

TENNESSEE CLINICAL PRACTICE GUIDELINES FOR OUTPATIENT MANAGEMENT OF CHRONIC PAIN

The purpose of these guidelines is to define appropriate treatment of chronic pain, a common and often serious condition. We want 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 particular reference to the prescribing of opioid medications. We want to avoid addiction and adverse outcomes. Optimal treatment of chronic pain, defined as pain lasting longer than 90 days, is an interdisciplinary process that includes many interventions 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 of a multidisciplinary steering committee and recommendations of 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 mental health and substance abuse and workman's compensation programs.

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

- In 2011, Tennessee had the second highest per capita prescription rate for opioids in the US.
- Unintentional overdose deaths increased more than 250% from 2001 to 2011, exceeding deaths due to motor vehicle accidents, homicide or suicide in 2010.
- The number of babies born dependent to drugs who suffered from Neonatal Abstinence Syndrome (NAS) grew ten-fold from 2001 to 2011.
- Worker's compensation programs have seen the number of people treated for substance abuse increase five-fold in ten years.
- In the midst of this substance abuse 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.
- Acute and chronic pain are among the most common reasons for physician visits, for taking medications and are major causes of work disability. Severe chronic pain affects physical and mental functioning, quality of life and productivity.

The long term goals of appropriate pain management are to improve symptoms, function and overall quality of life while minimizing adverse effects, addiction, overdose deaths and NAS. These guidelines can help providers 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.

These guidelines are not applicable to end-of-life care, emergency room care or acute pain management. 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 to those 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

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.
2. Reasonable non-opioid treatments should be tried before opioids are initiated. Opioids should be initiated only after other reasonable, appropriate and available treatments 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 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, etc. should be documented in the medical record prior to initiating opioid therapy.
6. Chronic pain shall not be treated by the use of controlled substances through telemedicine.

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. An initial, condition-appropriate physical examination of the patient should be conducted. A systems review shall be conducted as well.
3. 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.
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 abuse and, if present, these should be addressed in the creation of a treatment plan (See Mental Health Appendix).
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 (See Women's Issues Appendix).

Establishing a Diagnosis

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

Assessment of Risk for Abuse

1. The prescriber shall assess the patient's risk for misuse, abuse, diversion and addiction prior to initiating opioid therapy.(See Risk Assessment Appendix)
2. The prescriber should obtain a Urine Drug Test (UDT) (or a comparable test on oral fluids) prior to initiating opioid therapy (See Risk Assessment Appendix).
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. (See CSMD Appendix)

Goals for Treatment

1. The primary goal of treatment should be clinically significant improvement in function.
2. A treatment plan is expected to include other treatments or modalities beyond opioids, both non-pharmacological and pharmacological. The provider should make reasonable attempts to implement this treatment plan, allowing for barriers such as finances, accessibility and resource distribution.
3. 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 OPIOIDS

Key Principles When Considering Prescribing Opioids.

1. A patient should be prescribed a maximum of four doses of a short-acting opioid per day. If a provider deems it necessary to do so then he/she shall clearly document the medical reasons for this decision.
2. Prescribers who are not pain medicine specialists (See Pain Medicine Specialist Appendix) shall not prescribe methadone for a chronic pain condition.
3. Prescribers shall not prescribe buprenorphine in the form of oral or sublingual buprenorphine for a chronic pain condition.
4. 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.
5. Buprenorphine / naloxone combinations shall be avoided for the treatment of chronic pain.
6. Should treatment deviate from recommended guidelines, the reasons shall be documented in the medical record.

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 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. 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. As these new guidelines are implemented, practitioners may provide a bridge of opioids for up to six months while the assessment process is carried out. During this time a patient may be continued on a trial of opioids without a fully completed assessment. 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 need for opioids, a discussion about risks and possible treatment of withdrawal 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 twice a year at a minimum. (See Physiological Assessment Tools and UDT Appendix).

Women's Health

1. The provider should discuss a birth control plan with every woman of child-bearing age who has reproductive capacity before opioids are initiated.
2. The practitioner should obtain a signature indicating that any woman who wishes to become or is at risk to become pregnant 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 (See Women's Issues Appendix).

SECTION III -- TREATMENT WITH OPIOIDS

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. The five A's (analgesia, activities of daily living, adverse side effects, aberrant drug-taking behaviors and affect) should be discussed with patients at initiation of chronic opioid therapy and at follow up visits. Documentation of the discussion shall be included in the medical record.

Ongoing Therapy

1. Patients on opioid doses of 100mg 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 he/she shall clearly document why not.
2. 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 done twice a year at a minimum. (See Mental Health and Physiological Health Appendices)
3. Based on the combined information of patient behavior, collateral information, the validated risk assessment results, the CSMD results, the UDT (or OFT) 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
4. 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.
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.

Women's Health

1. The provider should discuss a birth control plan with every woman of child-bearing age who has reproductive capacity when opioids are initiated.
2. The provider shall recommend to every woman of child-bearing potential on opioids that she be on birth control.
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 a high risk obstetrician.
5. If UDT is performed, results must be documented appropriately in the medical record.

PAIN MEDICINE SPECIALIST

Pain Medicine is the medical specialty dedicated to the prevention, evaluation 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 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 deal with patients being treated with more than 120 milligram morphine equivalents daily dose because they are at least eleven times more likely to suffer an adverse effect including overdose death.

The American Board of Medical Specialties (ABMS) is the primary physician certification organization in the United States. It assists twenty four boards to grant certificates in 124 specialty areas. The ABMS certifies pain medicine fellowship programs that result in subspecialty certification in Pain Medicine are under the Boards of Anesthesiology, Physical Medicine & Rehabilitation, Psychiatry and Neurology.

The American Board of Pain Medicine (ABPM) is not affiliated with the ABMS and does not oversee fellowship training programs. The ABPM administers practice-related examination for Pain Medicine to qualified candidates who have achieved specified requirements in graduate medical education, licensure and controlled substances authorization, ABMS board certification (not necessarily in pain management), practice experience, continuing medical education, and adherence to ethical and professional standards. Diplomats of ABPM have certification in Pain Medicine.

The State of Tennessee sets forth two tiers for the treatment of pain management:

Tier 1 Non-Pain Medicine Specialist:

1. All providers who wish to treat patients requiring less than 120 milligram morphine equivalent daily dose (MEDD) shall:
 - a. Hold a valid Tennessee license issued by their respective board through the Department of Health and a current DEA certification.
 - b. Attend Continuing Education pertinent to pain management as directed by their governing board.
 - c. We recommend, but do not require, that providers have completed three years of residency training and be ABMS board eligible or board certified.
2. All providers wishing to treat patients requiring 120 MEDD or more shall consult with a Pain Medicine Specialist.
3. Providers treating patients with ongoing opioid therapy (prescribing of 120MEDD for more than six months in any calendar year) shall obtain at least one annual consultation with a Pain Medicine Specialist. Patients with more complicated cases may require more frequent consultation.

Tier 2 Pain Medicine Specialists:

A Pain Medicine Specialist shall hold:

1. ABMS subspecialty certification in Pain Medicine under the boards of, Anesthesia, Neurology, Psychiatry and Physical Medicine & Rehabilitation and:
 - a. An unencumbered Tennessee license and,
 - b. The minimum number of CME hours in pain management to satisfy retention of ABMS certification.
 - c. Any exceptions to this must be approved by the respective regulatory board; OR
2. ABPM diplomate status by 7/1/2016 and:
 - a. Unencumbered Tennessee license and,
 - b. The minimum number of CME hours in pain management to satisfy retention of ABPM diplomat status.
 - c. Any exceptions to this must be approved by the respective health related licensing and regulatory board.
 - d. Current pain medicine specialists who are qualified to take the ABPM exam may continue to practice as a pain medicine specialist until 7/1/16, when diplomate status will be required.

RISK ASSESSMENT TOOLS

There are several validated risk assessment tools available to pain clinicians. Find below some information on the most commonly used tools and links so that they can be obtained. Some tools are copyrighted and some are not, and practitioners should adhere to legal guidelines in making and obtaining copies for their use.

1. BRI (Brief Risk Interview). This is a short (5-10 minutes) clinical interview that is a validated risk assessment tool (Jones & Moore, 2013). Questions are asked about such topics as past misuse of opioid medications, presence of mental health disorders, personal history of substance abuse and family history of substance abuse. It also incorporates information from UDT's, past medical records and the CSMD. It classifies patients into risk categories of Low, Low Medium, Medium, Medium High, High and Very High. Contact Ted Jones, Ph.D. at tedwjones@comcast.net about copies and use.
2. DIRE (Diagnosis, Intractability, Risk, Efficacy score). This is a staff/interviewer rating scale that uses information about the patient's diagnosis, engagement in treatment and psychiatric issues (Belgrade, Schamber and Lindgren, 2007). The numerical score categorizes patients into the categories of "not a suitable candidate for long-term opioid analgesia," and "good candidate for long-term opioid analgesia".
<http://www.ucdenver.edu/academics/colleges/PublicHealth/research/centers/maperc/online/Documents/D.I.R.E.%20Score.pdf>.
3. ORT (Opioid Risk Tool). This is a brief ten-item patient-completed written questionnaire (Webster & Webster, 2005). It may be the most widely used risk assessment tool in the field. It asks for information such as personal and family history of substance abuse and psychiatric issues. It classifies patients into Low, Medium and High risk categories.
4. PMQ (Pain Medication Questionnaire). This is a 26-item patient-completed written risk questionnaire (Adams, Gatchel, Robinson, et. al., 2004). One study has shown that it is the best overall written risk assessment tool available.⁵ Questions include such topics as opinions about pain medication and pain treatment, obtaining pain medication, and past medication-aberrant behavior. A few items are reverse scored, making it just slightly more difficult for staff to score. It classifies patients into Low, Medium and High categories of risk. Here is one link to a copy: <http://www.opioidrisk.com/node/507>.
5. SOAPP (Screener and Opioid Assessment for Patients with Pain). This is a 24-item patient-completed written risk assessment questionnaire (Butler, Budman, Fernandez, et. al., 2004). One study has shown that this questionnaire has the best sensitivity of any patient-completed questionnaire (best at identifying those patients which later engage in medication aberrant behavior).⁷ Items use a five-point rating scale and ask about such topics as impulsivity, cigarette smoking, overtaking medication and past substance abuse. It classifies patients into Low and High risk (no Medium category). One link to a copy is: <http://www.painedu.org/soap.asp>.
6. SOAPP-R (Screener and Opioid Assessment for Patients with Pain - Revised). This 24-item patient-completed questionnaire is a revision of the SOAPP (Butler, Fernandez, Benoit, et. al., 2008). The SOAPP-R is a widely used risk assessment tool. It uses a five-point rating

scale in asking questions about such topics as impulsivity, legal problems, past substance abuse and past sexual abuse. It classifies patients in risk categories of Low and High risk (while it refers to a Medium category in the SOAPP-R manual, there has been no validation on the use of the Medium category). One link to a copy is: <http://www.opioidrisk.com/node/610>.

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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 a 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.

URINE DRUG TESTING

Urine drug testing (UDT) is a common practice accompanying chronic opiate therapy (COT). The purpose of UDT is to identify the presence or absence of prescribed medication and the presence of illicit or non-prescribed substances. UDT is an important tool to identify aberrant behavior regarding opiate use. It is one of the only objective measures for compliance monitoring. When used appropriately, it can improve the safety of COT. Unexpected UDT results are seen frequently even in patient populations identified as low risk. As detailed elsewhere in these guidelines, UDT with confirmation is required prior to the outset of COT and at least twice per year for all patients on COT.

1. There are two broad categories of UDT available: immunoassay and confirmation. Immunoassay tests are usually performed in the office (Point of Care Testing), while confirmation tests are usually completed in a laboratory. Immunoassay tests are qualitative in nature and detect the presence or absence of a drug class. They have the advantage of providing rapid results. Immunoassay tests have significant cross-reactivity with other substances. They have lower sensitivity and specificity compared to confirmation testing. Confirmation testing utilizes high performance chromatography/mass spectrometry technology.
2. Typical office based testing for COT patients usually includes opiates, benzodiazepines, cannabinoids, cocaine, amphetamines, alcohol, barbiturates, oxycodone, methadone, and fentanyl. Synthetic and semisynthetic opiates, such as oxycodone, methadone, fentanyl, and meperidine, may not appear on typical immunoassay tests. Points of care immunoassay tests are available for some of these drugs, but they have variable cut-off levels that affect sensitivity. Unexpected results on immunoassay tests should prompt confirmatory testing.
3. Frequency of UDT 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.

Lower risk patients would typically be screened 1-2 times per year. Moderate risk patients would be screened 3-4 times per year. Higher risk patients and those over 100mg MEDD should be screened 4-5 times per year. Instances of aberrant behavior such as lost or stolen medication may also prompt additional screening. Unexpected or inappropriate immunoassay results should be sent for confirmatory testing.

Higher risk patients may also need routine confirmation because there are certain aberrant behaviors that will appear normal with immunoassay testing.

4. Interpreting UDT results can be complicated. It should be noted that certain parent drugs can be metabolized into other commonly prescribed drugs. If questions exist, a provider should contact the laboratory director, toxicologist, or local Medical Review Officer. A prescriber should inform the patient of the reason for testing and the potential consequences of the results. UDT should be performed in an unannounced fashion when possible. There are many ways a sample can be adulterated to provide a "clean" sample. Validity testing using temperature, pH, or creatinine is recommended. UDT cannot be used to determine the source of drugs detected or the dose of drug taken. It may be helpful to discuss UDT in terms of "Universal Precautions" to minimize any associated stigma or detract from the physician patient relationship.

MORPHINE EQUIVALENT DOSE

Morphine equivalent dose (MED) 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 MED increases, the likelihood of an adverse effect increases, therefore identifying at-risk patients is a crucial first step towards improving patient safety. Various MED 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:

MED Conversion Formula:

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

CDC guidance states that fentanyl and buprenorphine patches are exceptions to using the above formula to compute MEDs. This exception only applies to the transdermal patch formulation, not the other dosage forms of either drug. A calculation of MED 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 MED as dose increases above approximately 30 to 40 milligrams of methadone per day. Particular 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 MED 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.

SPECIAL CONSIDERATIONS: WOMEN OF CHILD BEARING AGE

All women with reproductive capacity receiving a prescription for an opiate shall be educated about the risks of opiate use during pregnancy including the risk of physical dependence and addiction in the woman, the potential of physical dependence and withdrawal in the newborn, and possible long term consequences to the child.

1. Upon initiation of opioid therapy, the provider shall recommend reliable contraception such as long term reversible contraceptives and appropriate referrals should be made.
2. Any woman with reproductive capacity, who is presently under physician care for chronic pain management or medical replacement therapy, shall be counseled on the importance of reliable contraception such as long term reversible contraceptives. Appropriate referrals should be made.
3. The treatment plan shall include an expectation that a female patient will notify the provider if she becomes, or plans to become, pregnant.
4. The possibility of pregnancy should be assessed prior to initiation and continuation of any opioid or opioid replacement therapy. This risk should be assessed at each visit and prior to any refill for long-term therapies. A pregnancy test should be performed if there is any possibility of pregnancy. This should be documented in the medical record.
5. A woman who desires to become pregnant and is under physician treatment for chronic pain management and/or opioid replacement therapy shall be counseled on the potential risks of Intra-Uterine Drug Exposure. A referral for prenatal counseling should be made. Alternative treatment modalities should be discussed. Informed consent should be obtained prior to continuation of opioid or opioid replacement therapy.
6. Education shall include the potential risks of stopping her medications on her own during her pregnancy which include: the risk of relapse, risk of preterm delivery, intrauterine withdrawal, fetal distress, and fetal demise.
7. A woman on opioid therapy who becomes pregnant or desires to become pregnant shall be referred to or consult with an Obstetrician and appropriate Pain Management Specialist or Medical Replacement Treatment program.

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 CSMDDB 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.

DRAFT

CONTROLLED SUBSTANCE MONITORING DATABASE

Background

The Tennessee 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 assist in research, statistical analysis, criminal investigations, enforcement of state or federal laws involving controlled substances, and the education of health care practitioners concerning patients who, by virtue of their conduct in acquiring controlled substances, may require counseling or intervention for substance abuse, by collecting and maintaining data regarding all controlled substances dispensed in this state.

Access to Information

Information sent to, contained in, and reported from the database in any format is confidential, not public record and not subject to subpoena from any court and password access is made available only as provided for in Tennessee Code Annotated § 53-10-308 and to the following persons:

- personnel of the committee specifically assigned to conduct analysis or research;
- authorized committee, board, or department of health personnel or any designee appointed by the committee engaged in analysis of controlled substances prescription information as a part of the assigned duties and responsibilities of their employment;
- a prescriber of controlled substances to the extent the information relates specifically to a current or bona fide prospective patient of the prescriber, to whom the prescriber has prescribed or dispensed, is prescribing or dispensing, or considering prescribing or dispensing any controlled substance; or a prescriber conducting medication history reviews who is actively involved in the care of the patient; a prescriber or supervising physician of the prescriber conducting a review of all medications dispensed by prescription attributed to that prescriber;
- a dispenser or pharmacist of controlled substances to the extent the information relates specifically to a current or a bona fide prospective patient to whom that dispenser has dispensed, is dispensing, or considering dispensing any controlled substance; or a dispenser not authorized to dispense controlled substances conducting drug utilization or medication history reviews who is actively involved in the care of the patient;
- a county medical examiner appointed pursuant to T.C.A. § 38-7-104 when acting in an official capacity as established in § 38-7-109; provided, any access to information from the database shall be subject to the confidentiality provisions of this part except where information obtained from the database is appropriately included in any official report of the county medical examiners, toxicological reports or autopsy reports issued by the county medical examiner under T.C.A. § 38-7-110(c);
- personnel of the following entities actively engaged in analysis of controlled substances prescription information as a part of their assigned duties and responsibilities related directly to TennCare:
 - o the Office of Inspector General;
 - o the Medicaid Fraud Control Unit;

- o the Bureau of TennCare's chief medical officer, associate chief medical directors, director of quality oversight, and associate director of pharmacy;
- a quality improvement committee as defined in § 68-11-272 of a hospital licensed under title 68 or title 33, as part of the committee's confidential and privileged activities under § 68-11-272(b)(4) with respect to the evaluation, supervision or discipline of a healthcare provider employed by the hospital or any of its affiliates or subsidiaries, who is known or suspected by the hospital's administrator to be prescribing controlled substances for the prescriber's personal use;
- a healthcare practitioner extender, who is acting under the direction and supervision of a prescriber or dispenser, and only to the extent the information relates specifically to a current or bona fide prospective patient to whom the prescriber or dispenser has prescribed or dispensed, is prescribing or dispensing, or considering prescribing or dispensing any controlled substance;
- the following personnel of the department of mental health and substance abuse services actively engaged in analysis of controlled substances prescription information as a part of their assigned duties and responsibilities shall have access to the database for controlled substances prescription information for specific patients:
 - o The chief pharmacist;
 - o The state opioid treatment authority (SOTA) or SOTA designee; and
 - o The medical director.
 - o Aggregate controlled substances prescribing information from the database may be provided upon request by the following personnel of the department of mental health and substance abuse services, who are actively engaged in analysis of controlled substances prescription information as provided in this subsection (j), and may be shared with other personnel of the department of mental health and substance abuse services as needed to fulfill assigned duties and responsibilities:
 - The chief pharmacist;
 - The SOTA; or
 - The medical director.

Law enforcement personnel engaged in an official investigation or enforcement of state or federal laws involving controlled substances are authorized to request information from the CSMD under the guidelines outlined in T.C.A. § 53-10-306. The CSMD committee also examines database information to identify unusual patterns of prescribing and dispensing, taking into account a practitioner's specialty. The committee is authorized to refer outlying pharmacies to the chief board of pharmacy investigator and outlying prescribers to the Division of Health Related Boards' Bureau of Investigations.

CSMD Data

The CSMD contains prescription information from all dispensers of controlled substances in Tennessee and also those dispensers who ship to a patient residing in Tennessee. This includes mail-order pharmacies and some Veteran's Affairs pharmacies as well. The CSMD collects and maintains dispensing data regarding all controlled substances in Schedules II, III and IV, and Schedule V controlled substances identified by the controlled substance database advisory committee as demonstrating a potential for abuse. Data is to be submitted at least once every seven (7) days for all the controlled substances dispensed during the preceding seven-day period. The following information is required to be submitted for each dispensing in ASAP 2009 (4.1) format:

- Prescriber DEA number;
- Dispensing date;
- Patient identifier,
- Controlled substance NDC number;
- Quantity dispensed;
- Strength of controlled substance;
- Estimated day supply;
- Dispenser DEA number;
- Date the prescription was written;
- Whether the prescription was new or a refill;
- Source of payment.

All data in the CSMD is reported as submitted to the data collection website by the dispenser. Therefore, if there are any questions about the data a practitioner 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 Department of Health can edit prescription information found in the CSMD.

Registration

All prescribers and dispensers of controlled substances in Tennessee must register for access to the CSMD. 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 password will be sent to the approved registrant after validation and processing by CSMD administration. All passwords are case-sensitive, must be at least eight characters long and must contain an upper and lowercase letter, at least one number and one special character.

A healthcare provider may also choose to allow licensed and up to two unlicensed extenders per practice location to register with the CSMD in order to retrieve prescription information on the prescriber or dispenser's behalf. The extender should navigate to www.TNCSMD.com and register for a separate account. In addition to supplying self-identifying information, the extender must provide information which identifies the supervisor permitting access to the CSMD. After

validation by CSMD administrative staff, the supervisor must login to his/her account to approve the registrant as their extender. Once this process is complete, the extender may access CSMD information. All access by any user leaves an audit trail that can be monitored and accessed as needed. A supervisor may revoke CSMD access of their extender at any time if necessary.

Law enforcement personnel engaged in an official investigation or enforcement of state or federal laws involving controlled substances wishing to request information must follow a distinct process outlined in T.C.A. § 53-10-306 (a) (6) in order to request information from CSMD administration.

CSMD Reports

Patient Report

A patient's CSMD report contains a variety of information related to the prescriber or dispenser of controlled substances. After entering the search criteria, a box of potential patient matches appears to consider incorporating into the 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 report is generated, a CSMD user will see a list of all patients incorporated into the report along with address information. The user will also see a list of all prescriptions attributed to the selected patient(s) in reverse chronologic order. On the right side of the first page is an estimated morphine equivalent dose that the patient is currently taking. For further explanation of the morphine equivalent dose, see (Morphine Equivalent Dose Appendix.) At the end of the 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 morphine equivalent dose.

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 website by the dispenser. Therefore, if there are any questions about the data a practitioner 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 Department of Health can edit prescription information found in the CSMD.

Unsolicited Reports from the CSMD

Upon signing in to the CSMD, a user may see a series of alerts in the box labeled "Clinical Notifications." These notifications identify patients of the practitioner who meet criteria set by the CSMD Committee which places the patient at risk of overdose or may indicate potential doctor-shopping tendencies. The user must acknowledge receipt of the notification within three days by clicking on the hyperlink or a reminder email will be sent until the notification is acknowledged. Clicking on the hyperlink will bring up the patient report for further investigation. Please note that the risk levels are only suggestive of risk and are not an absolute contraindication to treatment of the patient.

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These notifications are provided as a clinical tool for use in the patient's treatment plan as well as to identify patients who may exhibit doctor shopping behaviors. The CSMD Committee has set the following criteria for notification levels:

- Number of Pharmacies:
 - Red - Four within 60 days
 - Yellow- Three within 60 days
- Number of Prescribers:
 - Red – Four within 60 days
 - Yellow – Three within 60 days
- Milligram Morphine Equivalents:
 - Red – 120 MME per day
 - Yellow – 90 MME per day

Please note that multiple providers within the same system are counted separately, whether or not the patient has the same medical record, prescription record or chart. Evaluate all information provided to determine patient risk.

Future Enhancements

The CSMD Committee and Department of Health are committed to utilizing the CSMD to protect patient health and prevent prescription drug abuse and diversion. As resources become available, enhancements will be incorporated into the CSMD to further this mission. Enhancements such as real-time reporting by dispensers and incorporation of the CSMD into electronic health records are being investigated as well as further sharing of data between states as laws allow. Any suggested improvements can be sent to csmd.admin@tn.gov for consideration.

Operational and Legal Resources

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

A form to report a potential doctor shopper to law enforcement is available at: <http://health.state.tn.us/boards/Controlledsubstance/PDFs/PH-4152.pdf>.

Please send the form to your local law enforcement or contact the Tennessee Meth and Pharmaceutical Task Force at 423-752-1479 to obtain the appropriate fax number.

Additional information about the CSMD can be obtained at: <http://health.state.tn.us/Boards/ControlledSubstance/index.shtml>

TABLE OF FREQUENTLY PRESCRIBED PAIN MEDICATIONS

Short-Acting Opioids	Controlled Substance Schedule	Available Strengths*
Acetaminophen/ Caffeine/Dihydrocodeine Capsule and Tablet	(C-III)	356.4/30/16, 712.8/60/32mg
Aspirin/Caffeine/Dihydrocodeine Capsule	(C-III)	356.4/30/16mg
Acetaminophen/Butalbital/Caffeine/Codeine Capsule	(C-III)	325/50/40/30mg
Aspirin/Butalbital/Caffeine Capsule	(C-III)	325/50/40mg
Aspirin/Butalbital/Caffeine/Codeine Capsule	(C-III)	325/50/40/30mg
Fentanyl Oral	(C-II)	100, 200, 300, 400, 600, 800, 1200, 1600 mcg
Hydrocodone/Acetaminophen	(C-III)	2.5/500, 5/325, 5/400, 5/500, 7.5/325, 7.5/400, 7.5/500, 7.5/650, 7.5/750, 10/325, 10/400, 10/500, 10/650, 10/660mg
Hydrocodone/Ibuprofen Tablet	(C-III)	7.5/200mg
Hydromorphone Tablet	(C-II)	2, 4, 8mg
Morphine Sulfate	(C-II)	
Solution		10mg/5ml, 20mg/5ml, 20mg/1ml
Tablet		15, 30 mg
Oxycodone/Acetaminophen Capsule or Tablet	(C-II)	2.5/325, 5/325, 5/500, 7.5/325, 7.5/500, 10/325, 10/650mg
Oxycodone/Oxycodone terephthalate/Aspirin Tablet	(C-II)	4.5/0.38/325 mg
Oxycodone	(C-II)	

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Capsule or Tablet		5, 7.5, 10, 15, 20, 30 mg
Solution		20mg/ml
Oxymorphone Tablet	(C-II)	5, 7.5, 10mg
Meperidine		
Syrup	(C-II)	50mg/5 ml
Tablet		50, 100 mg
Tapentadol Tablet	(C-II)	50, 75, 100mg
Tramadol/Acetaminophen Tablet	(C-IV)	37.5/325mg
Long-Acting Opioids	Controlled Substance Schedule	Available Strengths*
Buprenorphine Patch	(C-III)	5, 10, 15, 20mcg/hr
Fentanyl Patch	(C-II)	12, 25, 50, 75, 100mcg/hr
Hydromorphone ER Tablet	(C-II)	8, 12, 16, 32mg
Methadone Tablet	(C-II)	5, 10mg
Morphine Sulfate ER Capsule or Tablet	(C-II)	10, 15, 20, 30, 45, 50, 60, 75, 80, 90, 100, 120, 200mg
Oxycodone ER Tablet	(C-II)	10, 15, 20, 30, 40, 60, 80mg
Oxymorphone ER Tablet	(C-II)	5, 7.5, 10, 15, 20, 30, 40mg
Tapentadol ER Tablet	(C-II)	50, 100, 150, 200, 250mg
Tramadol ER Capsule or Tablet	(C-IV)	100, 150, 200, 300mg
Benzodiazepines	Controlled Substance Schedule	Available Strengths*
Alprazolam		
Tablet or Oral-Dissolving Tablet	(C-IV)	0.25, 0.5, 1 or 2 mg

ER Tablet		0.5, 1, 2, 3mg
Clonazepam		
Oral-Dissolving Tablet	(C-IV)	0.125, 0.25, 0.5, 1, 2mg
Tablet		0.5, 1, 2mg
Diazepam Tablet	(C-IV)	2, 5, 10 mg
Lorazepam Tablet	(C-IV)	0.5, 1, 2 mg
Muscle Relaxant	Controlled Substance Schedule	Available Strengths*
Carisoprodol Tablet	(C-IV)	250, 350mg
Carisoprodol/Aspirin Tablet	(C-IV)	325/200mg
Carisoprodol/Aspirin/Codeine Tablet	(C-III)	325/200/16mg
Other Pharmacotherapeutic Options	Controlled Substance Schedule	Available Strengths*
Anticonvulsants		
Antidepressants		
Dronabinol Gelcap	(C-III)	2.5, 5, 10 mg
Tramadol-Tablet	C(-IV)	
* Strengths are not intended to be exhaustive. Acetaminophen strength will soon be limited to 325mg in combination products.		

SAMPLE INFORMED CONSENT: CONTROLLED SUBSTANCE TREATMENT

Please read the information below carefully and ask your provider if you have any questions relating to the medication prescribed to you.

Using Controlled Medications to Treat Pain

- a. These medications are used to treat moderate-to-severe pain of any type, and to treat anxiety and stress associated with moderate-to-severe pain.
- b. These medications are best understood as potentially effective tools that can help reduce pain, improve function, and improve quality of life
- c. Using these medications requires that both the physician and patient work together in a responsible way to ensure the best outcome, lowest side effects, and least complications

How Do Opioids work?

- a. Opioid medications work at the injury site, the spinal cord, and the brain
- b. They dampen pain, but do not treat the underlying injury
- c. They may help to prevent acute pain from becoming persistent chronic pain d. These medications may work differently on different people because of a number of factors.
- d. Side effects and complications will also individually vary

How do Benzodiazepines work?

- a. The benzodiazepines are a class of drugs with varying properties, which act by slowing down the central nervous system.
- b. Benzodiazepines are useful in treating anxiety, insomnia, agitation, seizures, and muscle spasms. While Benzodiazepines do not treat acute or chronic pain, they are taken by patients with pain for other issues (such as anxiety or muscle spasms).
- c. These medications may work differently on different people because of a number of factors.
- d. Side effects and complications will also individually vary

What to Expect When You Take Controlled Medications for Pain and Related Conditions

- a. Pain relief
- b. Reduction of anxiety and stress caused by pain
- c. Side effects

What Should Not Be Expected From Treatment with Controlled Medications

- a. Cure of the underlying injury
- b. Total elimination of pain, anxiety, and stress
- c. Loss of ability to feel other physical pain

Negative Effects of Controlled Medications Vary in Different People

1. Opioid Side effects
 - a. Common effects include: Constipation, dry mouth, sweating, nausea, drowsiness, euphoria, forgetfulness, difficulty urinating, and itching
 - b. Uncommon effects include: Confusion, hallucinations, shortness of breath, depression, lack of motivation

2. Benzodiazepines Side effects
 - a. The most common side effects include: Clumsiness or unsteadiness, dizziness or lightheadedness and drowsiness; slurred speech
 - b. Less common side effects include: Anxiety; confusion (may be more common in the elderly); fast, pounding, or irregular heartbeat; mental depression; abdominal or stomach cramps or pain; blurred vision or other changes in vision; changes in sexual desire or ability; constipation; diarrhea; dryness of mouth or increased thirst; false sense of well-being; headache; increased bronchial secretions or watering of mouth; muscle spasm; nausea or vomiting; problems with urination; trembling or shaking; unusual tiredness or weakness
3. Physical dependency
 - a. Opioid medications will cause a physical dependency marked by abstinence syndrome when they are stopped abruptly. If these medications are stopped or rapidly decreased the patient will experience chills, goose bumps, profuse sweating, increased pain, irritability, anxiety, agitation, and diarrhea. The medicines will not cause these symptoms if taken as prescribed and any decision to stop these medications should be done under the supervision of your physician in a slow downward taper.
 - b. Benzodiazepines may be habit-forming (causing mental or physical dependence), especially when taken for a long time or in high doses. Some signs of dependence on benzodiazepines are: A strong desire or need to continue taking the medicine; a need to increase the dose to receive the effects of the medicine. Withdrawal effects occurring; for example, irritability, nervousness, trouble in sleeping, abdominal or stomach cramps, trembling or shaking.
4. Misuse of medications: Addiction

This is a psychological condition of use of a substance despite self-harm. Between six and ten percent of the population of the United States have problems with substance abuse and addiction. Controlled medications are likely to activate addictive behavior in this group of people
5. Diversion:

It is illegal to share your controlled medications with other people. It is illegal to provide false information to a prescriber in an attempt to obtain controlled medication. It is illegal to doctor shop, or visit multiple doctors in attempt to obtain controlled medications. Federal and state laws exist to address diversion problems. It is critical that you safeguard your controlled medications and use them only as prescribed by your doctor.
6. Driving

Studies of patients with chronic pain demonstrate improved driving skills when taking certain controlled medications, but individuals may have problems driving and need to realistically assess their own skills, as well as listen to others who drive with them to determine if they should be driving while taking these medications. You should consult the State Department of Transportation if you have questions about driving and taking controlled medications. This is especially important if your work involves driving, making important decisions that affect others, etc.

Common Sense Rules for Using Controlled Medications

- a. Follow your doctor's recommendations
- b. Do not take more or less pills than prescribed without discussing this first with your physician and receiving permission to do so
- c. Do not share medications with family or friends

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- d. Do not take medications from family or friends
- e. Do not stop these medications abruptly. Dose reductions need to be discussed and cleared by your physician. This is important no matter which controlled medication you take.
- f. Do not sell medications
- g. Do not take medications in any manner other than prescribed. For example do not chew or inject your medications
- h. Keep all medications out of reach of children
- i. Do not leave your prescriptions or controlled medications lying around unprotected for others to steal and abuse them
- j. Do not operate a motor vehicle if you feel mentally impaired using controlled medications. You are responsible for exhibiting good judgment in your daily affairs, including your use of controlled medications.
- k. Alcohol use should be curtailed when using controlled medications

Continued Use of Controlled Medication is based on your physician's judgment and a determination of whether the benefits to you of using controlled medications outweigh the risks of using them.

Your physician may discontinue treating you at his or her discretion. Your physician may require a consultation with an addiction specialist. Your physician may require more frequent visits.

We believe in treating your pain and we recognize the value of controlled medications in this process. When used properly, controlled medications can help restore comfort, function, and quality of life. However, as stated above, controlled medications may also have serious side effects and are highly controlled because of their potential for misuse and abuse. It is important to work with your physician and communicate openly and honestly with him or her about your pain control needs. By doing so, medications can be used safely and successfully.

By your signature below, you are acknowledging that you have read and reviewed these matters with your physician and that you have sufficient information to make a decision to use the controlled medications prescribed.

You should NOT sign this form if you do not believe you have enough information to make an informed decision about your use of controlled medications and how they fit in to your pain management treatment plan.

Patient Name: _____

Patient Signature: _____

Physician Signature _____

Date _____

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 manner in which 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 take when operating machinery or driving a car while taking these medications. When controlled substances are used long-term, some particular 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) primary care 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.

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- Pharmacy name/address/telephone:

- 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

Witness' Signature

Date

Date

MEDICATION ASSISTED TREATMENT PROGRAM

Methadone has been used in the treatment of opioid dependence for over 30 years. It has been found to be both effective and safe in long term administration. Medication Assisted Treatment (MAT) is the continual administering and dispensing of Methadone and other federally approved medications at relatively stable dosage levels, in conjunction with the provision of appropriate social, clinical, and medical services for an individual who is dependent on an opiate or morphine-like substance. An adequate individualized daily dose of methadone eliminates drug craving, prevents the onset of withdrawal, and blocks (through opiate cross-tolerance) the effects typical of other opiates, such as heroin or morphine. Efficacy of treatment is based on elimination of or reduction in illicit/inappropriate drug use, elimination or marked reduction in illegal activities, improved employment, pro-social behavior and improved general health. Patients taking stable doses of methadone are able to drive and operate heavy machinery in the same manner as individuals not taking methadone. Also methadone can be utilized when patients are pregnant (it is also monitored as needed and/or during every trimester). MAT is designed for an unknown and possibly indefinite period, according to the need of the individual. The only appropriate measure of time in treatment is how long it takes the individual to overcome a life of addiction.

All programmatic decisions regarding eligibility and admission criteria for MAT conform to regulations from the Dept. of Health and Human Services (DHHS), Substance Abuse and Mental Health Services Administration (SAMHSA), and Tn. State Methadone Authority. Clinics offering MAT are accredited through CARF (Commission for Accreditation of Rehabilitation Facilities) or similar bodies.

Most patients are self-referred and must agree to coordination of care with their primary care physician and/or mental health practitioner. Dual enrollment in pain management is inappropriate and not allowed. Patients are subject to random bottle checks. Initially, all patients are required to visit the clinic daily for dosing. As patients establish a reliable track record (counseling, licit drug screens, absence of behavioral problems/criminal activity, gainful vocational, educational, or employment activity, safeguarding of medication), they gradually earn "take home" medication for self-administration. The most trustworthy patients come to the clinic once every 28 days. Typical methadone doses range from 60-120 mg daily.

Longstanding opiate abusers with high tolerance often do best staying on MAT with the supportive environment of the clinic staff. Younger patients or those with shorter abuse histories are more likely to be able to wean off methadone entirely.

PSYCHOLOGICAL ASSESSMENT TOOLS

There are several validated mental health screening and assessment tools available for use by physicians and healthcare professionals. Below are some names and links to these.

1. Patient Health Questionnaire – 2 (PHQ-2). This is a simple two-item screening tool. If it is positive on either item, the clinician should offer another more detailed questionnaire to better assess the presence or absence of a depressive disorder. One link to this screening tool: http://www.cqaimh.org/pdf/tool_phq2.pdf.
2. Patient Health Questionnaire – 9 (PHQ-9). This nine-item tool screens for a depressive disorder, and often is used as a follow-up to the PHQ-2. It's easy to score and use. Here's one link to a copy: <http://www.integration.samhsa.gov/images/res/PHQ%20-%20Questions.pdf>.
3. Zung Self-Rating Depression Scale (Zung). This is a 20-item written questionnaire. One copy is at <http://healthnet.umassmed.edu/mhealth/ZungSelfRatedDepressionScale.pdf>.
4. Hamilton Depression Rating Scale (Ham-D). This is 21-item screening questionnaire. Cutoff scores is <7 is normal. <http://img.medscape.com/pi/emed/ckb/psychiatry/79926-1889862-1859039-2124408.pdf>
5. A fairly comprehensive article on screening for depression in medical settings is <http://emedicine.medscape.com/article/1859039-overview>. This article reviews several scales.
6. Generalized Anxiety Disorder 7-item Scale (GAD-7). This is a 7-item scale to screen for generalized anxiety. One link is: <http://www.integration.samhsa.gov/clinical-practice/GAD708.19.08Cartwright.pdf>.
7. Primary Care PTSD (PC-PTSD). This is a four item screening test for Post-Traumatic Stress Disorder. One link is: <http://www.integration.samhsa.gov/clinical-practice/PC-PTSD.pdf>.
8. One excellent source for a number of screening tools for various mental health disorders is from the Substance Abuse and Mental Health Services Administration (SAMHSA), which is a branch of the U.S. Department of Health and Human Services. A link to a site that lists a number of tools is: <http://www.integration.samhsa.gov/clinical-practice/screening-tools>.
9. CAGE Questionnaire for Drug Use
 - a. Have you ever felt you ought to cut down on your drinking or drug use?
 - b. Have people annoyed you by criticizing your drinking or drug use?
 - c. Have you felt bad or guilty about your drinking or drug use?
 - d. Have you ever had a drink or used drugs first thing in the morning to steady your nerves or to get rid of a hangover (eye-opener)?

Scoring: Item responses on the CAGE questions are scored 0 for "no" and 1 for "yes" answers, with a higher score being an indication of alcohol problems. A total score of two or greater is considered clinically significant.

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TERMS/DEFINITIONS

Acute Pain: pain of sudden onset usually from a single, “fixable” event commonly seen with surgery, accidental injury or inflammation, however, can be from unknown cause; short duration from days to less than 3-6 months as associated with healing; considered our biological red flag that sends warning signals through the nervous system that something is either wrong within the body or that a hurtful activity should be avoided to prevent further or repeat damage.

ABAM: American Board of Addiction Medicine. The American Board of Addiction Medicine, Inc. (ABAM) is a not-for-profit 501 (c)(6) organization whose mission is to examine and certify diplomats. It was founded in 2007 following conferences of committees appointed by the American Society of Addiction Medicine. This action was taken as a method of identifying the qualified specialists in Addiction Medicine. ABAM offers a rigorous certifying examination that was developed by an expert panel and the National Board of Medical Examiners, as well as maintenance of certification examination to ensure that ABAM-certified physicians maintain life-long competence in Addiction Medicine. (From ABAM Web Site.)

ASAM: American Society of Addiction Medicine. American Society of Addiction Medicine is a professional society representing over 3,000 physicians and associated professionals dedicated to increasing access and improving the quality of addiction treatment; educating physicians, other medical professionals and the public; supporting research and prevention; and promoting the appropriate role of physicians in the care of patients with addictions. (From ASAM Web Site.)

Allodynia: pain caused by a stimulus or action that does not normally cause pain, like light touch, pressure or a gentle breeze on skin.

Chronic Pain: pain lasting longer than expected healing time, may last for many months, years or a lifetime, may be constant or in intervals; cause may be unknown or result of recent or previous acute pain episode; may be related to another chronic disorder, such as arthritis, peripheral vascular disease, diabetes, or cancer.

Hyperalgesia: an increased response to a stimulus that normally would induce a mild discomfort.

Neuropathic Pain: chronic pain caused by the nervous system.

Nociceptive Pain: acute pain as a response to a noxious stimulus.

Opioid Naïve: patients who are not chronically receiving opioid analgesics on a daily basis.

Opioid Tolerant: patients who are chronically receiving opioid analgesics on a daily basis.

Pain: is an unpleasant sensory and emotional experience associated with actual or potential tissue damage. Pain is personal and subjective.

Pain Medicine Specialist: Pain Medicine is the medical specialty dedicated to the prevention, evaluation and treatment of people with chronic pain. Additionally (See Pain Medicine Specialist Appendix)

Somatic Pain: pain originating from the muscles and/or bones.

Visceral Pain: pain originating from within internal organs.

SAFETY NET

Tennessee's Substance Abuse System

1. Substance abuse is a pervasive public health issue that has roots in individual, family, peer, and community conditions. Substance abuse negatively impacts 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 National Survey of Substance Abuse Treatment Services (N-SSATS) examines facilities providing substance abuse treatment services conducted by the Substance Abuse and Mental Health Services Administration (SAMHSA). N-SSATS collects data on the location, characteristics, services, and number of clients in treatment at alcohol and drug abuse treatment facilities (both public and private) throughout the 50 states, the District of Columbia, and other U.S. jurisdictions. It looks at 208 facilities in Tennessee:
3. Along with these numbers, N-SSATS found that 81.7% of Tennessee's substance abuse treatment providers offer outpatient treatment services, 32.7% offer residential services, and 6.7% offer hospital inpatient services.
4. 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 substance abuse treatment services, fostering self-sufficiency and protecting those who are at risk of substance abuse, dependence and addiction.
5. TDMHSAS licenses organizations to provide a continuum of substance abuse treatment services throughout the state. Services include outpatient, intensive outpatient, partial hospitalization, residential treatment, clinical halfway house, social detoxification, medically monitored detoxification, medically managed detoxification, and opioid treatment. All treatment providers use an assessment tool to determine the severity of a person's substance use disorder and the most appropriate service for the individual. Many of these agencies accept commercial insurance, TennCare, and self-pay.
6. To locate a substance abuse treatment facility in your community, visit www.samhsa.gov/treatment.

PRESCRIPTION DRUG DISPOSAL

Proper Disposal

Unwanted, unused or expired prescription drugs present substantial risks to communities through the potential for abusive use or by damaging the environment as a result of improper disposal. Residential supplies of pharmaceutically controlled substances, those found in home medicine cabinets, have become the supply source of choice for many young people and individuals abusing substance. According to the 2011 Substance Abuse and Mental Health Services Administration's National Survey on Drug Use and Health (NSDUH), more than 70 percent of people abusing prescription pain relievers got them through friends or relatives, a statistic that includes raiding the medicine cabinets of family and friends. Easy access to prescription drugs is one factor leading to the prescription drug epidemic and an effective method to control access is development of mechanisms for safe, convenient, and responsible disposal. The State of Tennessee has been actively engaged in two types of disposal activities: **Take-Back Events and Permanent Prescription Collection Boxes.**

Take-back events are one-day events where the public is encouraged to discard their unused, unwanted, and expired medications including prescription drugs from their homes. In addition to removing prescription drugs from the community these events are intended to increase awareness of the prescription drug epidemic, inform the public about the need for safely disposing of prescription drugs, and raise awareness of local permanent disposal sites available year round.

Prescription drug collection boxes are established as permanent disposal sites located within law enforcement agencies where community members can safely deposit prescription drugs in a secure container. To be compliant with Drug Enforcement Administration (DEA) regulations, drug collection boxes must be located with a law enforcement entity to ensure access to prescription drugs is carefully controlled and that substances are properly destroyed once collected. Since the beginning of 2012, the number of permanent prescription drug collection boxes has more than doubled from 36 to 82 boxes. This achievement would not have been possible without the Tennessee Department of Mental Health and Substance Abuse Services, the Tennessee Department of Environment and Conservation, and the Tennessee Department of Health working together to ensure the availability of disposal boxes and working with law enforcement agencies to identify and establish safe prescription drug disposal sites. One of the goals of this multi-agency collaboration is to establish at least one permanent prescription drug collection box in all 95 counties of the state. Establishing permanent prescription drug collection boxes as the method for Tennessee citizens' to routinely dispose of medications will require continued public education concerning their use and ease of access, thereby increasing their use and reducing the amount of substances available for abuse and increase home and community safety. Locations of permanent drug collection boxes may be found at <http://www.tn.gov/mental/publications/Permanent%20Drug%20Take-Back%20Boxes.pdf>.

USE OF OPIOIDS IN WORKERS' COMPENSATION MEDICAL CLAIMS

The use of opioids in Workers' Compensation is a significant component of the medical care of injured workers, not only in Tennessee but across the United States. Injuries to the back, knees, and shoulders are among the most frequently occurring workers' compensation injuries. These injuries frequently result in the injured worker experiencing chronic pain and the use of opioids has become a routine practice in the medical care for this type of injury.

A recent study by NCCI for the state of Tennessee found that 11% of workers' compensation medical costs nationwide were attributable to drugs. In Tennessee the percentage is even higher, 16%. Of the top ten drugs prescribed for workers' compensation patients in Tennessee, 22.5 % were opioids (Hydrocodone-Acetaminophen – 16.0 %, Tramadol – 4.3%, Oxycodone HCl-Acetaminophen – 2.2%).

The number of deaths attributable to accidental overdose is not tracked in Tennessee or most other states. It has been estimated that the number of deaths countrywide is in excess of 200, but that estimate may be low as the number of deaths in the two states that track opioid use would account for 25% of that estimate.¹

These statistics are cause for concern and were a consideration in Public Chapter 289 passed by the General Assembly in 2013 that included a provision mandating the adoption of medical treatment guidelines to be effective January 1, 2016. Pain management will be the first guideline developed.

Tennessee is one of many states that are undertaking the development of guidelines for pain management with the goal of promoting the optimum use of opioids. The table below lists the states with pain management medical treatment guidelines and the basis of those guidelines.

¹ Reducing Inappropriate Opioid Use in Treatment of Injured Workers: A Policy Guide. International Association of Industrial Accident Boards and Commissions. September 5, 2013. Found at: <http://www.iaabc.org/i4a/pages/index.cfm?pageID=4169>

Medical Treatment Guidelines for Pain Management for Workers' Compensation

State	Guideline type	Website, if available
California	ODG	proprietary
Colorado	state specific	http://www.colorado.gov/cs/Satellite/CDLE-WorkComp/CDLE/12480953116866
Connecticut	state specific	http://wcc.state.ct.us/download/acrobat/protocols.pdf
Delaware	state specific	http://dowc.ingenix.com/info.asp?page=pracguid
Hawaii	ODG	Proprietary
Kansas	ODG	Proprietary
Louisiana	state specific modeled on Colorado, ODG	http://www.laworks.net/WorkersComp/OWC_MedicalGuidelines.asp
Massachusetts	state specific	http://www.mass.gov/lwd/workers-compensation/hcsb/tg/
Minnesota	state specific	http://www.dli.mn.gov/wc/TopToc.asp
Montana	state specific, Colorado model, ACOEM	www.mtguidelines.com
New Mexico	ODG	proprietary
New York	state specific, adopted from Colorado model, ACOEM	http://www.wcb.ny.gov/content/main/hcpp/MedicalTreatmentGuidelines/2010TreatGuide.jsp
North Dakota	ODG, ACOEM et al professional organization guidelines	proprietary
Ohio	ODG	proprietary
Oklahoma	ODG	proprietary
Rhode Island	state specific	http://www.courts.ri.gov/Courts/workerscompensationcourt/Medical_AdvisoryBoard/Pages/Protocols.aspx
Texas	ODG	proprietary
Washington	state specific	http://www.lni.wa.gov/claimsins/providers/treatingpatients/treatguide
Wisconsin	state specific	N/A
Wyoming	ODG	proprietary
ODG: Official Disability Guidelines for Treatment in Workers' Compensation, published by Work Loss Data Institute		
ACOEM: American College of Occupational and Environmental Medicine, Occupational Medicine Practice Guidelines, 3rd Ed		

NALOXONE

Public Chapter 623 allows licensed healthcare providers to prescribe an opioid antagonist (Naloxone) when acting in good faith and exercising reasonable care via a direct or standing order for the following individuals:

1. A person at risk of experiencing an opiate related overdose, or
2. A family member, friend, or other person in a position to assist a person at risk of experiencing an opiate-related overdose

Evidence of the use of reasonable care in administering the drug shall include the receipt of basic instruction and information on how to administer the opioid antagonist, including successful completion of the online overdose prevention education program offered by the Department of Health as evidenced by a certificate of completion.

Naloxone is a pure opioid antagonist, reversing the effects of opioids including respiratory depression, sedation, and hypotension. The onset of action is within 2 minutes when given IV, however, nasal and IM administrations have been documented in the literature. Because of variability in response, an individual may still experience withdrawal symptoms after administration.

The commissioner of health or the commissioner's designee, in consultation with other state, federal or local government personnel, including contractors, shall create and maintain an online education program with the goal of educating laypersons and the general public about the administration of opioid antagonists and appropriate techniques and follow-up procedures for dealing with opioid-related drug overdose.

The following individuals are immune from civil liability in the absence of gross negligence or willful misconduct for actions authorized by this section:

1. Any licensed healthcare practitioner who prescribes or dispenses an opioid antagonist pursuant to subsection (c); and
2. Any person who administers an opioid antagonist pursuant to subsection (e).

The duration of action of some opioids may exceed that of naloxone. Depending on a patient's age and route of administration of naloxone, the duration of action may vary from minutes to hours. The patient must be watched closely until stabilized in the appropriate healthcare facility. A repeat dose may be necessary before patient reaches a healthcare facility.

Intranasal administration via atomizer is considered a safe and effective alternative to traditional administration routes for naloxone. Advantages include elimination of the risk of needle exposure. Institution of a collaborative agreement may allow dispensing of naloxone by a pharmacist.