maps | Drug Overdose | CDC Injury Center](#).
- In 2021, a total of 3,814 Tennesseans died of a drug overdose, representing a 26% increase from 2020. Over the past five years, drug overdose deaths in Tennessee increased consistently. Opioids have consistently played a role in drug overdose deaths in Tennessee and were involved in 80% of overdose deaths in 2021. *See [Tennessee Drug Overdose Deaths](#)*
- In Tennessee, 824 babies were born with Neonatal Abstinence Syndrome (NAS) in 2020. *See <https://www.tn.gov/tntfacesofopioids.html>*.
- In the midst of this Substance Use Disorder epidemic, chronic pain is likewise a significant public health problem. At least 116 million US adults—more than the number affected by heart disease, diabetes and cancer combined—suffer from common chronic pain conditions.
- The long-term goals of appropriate pain management are to improve symptoms, function and overall quality of life while minimizing adverse effects, substance-use disorders, fatal and non-fatal overdoses, and NAS. These guidelines can help clinicians reduce problems associated with prescription opiates while maintaining access to compassionate care and appropriate medications for patients living with chronic pain. These guidelines are organized into three sections and appendices contain additional tools and guidance.

The guidelines apply to all healthcare providers. These guidelines would not apply to patients in a hospice program or in a palliative care setting with a life expectancy of six months or less. These guidelines do not apply to patients admitted to a hospital. These guidelines are not meant to dictate medical decision making. They are guidelines of generally accepted medical practice rather than absolutes. Providers still have flexibility to deal with exceptional cases. Occasional deviation from these guidelines for appropriate medical reasons is to be expected and documented.

SECTION I:

Prior to Initiating Opioid Therapy for Chronic Non-Malignant Pain

SECTION I: PRIOR TO INITIATING OPIOID THERAPY FOR CHRONIC NON-MALIGNANT PAIN

A. Key Principles Prior to Initiating Opioid Therapy

1. A patient having been prescribed opioids by a previous provider is not, in and of itself, a reason to continue opioids. The provider should consider the risks of abrupt discontinuation, continuation, and gradual tapering when creating an initial treatment plan.
2. For opioid naïve patients, reasonable non-opioid therapies should be tried before opioids are initiated. Opioids should be initiated only after other reasonable, appropriate and available therapies for the pain condition have been considered.
3. All newly pregnant women should have a urine drug test administered by the appropriate women's health provider.
4. The provider should discuss a birth control plan to prevent unintended pregnancy with every woman of child-bearing age who has reproductive capacity when opioids are initiated.
5. The 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.
6. Chronic non-malignant pain shall not be treated using controlled substances through telemedicine.

B. Initial Evaluation: Steps Prior to Initiating Trial of Opioid Therapy

1. A specific evaluation and history of the patient's pain condition should be obtained. The examination 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.
2. The presence of important co-morbid medical conditions should be assessed and considered when deciding whether to initiate opioids. This includes age of the patient and medical conditions such as chronic obstructive pulmonary disease, sleep apnea, diabetes or congestive heart failure.
3. An initial, condition-appropriate physical examination of the patient should be conducted. A systems review shall be conducted as well.
4. The possible presence of co-occurring mental health disorders should be considered when deciding whether to initiate a trial of opioids. Screening should occur for disorders such as depression, anxiety and current or past Substance Use Disorder and, if present, these should be addressed in the creation of a treatment plan. (See Sample Patient Agreement in Appendices).
5. A review of prior records directly related to the patient's chronic pain condition is encouraged before opioids are prescribed.
6. Women of child-bearing age who have reproductive capacity should be asked about the possibility of pregnancy at each visit. For women who wish to avoid unintended pregnancy, use of long-acting reversible contraceptives should be discussed, or referral to appropriate high-risk obstetrician made.

SECTION I: PRIOR TO INITIATING OPIOID THERAPY FOR CHRONIC NON-MALIGNANT PAIN

C. Establishing a Diagnosis

There shall be the establishment of a current diagnosis that justifies a need for opioid medications.

D. Assessment of Risk for Abuse

1. The prescriber shall assess the patient's risk for misuse, abuse, diversion, and addiction using a validated risk assessment tool prior to initiating opioid therapy. The prescriber must also consult the Controlled Substance Monitoring Database (CSMD, see Appendices) prior to the initiation of opioid therapy.
2. The prescriber should obtain a Urine Drug Test (UDT) (or a comparable test on oral fluids) prior to initiating opioid therapy. Prescribers should compare UDT results, the CSMD, and the patient's self-report before prescribing.
3. Based on the combined information of the validated risk assessment results, the Controlled Substances Monitoring Database (CSMD) results and the UDT results and past records, an initial 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 in the prescribing of opioids and the patient's treatment plan.

E. Goals for Treatment

1. The primary goal of treatment should be clinically significant improvement in function.
2. A treatment plan should be developed at the onset of treatment and is expected to include other treatments or modalities beyond opioids, both non-pharmacological and pharmacological, and an initial proposed timeline for treatment. The provider should make reasonable attempts to implement this treatment plan, allowing for barriers such as finances, accessibility, and resource distribution.
3. Treatment Plans should establish treatment goals with all patients, including realistic goals for pain and function. One widely used assessment is the 3- item PEG Assessment Scale
 - Pain average
 - Interference with Enjoyment of life
 - Interference with General Activity
4. The patient should be counseled that the goal of chronic opioid therapy is to increase function and reduce pain, not to eliminate pain. Documentation of this discussion shall be included in the medical record.

SECTION II:

Initiating Opioid Therapy for Chronic Non-Malignant Pain

Section II: Initiating Opioid Therapy for Chronic Non-Malignant Pain

A. Key Principles When Considering Prescribing Opioids.

1. National data suggests risk of overdose death starts at 40 MEDD (morphine equivalent daily dose) in opioid naïve patients with the greatest risk in the population is in the first two weeks of treatment. The risk of overdose for all patient populations increases tenfold at 100 MEDD. Tennessee data suggests the tenfold risk may start closer to 81 MEDD.
2. When starting opioid therapy as a provider for chronic pain, clinicians should generally prescribe immediate-release opioids instead of extended-release or long-acting opioids. Some deviations are expected, and the reason should be documented.
3. Any product containing buprenorphine, whether with or without naloxone, may only be prescribed for a use recognized by the federal food and drug administration, in accordance with T.C.A § 53-11-311(a). Unless there is a documented diagnosis of opiate addiction in medical record, the patient received treatment from a provider practicing under a 21 U.S.C. § 823(g)(2) and who is counted toward the total of number of patients set forth in that statute.
4. Benzodiazepines should be generally avoided in combination with chronic opioid therapy. When a person is being treated for chronic pain with opioid medication and benzodiazepines are being co-prescribed for mental health purposes, the provider should make all reasonable efforts to consult with, or refer the patient to, a mental health professional to assess necessity of benzodiazepine medication.
5. If Methadone is being prescribed for chronic pain, the prescriber should understand the complexities of Methadone and take all reasonable steps to refer the patient to a pain specialist. The decision to treat should consider all available treatment options.
6. Should treatment deviate from recommended guidelines, the reasons shall be documented in the medical record.

B. Upon Initiating Opioid Therapy

1. The initiation of opioids should be presented to the patient as a therapeutic trial.
2. When initiating opioid therapy, the lowest dose of opioids should be given to an opioid-naïve patient and then titrated to effect.
3. Informed consent for the use of opioids in treating pain must be obtained prior to initiating treatment. Informed consent documents typically cover potential risks and anticipated benefits of opioid therapy, potential side effects, likelihood of physical dependence, risk of over-sedation, pregnancy, risk of impaired motor skills, risk of addiction and death.
4. A written pain treatment agreement should be used with the patient at the time opioids are first prescribed for chronic pain. Treatment agreements typically cover reasons, for which opioids may be discontinued, the practice policy on early refills, policy on lost prescriptions or medications, expectation for safe storage of medications, use of one pharmacy and expectations about periodic drug testing. (See Sample Patient Agreement in Appendices).

Section II: Initiating Opioid Therapy for Chronic Non-Malignant Pain

The treatment agreement shall include an expectation that a female patient will tell the provider if she wishes to avoid unintended pregnancy and if she becomes pregnant.

5. No provider is obligated to continue opioid therapy that has been initiated by another provider. If the initial evaluation of the patient does not support the medical necessity for opioids, a discussion about risks of continuation, discontinuation, weaning, and possible treatment of withdrawal along with the plan regarding the same shall be included in the documentation of clinical reasoning for opioid cessation.
6. Providers must continually monitor the patient for signs of abuse, misuse or diversion. An unannounced UDT (or a comparable oral fluids test) should be done at least every 6 months.

C. Women's Health

1. The provider should discuss a method to prevent unintended pregnancy with every woman of child-bearing age who has reproductive capacity before opioids are initiated.
2. The practitioner should obtain a written acknowledgement from any female patient who wishes to become or is at risk to become pregnant that she has been educated about the risks and benefits of opioid treatment during her pregnancy.
3. Women of child-bearing age who have reproductive capacity shall undergo a pregnancy test prior to the initiation of opioids.
4. Women of child-bearing age who have reproductive capacity should be asked about the possibility of pregnancy at each visit. For women who wish to avoid unintended pregnancy, use of long-acting reversible contraceptives should be discussed, or referral to appropriate high risk obstetrician made.

SECTION III:

Ongoing Opioid Therapy for Chronic Non-Malignant Pain

SECTION III: ONGOING OPIOID THERAPY FOR CHRONIC NON-MALIGNANT PAIN

A. Key Principles

1. 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.
2. Opioids should be used at the lowest effective dose.
3. A provider should not use more than one short-acting opiate concurrently. If a provider deems it necessary to do so, then the medical reasons shall be clearly documented.
4. Documentation of the discussion of the five A's (analgesia, activities of daily living, adverse side effects, aberrant drug-taking behaviors and affect) at initiation of chronic opioid therapy and at follow up visits shall be included in the medical record.

B. Ongoing Therapy

1. 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 with a pain specialist, then he/she shall clearly document why not.
2. Clinicians should review the patient's history of controlled substance prescriptions using the Controlled Substance Monitoring Database (CSMD) data to determine whether the patient is receiving opioid therapy from other providers and / or potentially dangerous combinations of controlled substances.
3. Providers must continually monitor the patient for signs of abuse, misuse or diversion. A UDT (or a comparable oral fluids screen or test) should be performed at least every 6 months.
4. Based on the combined information of patient behavior, collateral information, the CSMD results, the UDT (or Oral Fluids Test) results and past records, 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. Adjustments to the patient's treatment should occur in a timely manner based on this information. Inconsistent results from the treatment plan should be addressed immediately and documented action taken as appropriate.
5. Opioids are to be discontinued when the risks, side effects, lack of efficacy or presence of medication or aberrant behavior outweigh the benefits. Opioids sometimes have to be discontinued due to financial or third-party coverage issues. A taper of opioids may or may not be indicated, depending on the clinical situation.
6. Appropriate documentation of CSMD query should be included in the medical record.
7. Clinicians should offer or arrange evidence-based treatment for patients with substance use disorder. Referral to an Addiction Specialist may be appropriate in some cases.

SECTION III: ONGOING OPIOID THERAPY FOR CHRONIC NON-MALIGNANT PAIN

C. Women's Health

1. The provider should discuss a method to prevent unintended pregnancy with every woman of child-bearing age who has reproductive capacity when opioids are initiated.
2. The provider shall advise every woman of child-bearing potential on opioids that she be on a method to prevent unintended pregnancy specifically considering long-acting contraceptive methods.
3. The treatment agreement shall include an expectation that a female patient will tell the provider if she becomes pregnant or plans to become pregnant.
4. If she plans to become or becomes pregnant, she shall be referred to an obstetrician.
5. When a UDT is performed, results must be documented in the medical record.

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PREGNANT WOMEN

1. The OB and medical treatment physician should work together to encourage compliance with both chronic pain management or medical replacement therapy plan, and prenatal care.
2. A risk assessment, UDT, and CSMD check should be performed before initiating any opiate or benzodiazepine during pregnancy.
3. A UDT should be performed at intake to prenatal care. If positive, the mother should be referred to appropriate chronic pain management or replacement therapy specialists. The risks of Intra-Uterine Drug Exposure should be discussed, and documented, and random UDT should be performed during the prenatal course.
4. If a woman has a positive UDT on initial prenatal visit, A UDT should be performed upon admission for delivery to help identify the infant at risk for NAS.
5. Appropriate discontinuation has been shown to be safe for fetus during pregnancy. However, unintended consequences from tapering may outweigh benefits. *(Bell J, Towers CV, Hennesy MD, et al. Detoxification from opiate drugs during pregnancy. Am J Obstet Gynecol 2016)*

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CSMD: CONTROLLED SUBSTANCE MONITORING DATABASE

Information

The Tennessee (TN) Controlled Substance Monitoring Database (CSMD) is a prescription monitoring program designed to provide healthcare practitioners with a comprehensive view of a patient's controlled substance prescription history. The purpose of the CSMD is to increase the quality of patient care by equipping healthcare practitioners with accurate, timely information that the practitioners can use to determine when patients acquiring controlled substances may require counseling or intervention for substance abuse, by collecting and maintaining data regarding all controlled substances in Schedules II, III, and IV dispensed in this state, and Schedule V controlled substances identified by the controlled substance database committee as demonstrating a potential for abuse. *See* Tenn. Code Ann. § 53-10-304. Further, the database is to be used to assist in research, statistical analysis, criminal investigations, enforcement of standards of health professional practice, and state or federal laws involving controlled substances. Information sent to, contained in, and reported from the database in any format is confidential, not public record and not subject to subpoena. Access is made available to the CSMD only as provided for in Tenn. Code Ann. § 53-10-308.

Registration

All healthcare practitioners who prescribe or dispense controlled substances in Tennessee by prescribing or dispensing on more than fifteen (15) days in a calendar year and are required to have a federal drug enforcement administration (DEA) registration pursuant to federal law must register for access to the CSMD. *See* Tenn. Code Ann. § 53-10-305. Healthcare practitioners or their agents shall have up to thirty (30) calendar days after receiving a DEA number to register in the database; such privilege shall apply equally to both prescribers and dispensers. Healthcare practitioners wishing to register with the CSMD to access prescription information are required to navigate to www.TNCSMD.com and choose the “register” link. A registration form will appear requesting information used to validate a healthcare provider's statutory authority to access CSMD data. A username and instructions to set up a password will be sent to the approved registrant after validation and processing.

A healthcare provider may also choose to allow an unlimited number of licensed and unlicensed delegates to register with the CSMD in order to retrieve prescription information on the prescriber or dispenser's behalf. The delegate should navigate to www.TNCSMD.com and register for a separate account. In addition to supplying self-identifying information, the delegate must provide information which identifies the supervisor permitting access to the CSMD. A username and instructions to set up password will be sent to the delegate after validation and processing. The delegate will get an email with a username and instructions to set up a password that will allow the delegate to log into the CSMD but delegate will not be able to run a patient report until the supervisor logs into to the CSMD and approves the relationship with the delegate. Once the approval process is complete, the delegate may access CSMD information on behalf of the healthcare provider. All access by any user leaves an audit trail that can be monitored and accessed as needed. A supervisor and or delegate may revoke the relationship in the CSMD at any time.

When prescribing or dispensing a controlled substance, all healthcare practitioners must check the CSMD:

1. prior to prescribing or dispensing an opioid, benzodiazepine, or Schedule II amphetamine to a patient at the beginning of a new episode of treatment,

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2. prior to the issuance of each new prescription for the opioid, benzodiazepine, or Schedule II amphetamine during the first ninety (90) days of a new episode of treatment, and
3. at least every six (6) months when that prescribed, or dispensed, controlled substance remains part of the treatment.

An authorized healthcare practitioner's delegate may check the controlled substance database on behalf of the healthcare practitioner. A "new episode of treatment" means a prescription for a controlled substance that has not been prescribed by that healthcare practitioner within the previous six (6) months. *See* Tenn. Code Ann. § 53-10-310.

Reports

Patient Report

A patient's CSMD report contains a variety of information related to the prescriber and dispenser of controlled substances. After entering the search criteria, a pick list of potential matches appears to consider incorporating for creation of the patient report. Please note that many patients may have a similar name or date of birth as another patient in the CSMD and it is possible for erroneous information to be incorporated into the patient report if inappropriate patients are selected during this process.

Once the patient report is generated, a CSMD user will see a list of all patient IDs incorporated into the report along with address information. The user will also see a list of all prescriptions attributed to the selected patient IDs in reverse chronologic order. On the right side of the first page is an estimated morphine equivalent daily dose (MEDD) that the patient is currently taking. At the end of the patient report there is a listing of all prescribers and dispensers associated with the patient's selected prescription history, as well as additional information used to calculate the MEDD.

Prescriber Self-Lookup

A prescriber can utilize the prescriber self-lookup report for multiple purposes. The report is useful for identifying potential prescription fraud, i.e. a stolen prescription pad or phoned-in prescriptions. It is also a useful snapshot of a prescriber's patient population and the prescriptions attributed to the prescriber. All data in the CSMD is reported as submitted to the data collection vendor by the dispenser. Therefore, if there are any questions about the data a prescriber should contact the dispenser identified within the report. The dispenser can, in turn, correct any errant information by coordinating with the State's data collection vendor. Neither the data collection vendor nor the TN Department of Health can edit prescription information found in the CSMD. A prescriber can only look up one DEA number at a time. For those prescribers who have more than one DEA number, the prescriber will need to reach out to the CSMD office by phone, 615-253-1305, or email: CSMD.Admin@tn.gov.

Additionally, if a prescriber is a collaborating or supervising physician, the prescriber can review prescriptions written by the prescriber's supervisees. From the CSMD "Practitioner Self-Lookup" page, there is a dropdown box which lists the prescribing supervisees associated with the prescriber's account. From here, the prescriber may run a report on a selected supervisee or select to run on all supervisees. *See* <https://www.tn.gov/health/health-program-areas/health-professional-boards/csmd-board/csmd-board/faq.html>

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Operational and Legal Resources

The statute governing the operation of the CSMD is found under Tenn. Code Ann. § 53-10 Part 3 and the supporting rules are 1140-11 and 1145-01. Current Federal Regulations (42 CFR Part II) protect the confidentiality of patients in a federally recognized Substance Use Disorder treatment facility and thus their dispensed medications are not included in the CSMD. The statute making doctor shopping illegal is found under Tenn. Code Ann. § 53-11-402 and § 71-5-2601. The statute requiring reporting of a doctor shopper to law enforcement can be found at Tenn. Code Ann. § 53-11-309.

A form to report a potential doctor shopper to law enforcement is available at: <https://www.tn.gov/content/dam/tn/health/healthprofboards/csmd/PH-4152.pdf>, and please send the form to the Tennessee Dangerous Drug Task Force at 423-267-8983.

Additional information about the CSMD as well as Frequently Asked Questions (FAQs) and the Data Collection Manual can be obtained by navigating to the state CSMD website located at: <https://www.tn.gov/health/health-program-areas/health-professional-boards/csmd-board.html>

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SAMPLE PATIENT AGREEMENT: Controlled Substance Treatment

PATIENT NAME: _____

PRIMARY CARE PHYSICIAN/SITE: _____

I understand that this agreement between myself, and (insert name of medical office/group) is intended to clarify the way chronic (long-term) controlled substances will be used to manage my chronic pain. Chronic controlled substance therapy for patients who do not suffer from cancer pain is a controversial issue.

I understand that there are side effects to this therapy; these include, but are not limited to, allergic reactions, depression, sedation, decreased mental ability, itching, difficulty in urinating, nausea and vomiting, loss of energy, decreased balance and falling, constipation, decreased sexual desire and function, potential for overdose and death. Care should be taken when operating machinery or driving a car while taking these medications. When controlled substances are used long-term, some concerns include the development of physical dependence and addiction. I understand these risks and have had my questions answered by my physician.

I understand that my (insert name of medical group) physician will prescribe controlled substances only if the following rules are adhered to:

- All controlled substance prescriptions must be obtained from your (insert name of medical group) primary care physician. If a new condition develops, such as trauma or surgery, then the physician caring for that problem may prescribe narcotics for the increase in pain that may be expected. I will notify my primary care physician within 48-hours of my receiving a narcotic or any other controlled substance from any other physician or other licensed medical provider. For females only: If I become pregnant while taking this medicine, I will immediately inform my obstetrician and obtain counseling on risks to the baby.
- I will submit urine and/or blood on request for testing at any time without prior notification to detect the use of non-prescribed drugs and medications and confirm the use of prescribed ones. I will submit to pill counts without notice as per physician's request. I will pay any portion of the costs associated with urine and blood testing that is not covered by my insurance.
- All requests for refills must be made by contacting my (insert name of medical group) physician during business hours at least 3-workdays in advance of the anticipated need for the refill. All prescriptions must be filled at the same pharmacy, which is authorized to release a record of my medications to this office upon request. A copy of this agreement will be sent to my pharmacy.

Pharmacy name/address/telephone:

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- The daily dose may not be changed without my (insert name of medical group) primary care physician's consent. This includes either increasing or decreasing the daily dose.
- Prescription refills will not be given prior to the planned refill date determined by the dose and quantity prescribed. I will accept generic medications.
- Accidental destruction, loss of medications or prescriptions will not be a reason to refill medications or rewrite prescriptions early. I will safeguard my controlled substance medications from use by family members, children, or other unauthorized persons.
- You may be referred to an appropriate specialist to evaluate your physical condition.
- You may be asked to have an evaluation by either a psychiatrist or psychologist to help manage your medication needs.
- If your physician determines that you are not a good candidate to continue with the medication, you may be referred to a detoxification program or evaluation by a pain management center.
- These medications may be discontinued or adjusted at your physician's discretion.
- I understand that it is my physician's policy that all appointments must be kept or cancelled at least 2-working days in advance. I understand that the original bottle of each prescribed controlled substance medication must be brought to every visit.

I understand that I am responsible for meeting the terms of this agreement and that failure to do so will/may result in my discharge as a patient of (insert name of medical group). Grounds for dismissal from (insert name of medical group) include, but are not limited to: Evidence of recreational drug use, of drug diversion, of altering scripts (this may result in criminal prosecution), of obtaining controlled substance prescriptions from other doctors without notifying this office, abusive language toward staff, development of progressive tolerance, use of alcohol or intoxicants, engagement in criminal activities, etc.

Patient's Signature

Date

Witness' Signature

Date

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URINE DRUG TESTING

Drug testing of patients receiving chronic opioid therapy (COT) is recommended by numerous entities, including the the American Academy of Pain Medicine (AAPM), American Society of Interventional Pain Physicians (ASIPP), the Institute of Medicine (IOM) and the Drug Enforcement Administration (DEA).¹⁻

¹⁸ The purpose of drug testing is to identify the presence of expected and unexpected prescribed medications and identify the use of illicit substances to enhance patient safety and promote public health and welfare. Therefore, testing should target common drugs of abuse, both prescription and illicit. A consistent approach to UDT based on validated risk models and clinical evaluation is advised. Due to high rates of false positive and negative results, consideration should be given to performing confirmatory testing when making treatment decisions.

Frequency of drug testing is left to the prescriber's discretion, but general guidelines can be discussed, based on the relative risk for addiction or death of the patient. As detailed elsewhere in these guidelines' confirmation testing is required prior to the outset of COT and at least every 6 months for all patients on COT. over risk patients would typically be maintained on this frequency. Moderate risk patients would be tested 3-4 times per year. Higher risk patients and those over 100mg MEDD should be tested 4-5 times per year. Instances of aberrant behavior such as lost or stolen medication may also prompt additional screening. Higher risk patients may also need routine confirmation testing because certain aberrant behaviors will appear normal with office based (POCT). Unexpected results from POCT should be sent for confirmatory testing. It is important to note that a patient's level of risk may change over time³⁰ and therefore risk should be reassessed periodically to determine if frequent testing is warranted. When conducting testing, a prescriber should inform the patient of the reason for testing and the potential consequences of the results. Ideally, testing should be performed at random intervals, when possible, to maximize effect on compliance.

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TAPERING PROTOCOL

There are many reasons to discontinue chronic opiate therapy. Any time the risks of the continued opiate use outweigh its potential benefit, the therapy should be discontinued. Violation of the controlled substances could be another reason to discontinue opiates.

1. Opiate discontinuation does pose the potential for withdrawal syndrome. This typically consists of nausea, vomiting, myalgia, headaches, abdominal pain, and sweating. These symptoms are not usually serious, and while not fatal, opiate withdrawal can cause discomfort. It should be noted, however, that benzodiazepine withdrawal does have the potential to be life threatening.
2. Low dose opiates may not require weaning at all. If the decision is made to discontinue opiates, steps should be taken to minimize the impact of opiate withdrawal syndrome. It is the responsibility of the current prescribing provider to address this issue.
3. There are several different weaning protocols outlined by various sources. A conservative approach recommends a 10% reduction in the original dose per week. Other sources state that 25% reduction every 4 days should avoid withdrawal syndrome. The more rapid protocols recommend for a daily reduction of 25-50% of the previous days dose. The Tennessee Department of Health does not recommend any one specific weaning protocol.
4. There are also several different medications that can help alleviate the symptoms of opiate withdrawal. Clonidine can diminish some of the symptoms of opiate withdrawal. Clonidine can be administered 0.1- 0.2mg orally every 6 hours or with a transdermal patch at 0.1mg/24hours. Hypotension and anticholinergic side effects may be encountered with clonidine. Weaning opiates is not always indicated when they are to be discontinued. If recent urine drug screening has shown that opiates are not present in the patient's system, then a weaning protocol would not be necessary.
5. If drug diversion were suspected, then prescribing additional opiates would not be indicated. In any circumstance where prescribing additional opiates to a patient is thought to constitute more risk to the patient or to the community than the potential for withdrawal syndrome, no additional opiates should be prescribed.

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MORPHINE EQUIVALENT DOSE

Morphine equivalent daily dose (MEDD) is the equipotent dose of any opioid in terms of morphine. Morphine is widely regarded as the “standard” for the treatment of moderate to severe pain and is used as the reference point. As MEDD increases, the likelihood of an adverse effect increases, therefore identifying at-risk patients is a crucial first step towards improving patient safety. Various MEDD charts are available for use in clinical practice, for instance, the Tennessee Controlled Substance Monitoring Database (CSMD) utilizes a chart of conversion factors created by the US Centers for Disease Control and Prevention. The conversion factor is entered into the following formula:

MEDD Conversion Formula:

$$\text{MEDD} = \frac{(\text{Drug Strength}) * (\text{Drug Quantity}) * (\text{Morphine Equivalent Multiplier})}{(\text{Day Supply})}$$

CDC guidance states that fentanyl and buprenorphine patches are exceptions to using the above formula to compute MEDDs. This exception only applies to the transdermal patch formulation, not the other dosage forms of either drug. A calculation of MEDD for these transdermal patch formulations must incorporate the frequency of patch rotation, which may vary depending upon the prescriber’s directions. Therefore, even though the duration of use of each patch may be less than the typical number of days, the quantity of drug that a patient receives each day remains constant because of the continuous release rate of active ingredient from the patch. Due to its complex pharmacokinetic properties, methadone exhibits an exponential increase in MEDD as dose increases above approximately 30 to 40 milligrams of methadone per day. Caution is warranted when methadone therapy approaches or exceeds these daily doses, or when a concomitant medication may inhibit methadone metabolism through the cytochrome CYP450 system.

No MEDD chart can adequately account for the patient-specific responses to a particular agent as risk of adverse events from taking any opioid can be dose-independent and may begin at low doses. Some of the variables include age, gender, genetic variability in drug metabolism, drug-drug interactions, opioid tolerance, and organ dysfunction such as renal and hepatic impairment, adrenal insufficiency, hypothyroidism, and abnormal levels of protein binding. Therefore, any conversion chart should only be used as a guide when formulating treatment plan. Dosing should be individualized and begun at conservative doses, based on assessment of risk.

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CO-PRESCRIBING NALOXONE

The Tennessee Chronic Pain Guidelines Committee recommend that clinician(s) should incorporate into the management plan strategies to mitigate risk, including offering naloxone when factors that increase the risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (greater than or equal to 50 MEDD), or concurrent benzodiazepine use, are present. Prescribers should consider prescribing naloxone to the patient at the same time a prescription for an opioid is written. While there are other introduction points for naloxone before an overdose, this can ensure that an at-risk patient has access to naloxone before a prescription opioid overdose can transpire.

The prescriber should provide a prescription for naloxone hydrochloride, or another drug approved by the United States Food and Drug Administration for the complete or partial reversal of an opioid overdose event to a patient at risk. *Exclusions for palliative and hospice care may be considered.*

APPENDICES

I. Options for Providing/Receiving Naloxone

1. According to Tennessee Code Annotated § 63-1-152, a licensed healthcare practitioner may write a prescription for naloxone for a patient, when acting in good faith and exercising reasonable care, both with an opioid prescription or any time following the prescription of an opioid.
2. Patient may receive naloxone from a dispensing licensed pharmacist educated on the proper use of naloxone who is dispensing under the supervision of a prescriber(s) by way of collaborative pharmacy practice agreement pursuant to Tennessee Code Annotated § 63-10-217. In 2016, Public Chapter 596 authorized pharmacists across the state to enter into a collaborative pharmacy practice agreement with the Chief Medical Officer for the Tennessee Department of Health which allows a trained pharmacist to initiate a prescription for naloxone for those that are at risk for an opioid overdose or may be able to assist someone who is at risk for experiencing an opioid overdose.
3. Patient may receive naloxone through a pharmacy that has an active standing order.
4. Drug Coalitions may also have Naloxone provided by grant.

II. New Naloxone Prescription Requirements

1. On July 1, 2022, a new law went into effect, Tennessee Code Annotated § 53-11-308, which requires a healthcare prescriber to offer Naloxone to patients when certain conditions are met:
 - a. The provider prescribes more than a three-day supply of an opioid medication; and
 - b. The provider prescribes an opioid medication concurrently with a prescription by the same provider for benzodiazepine; or the patient presents with an increased risk for overdose, including a history of overdose, a history of substance use disorder, or being at risk for returning to a high dose of opioid medication to which the patient is no longer tolerant.
 - c. *See* Tenn. Code Ann. § 53-11-308.
2. This does not apply to an opioid prescription that is written as part of a patient's palliative care treatment.

III. Healthcare Provider Education

As stated previously, per Tennessee Code Annotated § 63-1-152, evidence of the use of reasonable care shall include the receipt of training regarding how to administer naloxone, which can be achieved through the completion of the online overdose prevention education program offered by the Department of Health as evidenced by a certificate of completion. More information on Naloxone Training for healthcare professionals, please visit:

<https://www.tn.gov/health/health-program-areas/health-professional-boards/csmd-board/csmd-board/naloxone-training-information.html>

IV. Patient Education

According to Board of Pharmacy Rule 1140-03-.01 - Responsibilities for Pharmaceutical Care, "Upon the receipt of a medical or prescription order and following a review of the patient's record, a pharmacist shall personally counsel the patient or caregiver "face-to-face" if the patient or caregiver is present." A licensed, authorized pharmacist must educate and train the patient or caregiver on the proper use of naloxone upon

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the dispensing of the medication. Training on the administration of naloxone for the general public can also be found at:

<https://www.tn.gov/health/health-program-areas/health-professional-boards/csmd-board/csmd-board/naloxone-training-information.html>

APPENDICES

SAFETY NET

Tennessee's Substance Use Disorder Treatment System

1. Substance Use Disorders are a pervasive public health issue that has roots in individual, family, peer, and community conditions. Substance Use Disorders negatively impact families and children, increases crime, threatens public safety, and imposes tremendous social and economic costs to every community. Not surprisingly, it also prompts a wide range of responses across the public and private institutional systems.
2. The Tennessee Department of Mental Health and Substance Abuse Services, Division of Substance Abuse Services (TDMHSAS-DSAS), serves as the single state authority for receiving and administering federal block grant funding from the U.S. Department of Health and Human Services/SAMHSA and state funding to serve indigent uninsured individuals around the state who have a substance use disorder. The mission of TDMHSAS-DSAS is to improve the quality of life of Tennesseans by providing an integrated network of comprehensive treatment services for Substance Use Disorder, fostering self-sufficiency, and protecting those who are at risk of substance misuse, dependence, and addiction.
3. TDMHSAS licenses organizations to provide a continuum of treatment services for substance use disorders throughout the state. To find a listing of treatment and recovery resources in your area, please visit the licensure page on the TDMHSAS website at <https://www.tn.gov/behavioral-health/licensing/find-a-licensed-facility-or-service.html>.
4. The Tennessee Redline, 1-800-889-9789, is a 24/7 addiction treatment and recovery hotline that connects Tennessee residents with state funded, addiction treatment and recovery services. For more information on resources made available by TDMHSAS, including information certified peer recovery specialists, medication-assisted treatment, contact information for licensed providers, or best practices for treating substance use disorders, please visit: www.tn.gov/behavioral-health or call 1-800-560-5767.

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NON-OPIOID THERAPIES

Guideline:

“Non-opioid treatments should be tried before opioids are initiated. Opioids should be used only after all other appropriate and available treatments for the pain condition have been exhausted.”

Supporting rationale:

Modern pain medicine is a multi-disciplinary practice. When considering opioids for therapy, a practitioner should try a variety of appropriate non-opioid treatments for chronic pain prior to the initiation of opioids and use opioids only as a last resort. A thorough work up to support a diagnosis for opioids should include a history and physical, psychological screening, functional assessment, diagnostic studies, and specialist opinions. After an appropriate diagnosis for narcotics is found then the primary care provider can initiate non-opioid treatment such as:

1. Non-opioid medications
2. Functional treatments
3. Psychological treatments
4. Coordinated care with specialists
5. Injection therapy
6. Complimentary therapeutics

A variety of non-opioid medications are used in pain medicine. Anti-inflammatories are a first line medication used in arthritic pain and other mild to moderate chronic pain conditions. Anti-spasmodic and muscle relaxants are useful adjuvants for patients with chronic musculoskeletal pain conditions like chronic spasticity, myofascial pain. Antidepressants and anti-neuroleptics are commonly used, neoadjuvant used for fibromyalgia, peripheral neuropathy, radiculopathies, and myofascial pain. Antidepressants can also have an added benefit of relieving symptoms of anxiety and depression that are commonly associated with chronic pain patients. Any of the medication that can cause sedation should be used with care if they are initiated prior to or in conjunction with opioids.

Functional treatments are restorative modalities that can help patients to improve their general mobility and strength while improving pain. Early in a chronic pain condition a patient should be referred to a physical therapist or occupational therapist for an assessment and treatment of a chronic pain patient's disability. Manual manipulation, strengthening exercises, land-based therapies, aquatic therapy, electro-stimulation treatments, home exercise programs, bracing, ultrasound are part of the functional treatment armamentarium for chronic pain patients. Additionally, periodic functional assessments are encouraged to demonstrate the efficacy of treatment prior to and after the initiation of opioids.

Often patients will have a primary diagnosis that's best treated by a specialist while receiving concomitant chronic pain treatment. A specialist referral prior to the initiation of opioid treatment is encouraged especially if the etiology of the chronic pain condition can be treated without opioids and can be attenuated or cured with alternative pharmaceuticals or surgery. It is also helpful to get a specialist opinion on whether certain conditions constitute a chronic pain condition and whether that condition is best treated with opioids.

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Mental health referral for a chronic pain condition is helpful early in the treatment process. Recognition of anxiety disorders, depression, post-traumatic stress disorder, and other mental health disorders at the beginning in the treatment of pain is important. Chronic pain is a significant stressor and providing coping mechanisms and other strategies may reduce maladaptive behaviors in patients such as overtaking pain medications and obtaining medications not prescribed to the patient. Relaxation techniques, biofeedback, individual and group sessions, and other skills are all useful adjunctive treatments in the chronic pain patient population.

Simple injections for pain including joint injections trigger point injections, and botulinum injections have a role in the providers' non-opioid treatment plan. There are some injections that are best performed by a specialist and a referral to these specialists early in a patient's care is encouraged prior to the initiation of opioids.

Also, for consideration for providers treating pain are other non-Allopathic treatments for pain. Chiropractic treatments, exercise, massage, alternative supplements, and medications may all have a role in treating chronic pain conditions. Treatments like yoga, tai chi, acupuncture, and mindfulness meditation can attenuate pain and restore/ preserve function for some people.

APPENDICES

PERIOPERATIVE PAIN MANAGEMENT FOR THE CHRONIC PAIN PATIENT

Perioperative pain is pain in the period before, during, and after surgery. The pain can be an acute or chronic comorbid condition, an acute or chronic condition related to the disease or trauma for which the surgery is being performed or occurring because of the surgery. Pain during the perioperative period is best managed through a combination of targeted treatment methods (multimodal analgesia) including:

1. expectation and anxiety management
2. activity and mobilization when appropriate
3. medications when needed:
 - non-opioid pain medications should be trialed first-line for mild to moderate pain.
 - opioid medications for severe pain
4. regional anesthesia when appropriate

Effective multimodal pain management in the perioperative period can result in improved operative and postoperative outcomes and reduce the risks of adverse outcomes related to short-term and long-term opioid exposure. Coordination of care among providers on the surgery team and all prescribers managing the patient's chronic pain are crucial to a successful outcome for the patient.

APPENDICES

TENNESSEE BOARD OF DENTISTRY MINIMUM OPIOID PRESCRIBING GUIDELINES

The practice of dentistry has its own unique issues and concerns related to the prescribing of opioids to patients. The Board of Dentistry has created opioid guidelines for its licensees, which the Department adopts herein. These guidelines can be found on the Board of Dentistry's website at the link below.

[Tennessee-Board-of-Dentistry-Minimum-Opioid-Prescribing-Guidelines.pdf \(tn.gov\)](#)

LINKS

[Buprenorphine Guidelines](#)

[Pain Clinic Guidelines](#)

[Tennessee Drug Overdose Dashboard](#)

[Tennessee Prescription Safety Act of 2016](#)

[TCA 63-1-401 Development of Recommended Treatment Guidelines for Prescribing Opioids](#)

[TCA 63-1-402 - Prescribers to Hold a Current DEA and Complete Continuing Education](#)

[TCA 63-1-152 Prescription of Opioid Antagonists](#)

[Rules Governing Board of Medical Examiners](#)

[Rules Governing the Board of Osteopathic Examination](#)

[Rules Governing Pain Management Clinics](#)

[Rules Governing Board of Nursing - Advance Practice Nurses](#)

[Rules Governing Board of Physician Assistants](#)

[Board of Dentistry Minimum Opioid Prescribing Guidelines](#)

[Rules Governing Controlled Substance Monitoring Database](#)

[Commissioner's Controlled Substance Monitoring Database Rules](#)

[Information regarding pediatric pain medicine](#)

[CDC Clinical Practice Guidelines for Prescribing Opioids for Pain \(2022\)](#)

[Health and Human Services Pain Management Best Practices Inter-agency Task Force Report](#)