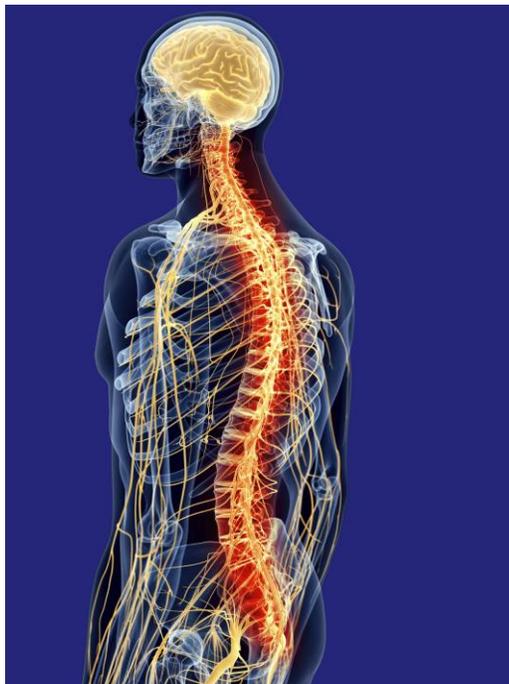


Tennessee Chronic Pain Guidelines

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



2nd Edition



STATE OF TENNESSEE
DEPARTMENT OF HEALTH

JOHN J. DREYZEHNER, MD, MPH
COMMISSIONER

BILL HASLAM
GOVERNOR

January 2017

Dear Friends and Colleagues:

We are pleased to share with you the Tennessee Chronic Pain Guidelines for 2017.

In 2013, when Public Chapter 430 was enacted directing the development of these guidelines, there was widespread acknowledgement that prescription drug abuse and misuse, and opioid abuse specifically, was a real, observable public health threat to people in Tennessee and across the country. Tennesseans had learned this fact the hard way: through the loss of loved ones; the birth of drug-dependent babies; the arrest and prosecution of drug seekers and pill mill operators and the devastation of communities.

We joined with other Tennessee policymakers and health experts who heard these stories and took action, developing a comprehensive strategy to change the culture of prescription drug consumption in Tennessee and the Southeast. Education and awareness were at the heart of our strategy, as well as a deep understanding that a problem as complex as this one will require collaboration and partnerships at every level. We have been humbled and inspired to find willing partners in every corner of the state and across the country: healthcare practitioners, elected officials, community coalitions, concerned citizens, federal agencies, members of the media, all rallying around this cause and the individuals struggling in their communities.

We have begun to see our policymaking efforts yield some very hopeful results. Since these guidelines were finalized in 2014, we have seen a 12 percent drop in the total number of morphine milligram equivalents prescribed in our state. The number of pain clinics in Tennessee has decreased from 333 in 2014 to 188 in 2016. However, in spite of these successes, overdose deaths continue to rise year after year, as do instances of neonatal abstinence syndrome, and we are just now developing an understanding of the adverse economic impact this epidemic has had on our state. It is clear much work remains.

As we press on, we will need your continued partnership. There is perhaps no class of individuals better positioned to stem the tide of this epidemic than the healthcare providers practicing in our state. Through conscientious and responsible prescribing, screening for substance use disorders and referral to substance use disorder treatment when indicated, providers can make a difference, and can do so without compromising quality of care. I recommend these guidelines to you in your pursuit of these goals.

Sincerely,

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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, 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 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.

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

- In 2015, Tennessee had the second highest per capita prescription rate for opioids in the US.
- Unintentional overdose deaths increased more than 250% from 2001 to 2015, exceeding deaths due to motor vehicle accidents, homicide or suicide in 2015.
- 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.
- Acute pain may be spontaneous, surgical or due to an injury. The lowest dose for the shortest duration is recommended to avoid dependence and abuse. Long acting opioids should be avoided in the acute setting.

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 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.

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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.
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 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 pain shall not be treated by the use of 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 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 of Child Bearing Age Appendix and Pregnant Women Appendix**).

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. **(See Risk Assessment Tools Appendix)**
2. The prescriber should obtain a Urine Drug Test (UDT) (or a comparable test on oral fluids) prior to initiating opioid therapy. **(See Urine Drug Testing 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)**

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. 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 **E**njoyment of life
 - Interference with **G**eneral 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 in opioid naive 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 81MEDD.
2. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days in some instances is appropriate and shall be documented in the medical record.
3. When starting opioid therapy as a primary care 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.
4. Any product containing buprenorphine, whether with or without naloxone, may only be prescribed for a use recognized by the federal food and drug administration. 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.
5. 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.
6. Buprenorphine/naloxone combinations shall be avoided for the treatment of chronic pain.
7. 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. **(See Sample Informed Consent Appendix)**
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

SECTION II: INITIATING OPIOID THERAPY FOR CHRONIC NON-MALIGNANT PAIN

include an expectation that a female patient will tell the provider if she wishes to avoid unintended pregnancy and if she becomes pregnant. **(See Sample Patient Agreement Appendix)**

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 Urine Drug Testing Appendix)**

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 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 of Child Bearing Age Appendix and Pregnant Women Appendix)**

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.

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 as outlined above, 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 patients receiving opioid dosages or potentially dangerous combinations
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 done twice a year at a minimum. **(See Urine Drug Testing Appendices)**
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. 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.
6. 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. **(see Tapering Protocol Appendix)**
7. Appropriate documentation of CSMD query should be included in the medical record. **(see CSMD Appendix)**
8. 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.

C. Women's Health

1. The provider should discuss a method to prevent unintended pregnancy with every woman

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

of child-bearing age who has reproductive capacity when opioids are initiated. **(See Women of Child Bearing Age Appendix and Pregnant Women Appendix)**

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.

The appendices that follow contain specific references from the guidelines as well as other pertinent information about the resources available in the State of Tennessee concerning substance abuse, the efforts to curb overdose death and other support systems centered around these topics.

APPENDICES

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, 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 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) and the American Osteopathic Association (AOA) are the primary physician certification organizations in the United States. The ABMS and the AOA assist 24 boards in granting certificates in 124 specialty and subspecialty areas. The AOA assists 18 boards in granting certificates in 57 specialty and subspecialty 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 or the AOA 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 or AOA 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.

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Tier 2 Pain Medicine Specialists:

A Pain Medicine Specialist is defined by T.C.A. § 63-1-301(9) as:

1. Has a subspecialty certification in pain medicine as accredited by the Accreditation Council for Graduate Medical Education (ACGME) through either the American Board of Medical Specialties (ABMS) or the American Osteopathic Association (AOA), or is eligible to sit for the board examination offered by ABMS or AOA;
 - a. Holds an unencumbered Tennessee license; and
 - b. Maintains the minimum number of continuing medical education (CME) hours in pain management to satisfy retention of ABMS or AOA certification. Any exceptions to this requirement shall be approved by the respective regulatory board;
2. Attains American Board of Pain Medicine (ABPM) diplomate status;
 - a. Holds an unencumbered Tennessee license; and
 - b. Maintains the minimum number of CME hours in pain management to satisfy retention of ABPM diplomate status. Any exceptions to this requirement shall be approved by the respective regulatory board;
3. Is board certified by the American Board of interventional Pain Physicians (ABIPP) by passing exam 1 on or before June 30, 2016, and holds an unencumbered Tennessee license and maintains the minimum number of CME hours in pain management to satisfy retention of ABIPP diplomate status; provided, that on and after July 1, 2016, a new applicant shall only qualify as a pain management specialist under this subdivision (9)(C) if the applicant is board certified by the American Board of Interventional Pain Physicians (ABIPP) by passing parts 1 and 2 of its examination, and holds an unencumbered Tennessee license and maintains the minimum number of CME hours in pain management to satisfy retention of ABIPP diplomate status; or
4. Has an active pain management practice in a clinic accredited in outpatient interdisciplinary pain rehabilitation by the commission on accreditation of rehabilitation facilities or any successor organization and holds an unencumbered Tennessee license.

It should be noted that should Tenn. Code Ann. § 63-1-301(9) change the law would render any part of these guidelines obsolete upon taking effect.

APPENDICES

MENTAL HEALTH 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 <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.

APPENDICES

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.

Public Chapter 912 will be enacted on January 1, 2017. The act creates nonresidential office-based opiate treatment facilities. This will require any facility defined as a Nonresidential office-based opiate treatment facility to attain licensure as such by the Department of Mental Health & Substance Abuse Services. Nonresidential office-based opiate treatment facilities refers to facilities that are prescribing buprenorphine or products containing buprenorphine to 50% or more of its patients and to one hundred fifty patients or more. This legislation requires the TDMH&SAS to promulgate rules in consultation with the Department of Health.

APPENDICES

WOMEN'S ISSUES: 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.

APPENDICES

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, Hennessy MD, et al. Detoxification from opiate drugs during pregnancy. Am J Obstet Gynecol 2016)*

APPENDICES

RISK ASSESSMENT TOOLS

There are several validated risk assessment tools available to pain clinicians. Below is 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. The scoring system and questions to be asked can be downloaded for free from www.tedjonesresearch.com. Interview information can also be scored on-line anonymously at that website.
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." Here is link to a pdf copy: <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. One link to a copy is: http://www.partnersagainstpain.com/printouts/Opioid_Risk_Tool.pdf.
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

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High risk (no Medium category). One link to a copy is: <http://www.painedu.org/soap.asp>. Please check with the authors about use and fees at 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>. Please check with the authors about use and fees at www.painedu.org/soapp.asp.
7. **BRQ** (Brief Risk Questionnaire). This is a 12-item patient-completed questionnaire (Jones, Lookatch and Moore, 2015)⁸. It asks patients about a wider range of variables than other risk assessment tools, asking about such issues as history of theft of medication, current help with medication storage, past incarceration and literacy. Patients are categorized into Low, Medium or High risk categories. It appears to be a more sensitive screening tool in identifying risk but may also tend to overrate a patient's risk. It can be obtained on a free download from www.tedjonesresearch.com.

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CSMD: 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;
- the state chief medical examiner, deputy chief medical examiner or 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);

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- 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:
 - the Office of Inspector General;
 - the Medicaid Fraud Control Unit;
 - the Bureau of TennCare's chief medical officer, associate chief medical directors, director of quality oversight, and associate director of pharmacy.
- Personnel of the bureau of TennCare who request aggregate controlled substances prescribing information from the database which does not contain personally identifiable data but only on request by the following personnel of the bureau:
 - The chief medical officer
 - Associate chief medical directors
 - Director of quality oversight and
 - Directors 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 judge of a drug court treatment program, created under the Drug Court Treatment Act of 2003, compiled in title 16, chapter 22, and pursuant to this part to the extent the information relates specifically to a current participant in the drug court treatment program.
- 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:
 - The chief pharmacist;
 - The state opioid treatment authority (SOTA) or SOTA designee; and
 - The medical director.
- 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 (*l*), and may be shared with other personnel of the department of mental health and

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substance abuse services as needed to fulfill assigned duties and responsibilities:

- o The chief pharmacist;
 - o The SOTA; or
 - o The medical director.
- Authorized committee, board, or department personnel and 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 may publish, or otherwise make available to healthcare practitioners and to the general public, aggregate unidentifiable personal data contained in or derived from the database for the purpose of educational outreach.

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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

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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.

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

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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>

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SAMPLE INFORMED CONSENT: Controlled Substance Agreement

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.
- e. 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

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- 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

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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
- 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: _____ Physician Signature: _____

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Patient Signature: _____ Date: _____

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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 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

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URINE DRUG TESTING

Drug testing of patients receiving chronic opioid therapy (COT) is recommended by numerous entities, including the American Pain Society (APS), 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. Unexpected urine drug test (UDT) results are seen frequently, with one study showing 27% of patients with no behavioral signs presenting with unexpected positive UDT results.⁶ A study in a pain management program at an urban teaching hospital reported a 45% rate of unexpected toxicology results. The prevalence of illicit drugs in UDT results of pain management patients has been reported between 10.9 and 24%.^{5,19,20} Given these circumstances, a consistent approach to UDT based on validated risk models and clinical evaluation is advised (**See Risk Assessment Tools Appendix**).

Historically, most urine drug testing performed for compliance assessment purposes incorporated two steps: screening and confirmation. This screen and confirm testing paradigm was developed for the workplace setting due to its ease of use and lower costs. However, this approach presents many pitfalls for use in the clinical setting.

Immunoassay (IA) is the most common method used for screening, and is frequently employed by on-site, point-of-care testing (POCT) in outpatient clinics and hospital laboratories. The most frequently used definitive or confirmatory methods include gas chromatography/mass spectrometry (GC/MS) and liquid chromatography/tandem mass spectrometry (LC/MS/MS). Depending on how LC/MS/MS is performed, it may also be used as a screening method.²¹

IA tests are qualitative in nature and detect the presence or absence of a drug class and provide the advantage rapid results. However, IA tests have significant cross-reactivity with other substances, resulting in lower sensitivity and specificity when compared to confirmation testing. Studies of presumptive positive IA tests show high rates of false-positive results when sent for confirmatory testing

Table 1

Table 1. Reported rates of presumptive positive results which did not confirm (false positives) ²²⁻²³		
Immunoassay	Manchikanti, et al (2011)	Kirsh, et al (2015)
Amphetamines	52.9%	21.4%
Barbiturates	Not tested	21.5%
Benzodiazepines	Not tested	11.4%
Cocaine	0.0%	12.3%
Marijuana	38.7%	21.3%
Methadone	18.3%	45.3%
Opiates	3.6%	22.4%
Oxycodone	38.8%	41.3%
MDMA/Methamphetamine	85.7%	99.5%
PCP	Not tested	100%
Tricyclic Antidepressants	Not tested	76.2%

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Table 2. Partial list of drugs which can cause a false-positive IA result.

Table 2: Cross-Reacting Compounds on Immunoassay (IA) ²¹			
IA Test	Potential Drugs Causing a False Positive Result		
Buprenorphine	Codeine	Morphine	
	Dihydrocodeine	Methadone	
Fentanyl	Trazodone	Risperidone	
Methadone	Chlorpromazine	Doxylamine	Tapentadol
	Clomipramine	Phenothiazine compounds	Thioridazine
	Cyamemazine	Olanzapine	Verapamil
	Diphenhydramine	Quetiapine	
Opiates	Dextromethorphan	Poppy seeds*	Ranitidine
	Diphenhydramine	Procaine	Rifampin
	Doxylamine	Quinine (tonic water)	Tolmetin
	Heroin*	Quinolone antibiotics	Verapamil

*These products either contain or metabolize to morphine, and are therefore a “true” positive result

A true negative test result means that at the time of collection, the concentration of drug/metabolite fell below the test cutoff, or threshold. Due to different rates of metabolism and excretion and interpatient variability in a drug’s period of detection, a true negative result may occur because the specimen was collected beyond the expected window of detection. A false negative result occurs when a drug/metabolite was present in the specimen, but was not detected by the testing method used. Reasons identified as possible causes of false negative immunoassay results include the following:

- Lack of cross-reactivity-Opiate immunoassays are targeted for natural opioids such as codeine and morphine and may not reliably detect synthetic or semi-synthetic opioids, such as hydrocodone, oxycodone or oxymorphone. Rates of false negatives have ranged from 30-72%.²³⁻²⁴
- Drugs not included in testing-Commonly abused prescription drugs may not be included in the immunoassay including drugs such as: carisoprodol, methadone, buprenorphine and tramadol.
- Metabolites do not react to immunoassay-Most immunoassays only detect parent drug. For instance, most immunoassays are cross-reactive to opioid normetabolites at a rate of 0.1%. However, many patients excrete only opioid normetabolites, ranging from 2.2-53.1%, depending on drug.²⁵⁻²⁶
- Thresholds are too high-Most immunoassay screens were developed for workplace drug testing where thresholds are typically higher than in clinical settings. False negatives for illicit drugs are common with immunoassay screening when higher thresholds are used.
- Dilute specimen-The most common attempt to beat a drug test is to ingest excess water, which can be effective in producing a false negative result. Specimen validity testing, performed as part of confirmatory testing, is effective in identifying dilution attempts.
- Adulterated or substituted specimens-Adulterants may be added to a specimen to mask the presence of illicit drugs. Specimen validity testing, performed as part of confirmatory testing, is effective in identifying adulteration attempts.

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Due to high rates of false positive and negative results, consideration should be given to performing confirmatory testing when making treatment decisions.

Oral fluid confirmation testing is a widely acceptable and growing alternative to UDT in pain management patients, especially in cases of shy bladder, severe renal impairment or suspected urine specimen tampering/substitution. Oral fluid testing is increasingly used due to ease of collection, limited invasiveness and opportunity for direct observation. Most prescription drugs of interest in pain management and illicit drugs are readily detectable in oral fluid when proper collection procedures are followed.²⁷⁻²⁸ One notable difference between oral fluid and urine is that the disposition of parent drug and metabolites is reversed. While metabolite concentrations typically exceed parent drug in urine, parent drugs are generally more readily detectable than metabolites in oral fluid. This may be relevant for patients with impaired or absent metabolism due to pharmacogenetics or drug-drug interactions, especially for drugs that are extensively metabolized and only detected by metabolite presence in urine. The increased detection of parent drugs in oral fluid may be useful to assess compliance in these circumstances, particularly when urine specimen adulteration or tampering is suspected.^{21,29}

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 twice per year for all patients on COT. Lower 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 more or less 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.

Interpretation of UDT results can be difficult, as opioids undergo extensive metabolism after ingestion; the metabolism is affected by pharmacogenetics, drug-drug and drug-food interactions.³¹⁻³² Many prescription opioids are metabolized to other commercially available opioids, which can complicate interpretation. (A metabolism chart for codeine, hydrocodone and oxycodone is included at the end of this appendix-Figure 1). Pharmaceutical impurities can be another source of unexpected results, which have been described as occurring in up to 1% of the label medication quantities. The following impurities have been described in literature:³³⁻³⁶

- Hydrocodone in oxycodone;
- Oxycodone in oxymorphone;
- Morphine and hydrocodone in hydromorphone; and
- Codeine in morphine.

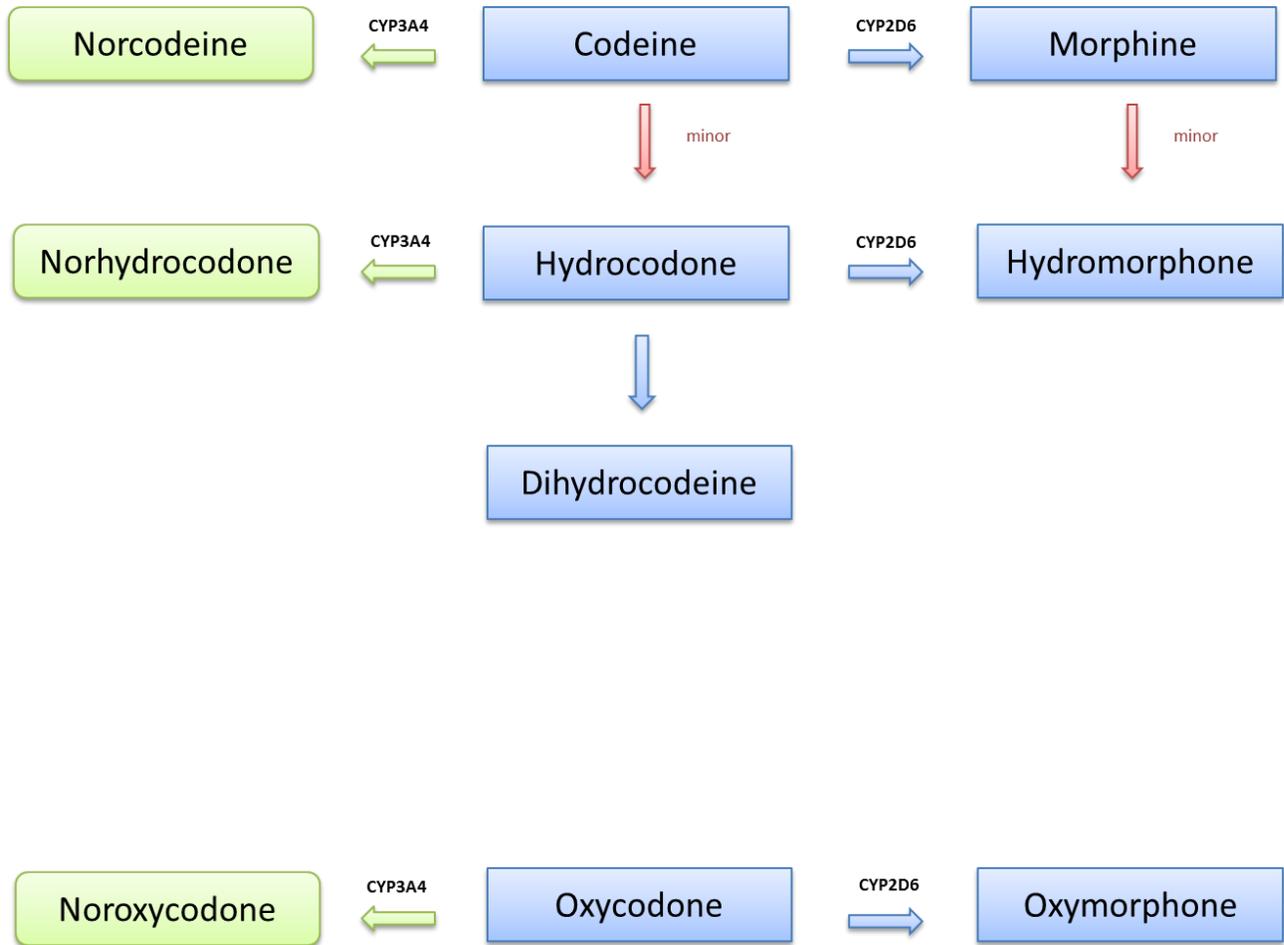
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In some instances, metabolites may be present in the absence of parent drug. Normetabolites are products of CYP3A4 metabolism, which is subject to induction and inhibition by drug-drug and drug-food interactions. Morphine, hydromorphone and oxymorphone are pharmacologically active metabolites which are products of CYP2D6 metabolism, which is subject to drug inhibition and pharmacogenetic variability. Additionally, minor metabolism can produce other metabolites. For example, small amounts of hydromorphone are possible after morphine use and small amounts of hydrocodone are possible after codeine use. The enzymes responsible for this metabolism have not been identified and metabolism may not take place in all patients.²¹ In confirmation testing, unexpected sources of a detected metabolite should be considered; a table of potential causes of unexpected positive results is included in Table 3.

Table 3: Possible sources of unexpected positive opioid markers	
Drug Identified	Comments on Alternative Sources
Codeine	<ul style="list-style-type: none"> • Pharmaceutical impurity in morphine (up to 0.5%).³³ • Pharmaceutical impurity in hydrocodone (up to 0.15%).³³ • Codeine may be present after use of heroin.³⁷ • Codeine is a component in several prescription and OTC cough suppressants. • Codeine may be present after ingestion of poppy seeds, typically at lower concentrations than morphine.¹² • Products containing opium may result in positive findings primarily for morphine, with codeine at lesser concentrations.
Dihydrocodeine	<ul style="list-style-type: none"> • Dihydrocodeine is a component in several prescription cough suppressants.
Heroin	<ul style="list-style-type: none"> • Heroin-specific markers include parent heroin, 6-acetylmorphine (6AM), and 6-acetylcodeine. • Other metabolites which may be present include codeine, morphine, and sometimes hydromorphone.
Hydrocodone	<ul style="list-style-type: none"> • Minor metabolite of codeine: hydrocodone concentrations in urine should be under 5% of the codeine concentration.³⁸ • Pharmaceutical impurity in hydromorphone (up to 0.1%).³³ • Pharmaceutical impurity in oxycodone (most notably OxyContin®, up to 1%).³³ • Hydrocodone is a component of several prescription cough suppressants (e.g., Tussionex®, Hycodan®).
Hydromorphone	<ul style="list-style-type: none"> • Minor metabolite of morphine: hydromorphone concentrations in urine are usually under 6% of the morphine concentration.³⁹⁻⁴³ • Hydromorphone sometimes appears as a metabolite of morphine after heroin ingestion. • Pharmaceutical impurity in oxymorphone (up to 0.15%).³³
Morphine	<ul style="list-style-type: none"> • Poppy seeds in food products (bagels, salad dressings, etc) may result in morphine concentrations in urine up to 2,000 ng/mL.¹² In rare instances, poppy seeds have resulted in higher morphine concentrations, but these occurrences are considered exceptions.⁴⁴⁻⁴⁹ • Codeine concentrations are typically less than half the morphine concentration (or lower) after poppy seed ingestion.⁴⁹⁻⁵⁰ • Poppy seeds are unlikely to cause a positive morphine result in oral fluid or blood.^{12,50-51} • Pharmaceutical impurity in hydromorphone (up to 0.15%).³³ • Products containing opium may result in positive findings primarily for morphine, with codeine at lesser concentrations.
Oxycodone	<ul style="list-style-type: none"> • Pharmaceutical impurity in oxymorphone (up to 0.5%).³³

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Due to interpatient variability, a broad range of observed patterns of parent drug and metabolites is possible. If a provider has questions about interpretation of toxicology results, they should contact the laboratory director, toxicologist, or local Medical Review Officer.



APPENDICES

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.

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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.

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TABLE OF FREQUENTLY PRESCRIBED PAIN MEDICATIONS		
Short-Acting Opioids	DEA Schedule	Available Strengths*
Acetaminophen/ Caffeine/Dihydrocodeine Cap and Tab	(C-III)	356.4/30/16
Acetaminophen/Butalbital/Caffeine/Codeine Capsule	(C-III)	325 (also as 300)/50/40/30mg
Aspirin/Butalbital/Caffeine/Codeine Capsule	(C-III)	325/50/40/30mg
Acetaminophen/Codeine Tablet	(C-III)	300/15, 30, 60mg
Acetaminophen/Codeine Solution/Suspension	(C-V)	120/12mg /5ml
Codeine sulfate Tablets	(C-II)	15, 30, 60mg
Fentanyl citrate Oral lozenge	(C-II)	200, 400, 600, 800, 1200, 1600mcg
Fentanyl citrate Oral spray		100, 300, 400 mcg
Fentanyl Oral spray		100, 200, 400, 600, 800, 1200, 1600 mcg
Fentanyl citrate Oral effervescent tab		100, 200, 400, 600, 800 mcg
Fentanyl citrate Oral sublingual tab		100, 200, 400, 400, 600, 800 mcg
Hydrocodone/Acetaminophen		(C-II)
Hydrocodone/Ibuprofen Tablet	(C-II)	2.5, 5, 7.5, 10/200mg
Hydromorphone HCl Tablet	(C-II)	2, 4, 8mg
Hydromorphone HCl liquid		1mg/ml
Levorphanol tartrate Tablet	(C-II)	2mg
Morphine sulfate Solution	(C-II)	10, 20, 100mg/5ml
Morphine sulfate Tablet		15, 30 mg
Oxycodone HCl/Acetaminophen Tablet	(C-II)	2.5/325, 5/300, 5/325, 7.5/300, 7.5/325, 10/300, 10/325 mg
Oxycodone HCl/Ibuprofen Tablet	(C-II)	5/400mg
Oxycodone/Oxycodone terephthalate/Aspirin Tablet	(C-II)	4.5/0.38/325 mg
Oxycodone HCl Capsule or Tablet	(C-II)	5, 7.5, 10, 15, 20, 30 mg
Oxycodone HCl Solution		5mg/5ml, 20mg/ml
Oxymorphone Tablet	(C-II)	5, 10mg
Meperidine HCl Solution	(C-II)	50mg/5ml
Meperidine HCL Tablet		50, 100 mg
Tapentadol Tablet	(C-II)	50, 75, 100mg
Butorphanol tartrate Spray	(C-III)	10mg/ml
Pentazocine HCl/Naloxone HCl Tablet	(C-III)	50/0.5mg

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TABLE OF FREQUENTLY PRESCRIBED PAIN MEDICATIONS		
Long-Acting Opioids	DEA Schedule	Available Strengths*
Buprenorphine Patch	(C-III)	5, 7.5, 10, 15, 20mcg/hr
Buprenorphine HCl Film	(C-III)	75, 150, 300, 450, 600, 750, 900mcg
Fentanyl Patch	(C-II)	12, 25, 37.5, 50, 62.5, 75, 87.5 100mcg/hr
Hydromorphone ER Tablet	(C-II)	8, 12, 16, 32mg
Hydrocodone Bitartrate ER (12 hour) Capsule	(C-II)	10, 15, 20, 30, 40, 50mg
Hydrocodone Bitartrate ER (24 hour) Tablet	(C-II)	20, 30, 40, 60, 80, 100, 120mg
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
Morphine Sulfate/Naltrexone ER Capsule	(C-II)	30/1.2, 50/2, 60/2.4, 80/3.2, 100/4mg
Oxycodone ER Tablet	(C-II)	10, 15, 20, 30, 40, 60, 80mg
Oxycodone Myristate Capsule	(C-II)	9, 14.5, 18, 27, 36mg
Oxymorphone ER Tablet	(C-II)	5, 7.5, 10, 15, 20, 30, 40mg
Tapentadol ER Tablet	(C-II)	50, 100, 150, 200, 250mg
Benzodiazepines	DEA Schedule	Available Strengths*
Alprazolam Tablet or Oral-Dissolving Tablet	(C-IV)	0.25, 0.5, 1 or 2 mg
Alprazolam ER Tablet		0.5, 1, 2, 3mg
Clonazepam Tablet or Oral-Dissolving Tablet	(C-IV)	0.125, 0.25, 0.5, 1, 2mg
Diazepam Tablet	(C-IV)	2, 5, 10 mg
Lorazepam Tablet	(C-IV)	0.5, 1, 2 mg
Muscle Relaxant	DEA 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	DEA Schedule	Available Strengths*
Selective Serotonin Reuptake Inhibitors		
Tricyclic Antidepressants		
Tramadol ER Capsule or Tablet	(C-IV)	100, 150, 200, 300mg
Tramadol Tablet	(C-IV)	50mg
Tramadol/Acetaminophen Tablet	(C-IV)	37.5/325mg
Dronabinol Gelcap	(C-III)	2.5, 5, 10 mg
Aspirin/Butalbital/Caffeine Capsule	(C-III)	325/50/40mg
*Strengths are not intended to be exhaustive.		

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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.)

ABMS: American Board of Medical Specialties. The ABMS is comprised of 24 medical specialty Member Boards.

AOA: American Osteopathic Association. The AOA serves as the professional family for more than 104,000 osteopathic physicians (DOs) and osteopathic medical students. The AOA promotes public health and encourages scientific research. In addition to serving as the primary certifying body for DOs, the AOA is the accrediting agency for all osteopathic medical schools and has federal authority to accredit hospitals and other health care facilities.

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.

MME: Morphine Milligram Equivalents

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.

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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.

APPENDICES

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.

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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>.

APPENDICES

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>

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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/TpToc.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		

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NALOXONE

T.C.A. 63-1-156 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

The chief medical officer of the department of health is authorized to implement a state-wide collaborative pharmacy practice agreement for opioid antagonist therapy with pharmacists. A collaborative practice is an agreement where a physician and a pharmacist enter into a contract allowing the pharmacist to dispense a medication in certain circumstances much like a standing order.

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).

Any person who in good faith seeks medical assistance for a person experiencing or believed to be experiencing a drug overdose shall not be arrested, charged, or prosecuted for a drug violation if the evidence for the arrest, charge, or prosecution of the drug violation resulted from seeking such medical assistance. Any person who is experiencing a drug overdose and who in good faith seeks medical assistance for or is the subject of a request for medical assistance shall not be arrested, charged, or prosecuted for a drug violation if the evidence for the arrest, charge, or prosecution of the drug violation resulted from seeking such medical assistance.

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This immunity from being arrested, charged, or prosecuted shall apply to the person experiencing a drug overdose only on the person's first such drug overdose. Also any such person experiencing their first over dose if seeking medical assistance shall be immune from:

1. Penalties for a violation of a permanent or temporary protective order or restraining order; or
2. Sanctions for a violation of a condition of pretrial release, condition of probation, or condition of parole based on a drug violation.

The act of providing first aid or other medical assistance to someone who is experiencing a drug overdose may be used as a mitigating factor in a criminal prosecution for which immunity, set out in subsection (b), is not provided.

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 or doses 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. The FDA has approved Intranasal Naloxone.

The chief medical officer of the department of health has implemented a state-wide collaborative pharmacy practice agreement for opioid antagonist therapy with pharmacists. The agreement can be found online at

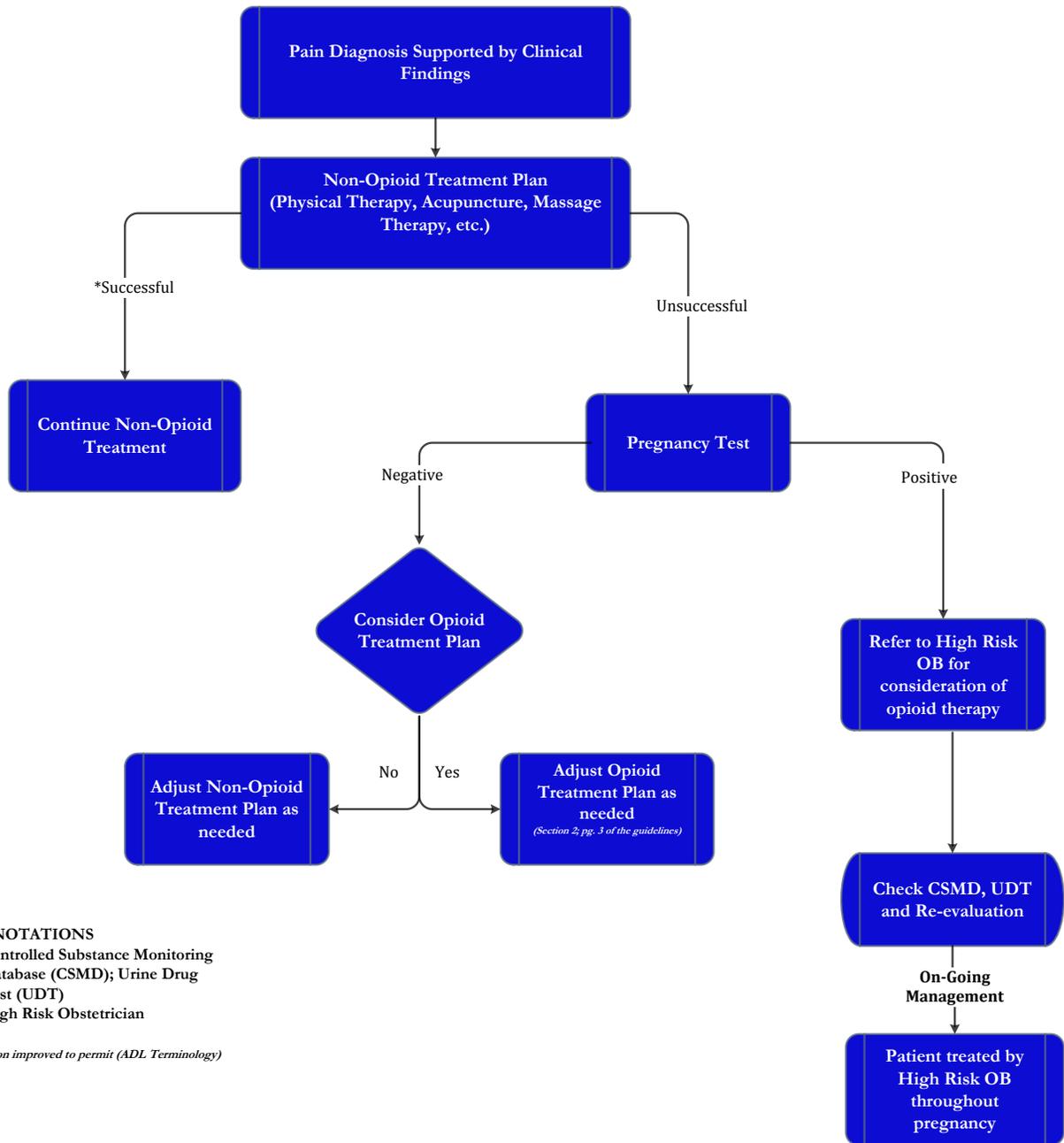
http://www.tn.gov/assets/entities/health/attachments/TDH_Naloxone_Collaborative_practice.pdf.

APPENDICES

CHRONIC PAIN GUIDELINE ALGORITHM WOMEN'S HEALTH

WOMEN'S HEALTH

Women of Childbearing Age With Reproductive Capability



ANNNOTATIONS

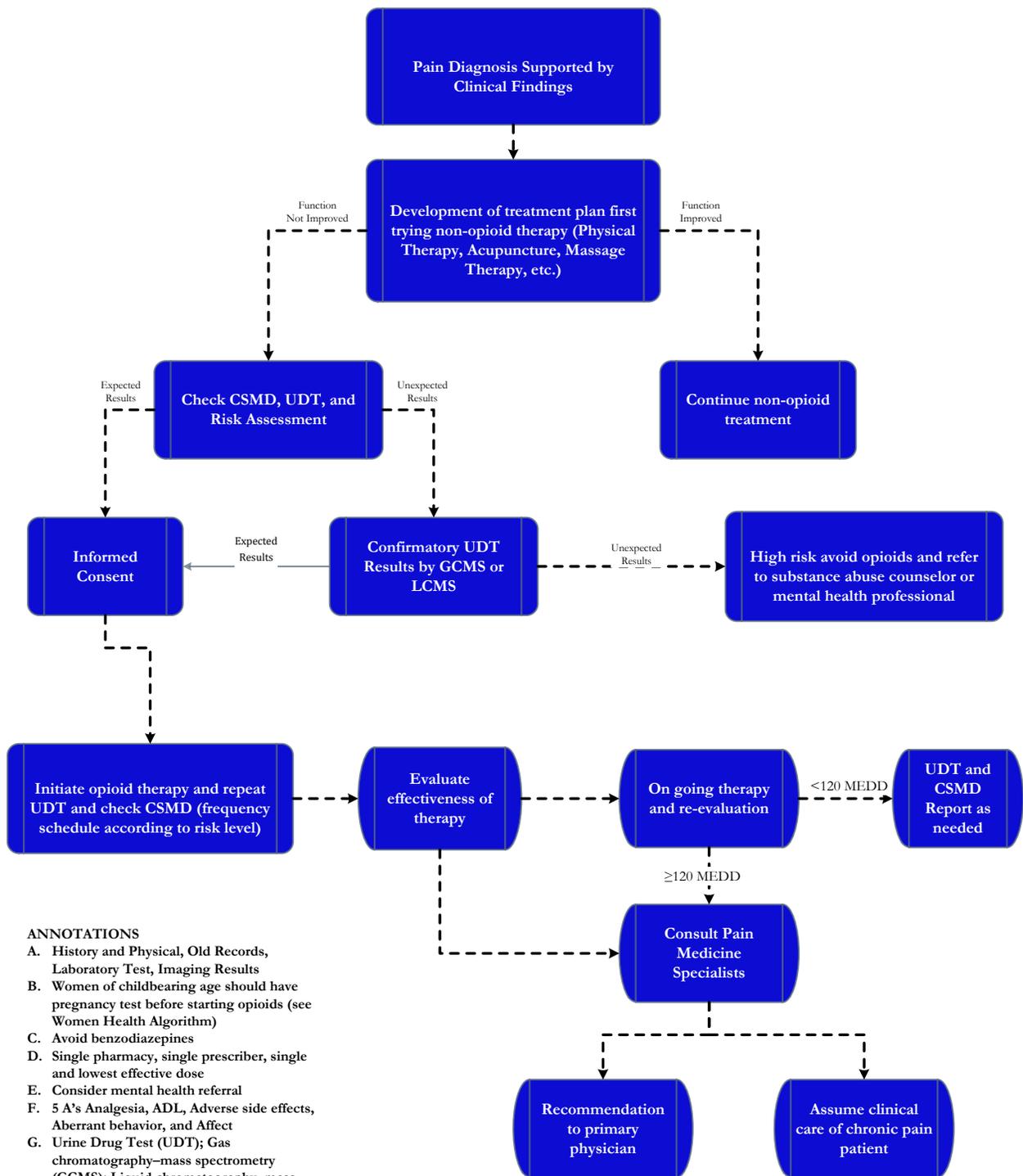
- A. Controlled Substance Monitoring Database (CSMD); Urine Drug Test (UDT)
- B. High Risk Obstetrician

**Function improved to permit (ADL Terminology)*

APPENDICES

CHRONIC PAIN GUIDELINE ALGORITHM OPIOID THERAPY

CANDIDATE FOR OPIOID THERAPY



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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 narcotics, 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 nonnarcotic 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-spasmodics 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 neuroadjuvants 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 aforementioned medication that can cause sedation should be used with care if they are initiated prior to or in conjunction with narcotics. 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 narcotics.

Often times 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 narcotic treatment is encouraged especially if the etiology of the chronic pain condition can be treated without narcotics 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 narcotics.

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

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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 primary care 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 narcotics.

Also for consideration for primary care 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

TENNESSEE EMERGENCY DEPARTMENT OPIOID PRESCRIBING GUIDELINES

1. One medical provider should provide all opioids to treat a patient's chronic pain.
2. The administration of intravenous and intramuscular opioids in the ED for the relief of acute exacerbations of chronic pain is discouraged.
3. Emergency medical providers should not provide replacement prescriptions for controlled substances that were lost, destroyed, or stolen.
4. Emergency medical providers should not provide replacement doses of methadone for patients in a methadone treatment program.
5. Long-acting or controlled – release opioids (such as OxyContin[®], fentanyl patches, and methadone) should not be prescribed from the ED. Exceptions may include terminal care and cancer-related pain.
6. ED providers are encouraged to review the Tennessee Controlled Substance Monitoring Database prior to writing prescriptions for controlled substances in the ED.
7. Physicians may send patient pain agreements to local EDs and work to include a plan for pain treatment in the ED.
8. EDs should coordinate the care of patients who frequently visit the ED using an ED care coordination program.
9. EDs should maintain a list of clinics that provide primary care for patients for all payer types.
10. EDs should perform screening, brief interventions and treatment referrals for patients with suspected prescription opiate abuse problems.
11. The administration of Demerol (Meperidine) in the ED is discouraged.
12. For exacerbations of chronic pain, the emergency medical provider may contact the patient's primary opioid prescriber. The emergency medical provider should only prescribe enough pills to last until the office of the patient's primary opioid prescriber opens.
13. Prescriptions for opioid pain medication from the ED for acute injuries, such as fractured bones, in most cases should not exceed seven days.
14. ED patients should be screened for substance abuse prior to prescribing opioid medication for acute pain.
15. The emergency physician is required by law to evaluate an ED patient who reports pain. The law allows the emergency physician to use their clinical judgement when treating pain and does not require the use of opioids.

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Tennessee Chronic Pain Guidelines

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