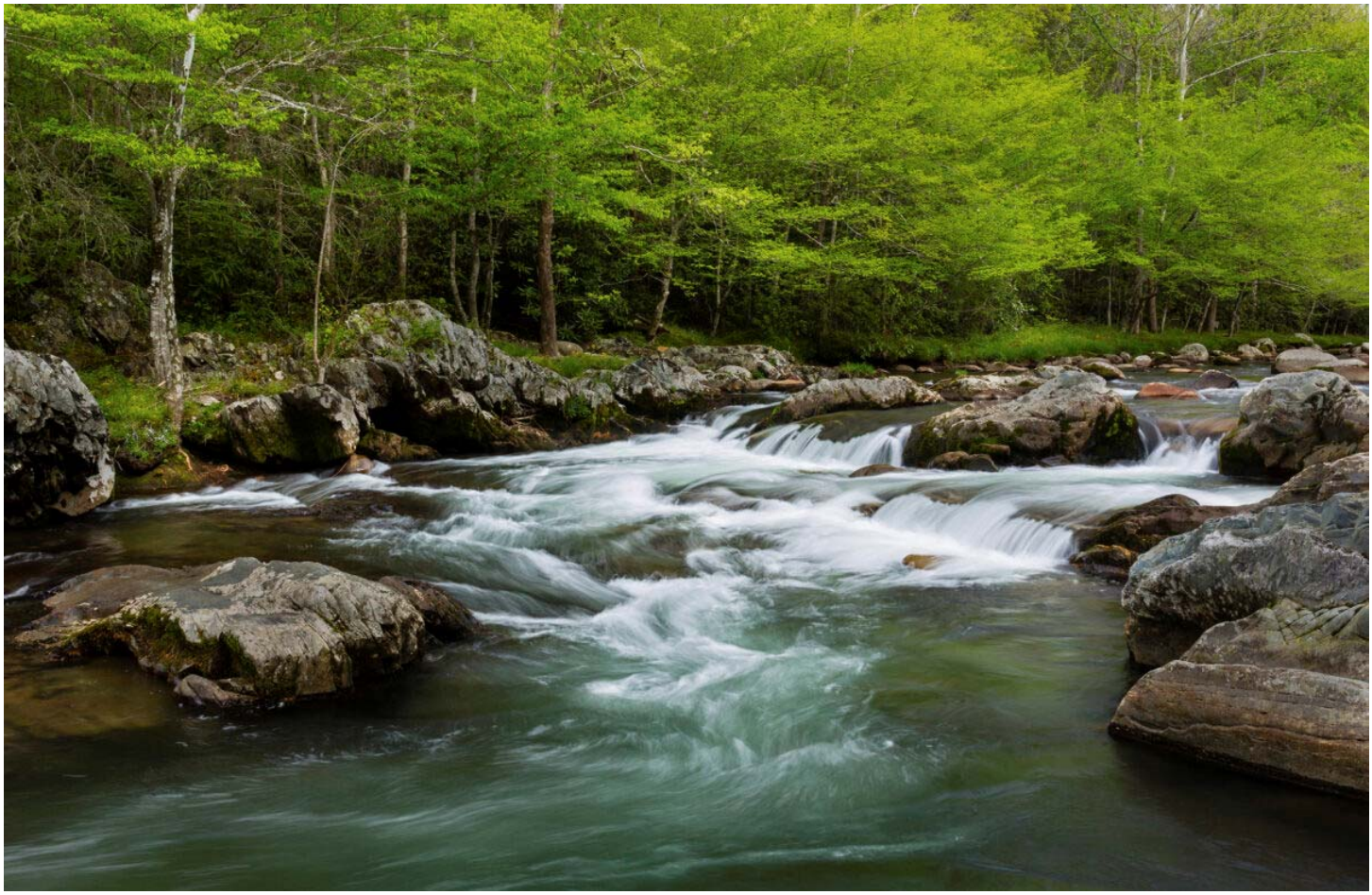

# Tennessee Nonresidential Buprenorphine Treatment Guidelines

***(Fall 2023 Update)***

TN Department of Mental Health & Substance Abuse Services

TN Department of Health

October 31st, 2023

Dear Friends and Colleagues,

We are pleased to share with you the Fall 2023 update of the Tennessee Nonresidential Buprenorphine Treatment Guidelines.

In response to Public Chapter 112 (2017), the inaugural Tennessee Nonresidential Buprenorphine Treatment Guidelines were created through a collaborative effort, engaging the expertise of the Tennessee Department of Mental Health and Substance Abuse Services (TDMHSAS) and the Tennessee Department of Health (TDH), clinical experts, policymakers, and esteemed stakeholders who provided invaluable guidance for the first publication of these guidelines.

The pressing issue of opioid-related overdoses remains a significant public health crisis among Tennesseans. While grappling with the complex landscape of substance use disorders affecting our friends, family, and neighbors, we express our gratitude to clinicians who extend hope by offering resources to aid their patients in embarking on the journey of recovery from the disease of addiction. Medications for opioid use disorder, such as products containing buprenorphine, are a valuable tool to help individuals engage and thrive in their recovery.

We extend our thanks for your support as we strive to ensure that these Guidelines reflect updated best practices. We acknowledge and appreciate your unwavering commitment to offering hope through evidence-based care within your respective communities across Tennessee. We strongly urge that any provider utilizing buprenorphine-containing products closely regard these Guidelines. Together, we can ensure that all Tennesseans receiving medications as part of their recovery from opioid use disorder receive the highest standard of care.

Sincerely,

Marie Williams, LCSW
Commissioner
TDMHSAS

Ralph Alvarado, MD, FACP
Commissioner
TDH

**The Tennessee Department of Mental Health and Substance Abuse Services (TDMHSAS) would like to extend special thanks to those who participated in the most recent Fall 2023 review meeting of these guidelines:**

Dr. Cooper Lloyd – TennCare
Tommy Farmer – Tennessee Bureau of Investigation
Patrick Powell – Tennessee Bureau of Investigation
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Chad Duncan – Tennessee Association of Mental Health Organizations
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Dr. Tracy Frame – Tennessee Pharmacist Association
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These Guidelines are intended for providers using buprenorphine-containing products for the treatment of an opioid use disorder in a nonresidential setting. These Guidelines are not meant to dictate medical decision making. They are Guidelines of generally accepted medical practice rather than absolutes. Providers still have flexibility to deal with exceptional cases. Occasional deviation from these Guidelines for appropriate medical reasons is to be expected and documented.

# Section I

# Prior to Treatment

## A. ASSESSMENT AND DIAGNOSIS

1. All prospective patients must present valid identification (e.g., driver's license, state-issued identification, etc.).

2. All prospective patients must be given an initial assessment to determine eligibility for treatment, to provide the basis for a treatment plan, and to establish a baseline measure for use in evaluating a patient's response to treatment. Accordingly, the initial assessment should be designed to achieve the following:
    a. Establish and document that the prospective patient meets the diagnosis of opioid use disorder (See APPENDIX B), including the duration, pattern, and severity of opioid misuse; the patient's level of tolerance; results of previous attempts to discontinue opioid use; past experience with agonist therapies; the nature and severity of previous episodes of withdrawal; and the time of last opioid use and current withdrawal status (See APPENDIX C as an example).
    b. Other clinicians may diagnose opioid use disorder, however, a diagnosis of opioid use disorder must be made by the prescriber prior to initiation of pharmacotherapy.
    c. Document the prospective patient's use of non-opioid substances, including alcohol, and incorporate how the use of those substances will be managed into the treatment plan.
    d. Evaluate the prospective patient's level of physical, psychological, and social functioning or impairment.
    e. Determine the prospective patient's readiness to participate in treatment.

3. The Controlled Substance Monitoring Database (CSMD) shall be checked prior to initiating buprenorphine treatment for all prospective patients. This check shall be documented.

4. The provider shall obtain an observed drug test for the prospective patient prior to initiating buprenorphine treatment and the results of this test shall be documented. In the event that obtaining an observed drug test is not possible at the first patient encounter, the provider shall document the reason for not being able to perform an observed drug test and the drug test shall be obtained at the second patient encounter.

## B. PATIENT SELECTION

1. Buprenorphine treatment may be appropriate for individuals meeting the following:
    a. Interested in opioid use disorder treatment.
    b. Agreeable to buprenorphine treatment after reviewing treatment options.
    c. Demonstrates a willingness to follow buprenorphine treatment contract/agreement.
    d. Demonstrates a willingness to adhere to the treatment plan.
    e. Demonstrates no contraindications to buprenorphine treatment.
    f. Demonstrates an understanding of the risks and benefits of buprenorphine treatment and other treatment options.

2. In cases where it is determined that buprenorphine treatment is not appropriate for, or agreeable to, the prospective patient, they shall be offered referral information regarding other forms of treatment.

3. Prospective patients who are pregnant may be given special consideration in the admissions process where applicable.

## C. CONSENT TO RELEASE INFORMATION

1. Where applicable, the provider shall obtain informed consent to release information in order to ensure continuity of care. When applicable, the treating provider will consult with the patient's other healthcare providers to ensure continuity of care and that the other providers are aware of the patient's current treatment plan.
    a. Required elements of an informed consent to release of information document include:
        i. Person or entity permitted to make disclosure;
        ii. Person or entity to which the disclosure will be made;
        iii. Patient name;
        iv. Purpose of disclosure;
        v. Nature of the information to be disclosed, including consent to report relevant information to the Controlled Substance Monitoring Database (CSMD), as required by law;
        vi. Signature of the patient;
        vii. Date on which the informed consent to release information document is signed;
        viii. Statement that the patient's informed consent to release information can be revoked at any time except to the extent that the program has already acted on it; and
        ix. Date, event, or condition upon which the patient's informed consent to release information will expire if not previously revoked.

## D. CONSENT TO TREATMENT

1. Except as otherwise authorized by law, no person shall be admitted for treatment without written consent from the patient and, if applicable, parent, guardian, or responsible party. When applicable, the treating provider will consult with the patient's other healthcare providers to ensure continuity of care and that the other providers are aware of the patient's current treatment plan. A documented, voluntary, written, program-specific informed consent to treatment from each patient at admission should include:
    a. Information about all treatment procedures, services, and other policies and regulations throughout the course of treatment, including clinic charges in the form of a fee agreement signed by the patient.
        i. This fee agreement should include an explanation of the financial aspects of treatment and the consequences of nonpayment of required fees, including the procedures for the patient (or patient's legal representative) in the event they are unable to pay for treatment.
    b. Consent to the individualized, prescribed therapy before dosing begins, including information about potential interactions with and adverse reactions to other substances, including those reactions that might result from interactions and adverse reactions to alcohol, other prescribed or over-the-counter pharmacological agents, other medical procedures, and food.
    c. Information regarding the possible risks of therapy and potential side effects, including potentially life-threatening drug interactions. See Subsection F below regarding requirements for benzodiazepine co-prescribing.
    d. Information to each patient that the optimal goal of treatment is the following:
        i. Suppression of opioid withdrawal;
        ii. Blocking the effects of illicit opioids;

iii. Reducing opioid craving and stopping or reducing the use of illicit opioids;
iv. Patient engagement in recovery-oriented activities, such as counseling

e. Acknowledgement that the patient has been informed of the provider's rules regarding patient conduct and responsibilities, including policies regarding diversion mitigation and non-adherence to treatment plan.
f. Acknowledgement that the patient has been informed of his/her rights.
g. Information that at regular intervals, in full consultation with the patient, the program should discuss the patient's present level of functioning, course of treatment, and future goals.
h. Information that the patient may choose to withdraw from or be maintained on the medication as he/she desires unless medically contraindicated.
i. Acknowledgement of informed consent between provider and patient regarding the risk of an infant developing neonatal abstinence syndrome (NAS) while the mother is taking buprenorphine. This informed consent shall be signed by the patient and provider and documented in the patient's medical record. The provider shall discuss the risk of developing NAS with the patient prior to signing. See Subsection E below regarding the required elements for consent to treatment regarding pregnancy and NAS prevention.
j. Acknowledgement that women of child-bearing age and ability will provide a serum or observed urine pregnancy test upon initial visit.

## E. REQUIRED ELEMENTS FOR CONSENT TO TREATMENT REGARDING PREGNANCY AND NAS PREVENTION

1. The provider should discuss a method to prevent unintended pregnancy with every woman of childbearing age and ability before buprenorphine is initiated.

2. The provider should obtain a signature indicating that any woman who wishes to become or is at risk of becoming pregnant has been educated about the risks of opioid use, as well as, the risks and benefits of buprenorphine treatment during her pregnancy.

3. Women of child-bearing age and ability shall provide a serum or observed urine pregnancy test to determine pregnancy prior to receiving treatment initiation.

4. Women of child-bearing age and ability should be tested monthly for pregnancy and must be asked about the possibility of pregnancy at each visit and information from such an inquiry shall be documented in the patient's chart. For women who wish to avoid unintended pregnancy, the use of voluntary, reversible, long-acting contraception (VRLAC) shall be discussed, and if after discussion, VRLAC is desired by the patient, the VRLAC service will be provided, or referral to appropriate VRLAC provider made.

5. More information on NAS for MAT providers can be found on the Tennessee Department of Mental Health and Substance Abuse Services' website by clicking here or visiting:
https://www.tn.gov/content/dam/tn/tenncare/documents/NASEducationMaterialForMATProviders.pdf

## F. REQUIREMENTS FOR BENZODIAZEPINE CO-PRESCRIBING

1. Benzodiazepines should only be prescribed to a patient after careful evaluation while utilizing caution and good judgment. Benzodiazepines may be prescribed to a patient on buprenorphine or a buprenorphine and naloxone combination under the following conditions:
    a. Patients who present with a longstanding prescription for benzodiazepines for a legitimate medical condition from another prescriber may be initiated on buprenorphine-containing products. Contact should be initiated with the prescriber of the benzodiazepine to coordinate care and clear documentation should be recorded in the patient's medical record.
    b. A provider may assume management of a patient's benzodiazepine prescribing from another provider if the patient is willing to initiate a program of tapering.
    c. If a patient presents with a dual diagnosis of opioid use disorder and a clear history of benzodiazepine use disorder, the duration and extent of the abuse should be clearly documented in the medical record. A provider may prescribe a long-acting benzodiazepine, such as clonazepam or its equivalent, under the following conditions:
        i. A patient may continue benzodiazepine therapy as medically indicated as long as there is an ongoing effort to taper the patient to the lowest effective dose in order to prevent benzodiazepine withdrawal syndrome and clear documentation of this effort is made in the patient's medical record.
            1) Prescribing more than two (2) milligrams of clonazepam or its equivalent daily is considered "high dose therapy".
            2) Patients receiving high dose therapy should have justification for the dosing clearly documented in the patient's medical record.
            3) Patients receiving high dose therapy should be tapered as rapidly as possible to two (2) milligrams or less of clonazepam or its equivalent daily, and if the taper is unsuccessful, the reason(s) shall be clearly documented in the patient's medical record.
            4) Patients receiving high dose therapy for a period of longer than six (6) weeks shall be managed by a physician who is board certified in addiction medicine or who is board certified or fellowship trained in addiction psychiatry, or by a prescriber who has obtained a formal consult from a physician who is board certified in addiction medicine or who is board certified or fellowship trained in addiction psychiatry. The formal consult shall be clearly documented in the patient's medical record.

## G. IMPACT OF FEDERAL ACTION REGARDING THE DATA 2000 WAIVER AND THE MATE ACT

1. The Consolidated Appropriations Act of 2023 (CAA) includes the Mainstreaming Addiction Treatment Act, which effectively ended the requirement for a DATA 2000 waiver to be able to prescribe buprenorphine for OUD outside of a Narcotic Treatment Program. For additional information on the effect of the removal of the DATA waiver and its impact on prescribing buprenorphine in Tennessee, please visit the Tennessee Department of Mental Health and Substance Abuse Services public guidance by clicking here or visiting: https://www.tn.gov/content/dam/tn/mentalhealth/documents/Public_Guidance_DATA_Waiver_Removal_2.27.23.pdf

2. The CAA also includes the Medication Access and Training Expansion (MATE) Act, which requires physicians, including residents and fellows, and other healthcare professionals who prescribe controlled substances, to complete a one-time-only eight hours of training on the treatment and management of patients with opioid or other substance use disorders.
    a. For more information about MATE Training requirements, please visit the SAMHSA website by clicking here or visiting: https://www.samhsa.gov/medications-substance-use-disorders/training-requirements-mate-act-resources
    b. Providers are encouraged to complete additional training in treating OUD, including the use of buprenorphine, especially if needed to comply with the MATE Act. Multiple organizations offer additional training that complies with the MATE Act, including the Provider Clinical Support System, the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, and the American Psychiatric Association.

# Section II

# Initiating Treatment

## A. INDICATIONS FOR BUPRENORPHINE WITHOUT NALOXONE

1. Buprenorphine with naloxone product formulations shall be considered for all patients; exceptions are only allowable for those who are pregnant, nursing, or have a documented adverse reaction or hypersensitivity to naloxone pursuant to TCA 53-11-311.
    a. An adverse reaction or hypersensitivity to a buprenorphine with naloxone product is rare. If a provider is prescribing buprenorphine without naloxone, due to adverse reaction or hypersensitivity, to more than 5% of their patients receiving a buprenorphine-containing product, the provider should reevaluate his/her practice habits and may be subject to review by the Boards of Medical Examiners or Osteopathic Examination. All patients receiving buprenorphine without naloxone shall have proper justification documented in the patient's medical record.
    b. Oral buprenorphine products that contain naloxone are generally considered safe and effective to be used in pregnant patients and are not known to convey any additional risk to the mother or child compared to products that contain buprenorphine alone. The provider shall document justification for using products containing buprenorphine without naloxone in pregnant patients.
    c. The risks associated with buprenorphine, either with or without naloxone, are similar in nursing mothers, and the prescriber should provide clear documentation for justifying the use of buprenorphine without naloxone to a nursing mother for more than 3 months.
    d. If the prescriber of buprenorphine without naloxone is treating a patient who is pregnant or nursing and is not the patient's obstetrical or gynecological provider, the prescriber shall coordinate care with the patient's obstetrical or gynecological provider to the extent possible to ensure appropriate treatment.

## B. SPECIAL POPULATIONS

1. These Guidelines acknowledge the diverse range of individuals seeking medication for opioid use disorder and recognize the importance of a tailored approach to meet the unique needs of special populations. The following is a summary providing an overview of the extended information on this topic found in APPENDIX E 1-8.

2. Adolescent treatment
    a. Caution is advised in prematurely diagnosing or labeling adolescents with substance use issues as this can potentially cause more harm than good. The clinician is encouraged to ensure adequate duration and criteria have been met prior to diagnosis of an adolescent with opioid use disorder.
    b. It is encouraged to advocate for the involvement of family in an adolescent's treatment as the family can play a role in understanding and addressing problematic behavior in the adolescent population and moving toward positive change in the adolescent's environment.
    c. An effort to refer to treatment programs specializing in the care of the adolescent patient is advisable and caution should be used when considering adult programs for the adolescent individual. The ASAM National Practice Guidelines for the Treatment of Opioid Use Disorder also caution against the utilization of group therapy in this population due to the risk for substance use behaviors to be reaffirmed by the other adolescent group members.
    d. Buprenorphine is FDA-approved in individuals 16 years and older, but current recommendations are primarily based on research with adults. Clinicians are encouraged by the ASAM National

Practice Guidelines for the Treatment of Opioid Use Disorder to consider all options for treatment, including medication, in the adolescent population, and while psychosocial interventions are acknowledged to be important, the inability to access them should not preclude the timely treatment of opioid use disorder in the adolescent patient when deemed appropriate by the clinician.

3. Buprenorphine and pain
    a. Chronic pain and substance use disorders share significant impacts on physical, social, emotional, and economic well-being. A holistic approach addressing both conditions is advisable to maximize positive outcomes.
    b. The accurate diagnosis of pain etiology is vital to appropriate treatment and nonpharmacological treatments, such as physical therapy, should be considered.
    c. When pharmacological treatment is warranted, non-narcotic options like acetaminophen and NSAIDs should be prioritized.
    d. Adjunctive medications and adjustment of the buprenorphine administration may be an effective strategy for managing pain in patients with opioid use disorder. Temporarily increasing the dose and/or frequency of the administration of buprenorphine may be warranted.
    e. The prescriber shall be aware of TCA §53-11-311(a) that states buprenorphine-containing products may only be prescribed for a use recognized by the federal Food and Drug Administration, unless that person is being treated for opioid use disorder.
    f. The ASAM National Practice Guidelines for the Treatment of Opioid Use Disorder suggest that adding short-acting full agonist opioids to regular buprenorphine regimens for severe acute pain treatment, in a supervised setting, may be appropriate when the options above do not adequately relieve pain. The provider shall fully document why non-narcotic pain relief options were not appropriate or did not relieve pain before considering opioids for pain.

4. Buprenorphine and surgery
    a. Discontinuation of buprenorphine before surgery or elective cesarean section is not necessary.
    b. Research has shown that adding full-opioid agonists can effectively treat pain in surgical patients who are administered buprenorphine as part of their opioid use disorder treatment when non-opioid agonist options are not adequate coverage to relieve surgical pain.
    c. It is recommended that the surgical team collaborate with the clinician prescribing buprenorphine if deciding to reduce or discontinue buprenorphine prior to a planned surgery.
    d. If the dose is temporarily reduced or stopped before surgery, patients may resume their pre-surgery dose within 1-3 days, or for longer periods, a gradual return to the prior maintenance dose may be necessary.
    e. In cases of acute pain, adjusting or splitting the buprenorphine dose may effectively manage the pain as described in the ‘Buprenorphine and pain’ section above.

5. Patients who are pregnant or breastfeeding
    a. According to the ASAM National Practice Guidelines for the Treatment of Opioid Use Disorder, pregnant women dependent on opioids should receive methadone or buprenorphine treatment instead of withdrawal management or counseling alone. Buprenorphine is recommended when the benefits outweigh the risks.
    b. The use of buprenorphine products containing naloxone are considered safe and effective in patients who are pregnant or nursing. The choice between the combination or mono-product of buprenorphine during pregnancy, postpartum, or nursing is a decision to be made collaboratively

between the clinician and patient, considering risks and benefits, and shall be documented in the patient's medical record.

c. Monthly drug screens, or more frequently if clinically indicated, should be conducted during pregnancy to monitor adherence to treatment and illicit substance use. Coordination of care between the clinician providing buprenorphine and the obstetrician should be documented in the patient's chart.
d. Providers who decline to treat individuals who are pregnant should make every effort to coordinate a referral and warm hand-off to appropriate treatment resources.

6. Co-occurring psychiatric disorders
    a. Prescribing medications for patients with opioid use disorder requires careful consideration of psychiatric diagnoses, medical co-morbidities, overall health, and substance interactions.
    b. Caution is needed with medications that depress the central nervous system or respiratory drive, such as benzodiazepines.
    c. Substance use such as alcohol, cannabis, stimulants, benzodiazepines, or sedative-hypnotics should not be the sole reason to withhold necessary treatment for the individual's symptoms of opioid use disorder.

7. Patients with significant medical comorbidities
    a. Patients with unstable or severe cardiovascular disease (e.g., advanced heart failure, angina) or severe lung disease (e.g., COPD) may struggle with buprenorphine due to the physiologic stress.
    b. Close monitoring is crucial for these patients throughout the substance use disorder treatment.
    c. Consider inpatient induction or if methadone treatment may be a better option for the individual.
    d. Patients with conditions causing increased somnolence (e.g., narcolepsy or sleep apnea) need close monitoring in early treatment to evaluate the effects of buprenorphine.

8. Buprenorphine and liver disease (Including Hepatitis C)
    a. Treatment involving buprenorphine may not be advisable in patients with transaminases (AST or ALT) elevated greater than five times the upper limit of normal.
    b. However, if a clinician decides that the benefits of treatment outweigh the risk in a patient with significantly elevated AST or ALT the ASAM National Practice Guidelines for the Treatment of Opioid Use Disorder recommend considering regular monitoring of liver enzymes and note studies have not concluded a significant risk for further elevation in the first six months of treatment.
    c. Evidence does not suggest an advantage of methadone over buprenorphine in the patient with elevated liver enzymes and therefore the decision should be made based on the individual needs of the patient and best clinical judgment of the buprenorphine prescriber.
    d. Patients with hepatitis C may require buprenorphine during hepatitis C treatment and studies show positive outcomes for patients with hepatitis C with daily, directly observed, buprenorphine treatment.

9. Buprenorphine and HIV
    a. Medication treatment for opioid use disorder, such as with buprenorphine, reduces HIV risk behaviors, such as sharing needles, among individuals with HIV.
    b. Adherence to buprenorphine treatment is linked to better viral suppression and higher CD4 counts in individuals with HIV.

c. Buprenorphine is metabolized to nor-buprenorphine primarily through CYP3A4. Medications that impact the CYP3A4 pathway may require adjustments to one or both medications. HIV protease inhibitors inhibit CYP3A4.
d. It is advisable that the patient's clinician who oversees the prescribing of their HIV protease inhibitor medication be collaborated with to be made aware of the buprenorphine medication being prescribed and the treatment plan.

## C. SELECTING A THERAPY

1. When to start buprenorphine, whether with or without naloxone.
    a. Patient will likely feel he/she is in the early stages of withdrawal. The prescriber may consider suggesting that the patient return during opioid withdrawal to confirm the diagnosis and reduce the risk of precipitated withdrawal.
    b. Dosage should be titrated based on an opioid withdrawal assessment, such as COWS score (See APPENDIX C).

2. Opioid withdrawal management alone, without ongoing treatment for opioid use disorder, is not a treatment method and is insufficient, and therefore not recommended. Patient dependence on short-acting or long-acting opioids should be considered in determining if detoxification will involve direct induction or buprenorphine tapering.
    a. Patients converting from methadone to buprenorphine may require referral to, or consultation with, a physician board-certified in addiction medicine.

3. For individuals for whom long-acting buprenorphine injections are clinically indicated:
    a. Public Chapter No. 674 of 2018 amends T.C.A. § 53-11-311 (See APPENDIX H) to clarify conditions in which injectable buprenorphine mono products can be used.
    b. Providers should review the product's prescribing information for important information including, but not limited to, the REMS program, dosing information, and contraindications.

## D. GENERAL DOSING GUIDELINES

1. The following dosing recommendations are adapted from the "ASAM National Practice Guidelines for the Treatment of Opioid Use Disorder."

2. Setting
    a. Initiation in the home or office environment is both considered safe and effective.
    b. For home-based inductions the patient's ability to recognize when they are experiencing mild to moderate withdrawal based on objective, physical symptoms (e.g., pupil dilation, goose bumps, and gastrointestinal discomfort) should be weighed when deciding if home induction is appropriate.
    c. For office-based induction a COWS score (See APPENDIX C) of 11 or higher is recommended to increase the likelihood of a comfortable initiation onto buprenorphine.

3. Dose
    a. Per the ASAM National Practice Guidelines for the Treatment of Opioid Use Disorder, a lower initial dose of buprenorphine can help reduce the risk of precipitated withdrawal. An initial dose of 2-4 mg followed by 60-90 minutes of observation to assess for precipitated withdrawal is recommended.
    b. If evidence of precipitated withdrawal is not apparent, the COWS score can be a helpful tool to evaluate the effectiveness of subsequent doses increased by increments of 2-8 mg to address continued withdrawal symptoms and/or cravings.
    c. Taking into consideration the changing landscape of high-potency synthetic opioids, the ASAM Practice Guidelines for the Treatment of Opioid Use Disorder may not apply to all clinicians and patients. In some limited situations, a high-dose buprenorphine initiation strategy may be appropriate. The prescriber shall document in the medical record the justification for utilizing higher doses during treatment initiation. For additional information on emerging recommendations from ASAM addressing these trends, see "ASAM Clinical Considerations: Buprenorphine Treatment of Opioid Use Disorder for Individuals Using High-potency Synthetic Opioids."
    d. Clinicians are advised to prioritize the administration of the minimum effective dose to mitigate the potential for diversion and minimize adverse side effects such as insomnia, anxiety, constipation, and mood disturbances. It is essential for each clinician to employ sound clinical judgment tailored to the unique needs and circumstances of each individual patient, rather than adhering rigidly to a standardized initiation dose for all patients.

4. Management of Precipitated Withdrawal
    a. Of note, sizable prospective cohort studies of emergency department patients with exposure to high potency synthetic opioids provided initial doses of 8 mg or greater of buprenorphine have rates of precipitated opioid withdrawal less than one percent. This is a population with considerable variability in ability to report accurately the time of last opioid agonist use and should be reassuring as to the rate of occurrence for precipitated withdrawal.
    b. It is also important to consider that discomfort after the first dose of buprenorphine may occur due to a variety of factors, such as ongoing opioid withdrawal that is progressing in severity as the patient has a greater length of time from last use of a full opioid agonist, withdrawal from other substances, adverse effects to the medication such as nausea, or precipitated withdrawal.
    c. If opioid withdrawal is precipitated from the initial dose, the most effective treatment is additional buprenorphine to maximize the mu opioid receptor activity.
    d. In addition to more buprenorphine, alpha-2 agonists such as clonidine, and other comfort medications or devices may be beneficial for precipitated withdrawal occurring during buprenorphine administration.

5. Practitioner knowledge regarding various buprenorphine formulations
    a. The provider should be knowledgeable of appropriate dosing considerations when switching between various formulations of buprenorphine (e.g., oral dosing to long-acting injectable formulations).
    b. A detailed chart of bioequivalence among various formulations of buprenorphine can be found in the ASAM National Practice Guideline for the Treatment of Opioid Use Disorder. It is recommended to utilize a dose equivalent when transitioning patients between products, but individual adjustments may be needed based on monitoring of patient's symptoms.

6. Education on correct administration
    a. Providing education on correct administration can help patients benefit from the lowest effective dose of medication and assist in the avoidance of adverse side effects.
    b. The Methods of Administration section of the FDA package insert will give detailed instructions about each formulation of buprenorphine and is available on the FDA website. In general, tablets or film should not be cut, chewed, or swallowed. Patients should be advised not to eat or drink anything until the tablet or film has completely dissolved.

7. Documentation of higher doses (See APPENDIX H)
    a. For doses greater than 16 mg a day for more than 30 consecutive days, the prescriber should document in the medical record why the higher dosage amount is required.
    b. For doses greater than 20mg a day for more than 30 consecutive days, the prescriber should consult with or refer to an addiction specialist as described by the Board of Medical Examiners and the Board of Osteopathic Examination.
        i. If the above-described consultation or referral cannot be made, the prescriber should document the reason in the patient's medical record.

8. APRN and PA Considerations
    a. Dosing and formulation limits
        i. For nurse practitioners and physician assistants, TCA § 53-11-311 (See APPENDIX H) contains prescribing limits on the formulation (combination buprenorphine and naloxone products), maximum dose (16 mg per day), and number of patients treated at a time.
    b. Approved clinical settings
        i. Nurse practitioners and physician assistants are currently limited in the clinical practice settings where they are permitted to prescribe buprenorphine. Community mental health centers, federally qualified health centers, and nonresidential office-based opiate treatment facilities are the only permissible settings allowed in TCA § 53-11-311 (See APPENDIX H).

## E. PATIENT MANAGEMENT

1. Assessment of a patient
    a. An assessment of a patient shall include documentation of a physical exam by an appropriate provider upon admission, but no later than seven days after initiating buprenorphine treatment (See APPENDIX D). The physical exam shall be completed or reviewed by the prescribing clinician. The physical exam shall include a screening for concomitant medical conditions, including psychiatric disorders, and shall include documentation of initial laboratory tests performed as indicated. If no laboratory tests are completed upon the initial assessment prior to initiating treatment, it should be completed with the physical exam, no later than seven days after initiating buprenorphine treatment.
    b. Patients shall receive communicable disease screening upon admission. If a practice does not have the proper resources to administer a disease screening, patients should be sent to the local health department (This is a mandatory referral).
        i. If risk factors are present, disease screening should, at a minimum, screen for the following: Tuberculosis, Hepatitis B and C, HIV, and STDs.
        ii. Hepatitis A and B vaccines should be offered, as appropriate.
    c. All providers treating patients with substance use disorders shall ensure the clinical treatment and the treatment environment are trauma-informed. SAMHSA encourages organizations and clinicians to

universally implement trauma-informed care into their practices of individuals with substance use disorders and provides guidance for doing so at both the organizational and patient care level in their guidance document "SAMHSA's Concept of Trauma and the Trauma-Informed Approach." Clinicians are encouraged to reference this document for additional information on best practices for implementing trauma-informed care for all patients, not just those who disclose a history of significant trauma.

d. Clinicians are encouraged to evaluate if the need for trauma-specific interventions is needed using an appropriate screening tool such as obtaining an Adverse Childhood Experiences (ACEs) score within 30 days of initiation of buprenorphine (See APPENDIX F). For those clinicians prescribing buprenorphine without a qualified counseling provider within their practice who can provide trauma-targeted treatment modalities (e.g., CBT-TF, EMDR, DBT), clinicians are encouraged to be aware of local referral sources for trauma-focused treatment.
e. Completion of all assessments should not delay or preclude initiation of buprenorphine treatment. If assessments are not completed before treatment initiation, they should be completed at the following appointment, no later than 7 days after the initiation of buprenorphine.

2. Treatment Planning
   a. The provider, with other members of the treatment team, as appropriate, shall develop a mutually agreeable individualized treatment plan for each patient within 30 days of treatment initiation and be reviewed and updated with the patient at least every 6 months, thereafter.
   b. The patient's treatment plan shall use goals and objectives using the S.M.A.R.T. goal framework. The S.M.A.R.T. goal framework aids in creating personal and professional goals for service recipients. These goals are intended to be utilized to track the achievement of short and long-term goals and treatment progress. The S.M.A.R.T. goal framework means that goals shall be Specific, Measurable, Achievable, Relevant, and Time-sensitive.
   c. The treatment plan shall incorporate goals and objectives for any significant findings from the initial or ongoing patient assessments that would impact the service recipient's success in treatment and recovery, such as biopsychosocial problems, mental or physical health needs, housing, or other environmental concerns.

3. Counseling
   a. See APPENDIX A for the definitions of a qualified provider.
   b. Counseling is essential, and a qualified provider should determine the best counseling option for each individual patient based upon the patient's history and assessments, agreeance of the patient, and the goals of the patient's individualized treatment plan (See APPENDIX G).
   c. The provider shall be responsible for determining and documenting that each patient is receiving counseling and that each patient is progressing towards meeting the goals listed in their individualized treatment plan. The provider should review and modify the individualized treatment plan if it is determined that a patient is not following through with counseling referrals.
   d. While counseling and social support such as 12-step programs should be encouraged and resources offered, a patient's decision to initially decline counseling, or the absence of available counseling, should not preclude or delay pharmacotherapy, with appropriate medication management. Motivational interviewing should be used to encourage patients to engage in counseling services appropriate for

addressing individual needs. The provider shall document all attempts to engage the patient in counseling.

e. If the provider utilizes their own staff to provide counseling, staff should be sufficient in number and in training to:
    i. Allow for adequate:
        1) Psychosocial assessment;
        2) Treatment planning; and
        3) Individualized counseling.
    ii. Allow for regularly scheduled counseling sessions (See Subsection A of Section III); and
    iii. Allow patients access to their counselor if more frequent contact is merited by need or is requested by the patient.
f. For providers referring patients for counseling, the provider should provide the patient, with the patient's consent, a list of available licensed treatment providers in the community and assist the patient in receiving these services by offering to make appointments on the patient's behalf and by coordinating care.

4. Naloxone
    a. All patients being treated for, or with a history of, opioid use disorder shall receive naloxone, or a prescription for naloxone, to prevent opioid overdose.
    b. All patients will also receive naloxone training on administration, use and signs or symptoms of an overdose.
    c. Naloxone may be administered to pregnant patients in the case of opioid overdose

# Section III

# Ongoing Treatment

## A. MAINTENANCE TREATMENT

Maintenance treatment consists of 3 phases: 1) induction, 2) stabilization, and 3) maintenance.

1. A patient in the induction or stabilization phases of treatment should:
    a. Have weekly scheduled office visits;
    b. Receive appropriate counseling sessions at least twice a month;
    c. Be subject to one (1) observed drug screen at least weekly; and
    d. Receive case management services weekly.

2. A patient in the maintenance phase of treatment for less than one (1) year should:
    a. Have a scheduled office visit at least every two (2) to four (4) weeks;
    b. Receive counseling sessions at least monthly;
    c. Be subject to a random observed drug screen at least twelve (12) times annually; and
    d. Receive case management services at least monthly.

3. A patient in the maintenance phase of treatment for one (1) year or more should:
    a. Have a scheduled office visit at least every two (2) months;
    b. Receive counseling sessions at least monthly;
    c. Be subject to a random observed drug screen at least eight (8) times annually; and
    d. Receive case management services at least monthly.

4. The prescriber should document the patient's current phase of treatment in the patient's medical record. Changes in the patient's phase of treatment should also be documented in the patient's medical record.

## B. MONITORING PARAMETERS

1. Providers or their designated healthcare practitioner extenders, should check the CSMD at each patient visit and documentation of each such check should be made in each patient's medical record. Providers should utilize the CSMD to confirm medication adherence and monitor for the use of other controlled substances.

2. When checking the CSMD, providers should be cognizant of checking a patient's prescription history in neighboring states. In addition, providers are required to report buprenorphine dispensing to the CSMD, providing they have obtained patient consent.

3. Laboratory Monitoring
    a. Drug testing procedures should follow the American Society of Addiction Medicine's "Appropriate Use of Drug Testing in Clinical Addiction Medicine."
        i. See https://www.asam.org/resources/guidelines-and-consensus-documents/drug-testing
    b. Monthly serum or observed urine pregnancy test for women of childbearing age and ability.

## C. TAPERING TREATMENT

1. A provider shall weigh the risk of relapse with the benefit of tapering off of buprenorphine.

2. Similar to other disease states, tapering from the treatment medication shall only occur when clinically appropriate and in agreement with the patient. Tapering schedules and durations are patient-specific.
    a. Providers shall initiate and lead a discussion regarding patient readiness to taper down or taper off treatment medications employed in the patient's treatment with each patient no later than one (1) year after initiating treatment and then every six (6) months thereafter or at any time upon the patient's request.

## D. RELAPSE INDICATORS

1. Patients may be in danger of relapse if any of the following occur:
    a. Patient is not adherent to buprenorphine as prescribed.
    b. Patient is still living in or around the "people, situations, places, and things" that were previously linked to poor behavior, specifically illicit drug use, and can sometimes include home environment.
    c. Patient is not engaged in a "recovery program" (e.g., as may be done through 12-step program, etc.), a sufficient support system, and/or is not using his/her recovery program and/or support system adequately.
    d. Patient displays difficulties managing stress.
    e. Patient inadequately manages and/or displays symptoms of an undiagnosed co-occurring mental disorder.
    f. Patient displays symptoms of untreated behavioral addictions (e.g., codependency, sex, gambling).
    g. Patient displays inadequate development of coping skills for triggers and cravings.
    h. Patient displays a need for more intensive ancillary treatment (e.g., intensive outpatient counseling or treatment).
    i. Patient displays insufficient motivation for change or is not suitable for treatment with buprenorphine for a variety of reasons (This should be essentially a diagnosis of exclusion).
    j. The treating provider receives information from other healthcare sources (i.e., other physicians, pharmacists, etc.) regarding a patient's non-adherence with treatment.

## E. PHARMACISTS

1. Pharmacists are crucial for ensuring safe and appropriate access to buprenorphine. Pharmacists and staff should be knowledgeable of buprenorphine in the treatment of OUD, using resources made available by APhA, ASHP, AAPP, or SAMHSA, for example.

2. Non-compounding and non-veterinarian community pharmacies that primarily dispense prescriptions for human patients, including other controlled substances, should make reasonable efforts to keep buprenorphine-containing products in stock.

3. Pharmacists shall attempt to collaborate with prescribers to resolve any concerns, such as distance from the provider, dose, or combination prescribing, before refusing to fill the prescription. For example, telehealth is increasing in prevalence, is a viable option for some patients, and may explain why some patients may be a considerable distance from their providers.

4. Pharmacists should consider collaborating with the provider to gain insight into the patient's treatment plan in an effort to assist the patient in meeting their therapeutic goals. Some patients may not feel comfortable sharing the treatment plan in its entirety due to potentially sensitive information, therefore having the treatment plan should not preclude access to medication. Collaboration between the pharmacist, patient, and provider should be attempted to determine what can and will be shared to allow the pharmacist to actively participate and facilitate the patient's recovery and progress toward their therapeutic goals.

5. Pharmacists should also offer other healthcare services, such as vaccinations, disease screening, and providing resources, as appropriate.

# Section IV

# Appendices

## APPENDIX A – Definitions

*Source: Adapted from TDMHSAS Rule Chapter 0940-05-35: Minimum Program Requirements for Nonresidential Office-Based Opiate Treatment Facilities.*

1. "Buprenorphine" means a FDA-approved pharmaceutical product that contains buprenorphine indicated for the treatment of opioid use disorder.

2. "Case Management/Care Coordination" means a collaborative process of assessment, planning, facilitation, care coordination, evaluation, and advocacy for options and services to meet an individual's and family's comprehensive health needs through communication and available resources to promote quality, cost-effective outcomes.

3. "Controlled Substance Monitoring Database" or "CSMD" means a program administered by the Tennessee Department of Health to monitor the prescribing and dispensing of Schedule II, III, IV and V controlled substances as set forth by T.C.A. Title 53, Chapter 10, Part 3.

4. "Counseling" or "Counseling Session" means a face-to-face individual therapeutic counseling session lasting not less than twenty (20) minutes with a qualified provider, or a group educational session of no more than twenty (20) patients and lasting not less than fifty (50) minutes facilitated by a qualified provider. Counseling shall be focused on issues related to the patient's opioid use disorder and shall not include discussions related to administrative procedures. Telehealth, pursuant to the Tennessee Code Annotated, may be utilized to facilitate counseling. Attendance of a 12-step program, such as Narcotics Anonymous, shall not be considered counseling. The provider shall document each counseling session in the patient's medical chart.

5. "DEA" means the United States Drug Enforcement Administration.

6. "Detoxification" or "Detoxification Treatment" means the providing of an opioid agonist treatment medication in decreasing doses to the patient to alleviate adverse physical or psychological effects incident to withdrawal from the continuous or substantial use of an opioid drug and as a method of bringing the patient to a drug-free state within that period.

7. "FDA" means the United States Food and Drug Administration.

8. "Medical Record" or "Medical Chart" means medical histories, records, reports, summaries, diagnoses, prognoses, records of treatment and medication ordered and given, entries, x-rays, radiology interpretations and other written electronics, or graphic data prepared, kept, made or maintained in a facility that pertains to services rendered to patients.

9. "Opiate/Opioid" means a drug that contains opium, derivatives of opium, or any of several semi-synthetic or synthetic drugs with agonist activity at the opioid receptor.

10. "Observed Drug Screen" or "Observed Urine Drug Screening" means a test used to determine the presence of illicit drugs in an individual's body conducted by and in the presence of medical or lab staff or contracted medical or lab staff so as to ensure against the tampering with or falsification of the results.

11. "Patient" shall refer to an individual receiving treatment for opioid use disorder by a licensed provider.

12. “Phases of Treatment” means the induction, stabilization, and maintenance phases associated with office-based opioid treatment as described in the Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction: A Treatment Intervention Protocol published by the Substance Abuse and Mental Health Services Administration’s (SAMHSA) Center for Substance Abuse Treatment (CSAT).

13. “Qualified Provider” means a qualified mental health professional as defined in T.C.A. § 33-1-101(20), qualified alcohol and drug abuse treatment personnel as defined in TDMHSAS Rule Chapter 0940-05-01-.16(7), or treatment staff operating under the direct supervision of either a qualified mental health professional or qualified alcohol and drug abuse treatment personnel.

14. “Relapse” means a process in which an individual who has established abstinence or sobriety experiences a recurrence of signs and symptoms of active addiction, often including resumption of the pathological pursuit of reward and/or relief through the use of substances and other behaviors.

15. “Taper”, “Tapering”, and “Medically Supervised Withdrawal” are interchangeable terms for the purposes of these Guidelines.

16. “Treatment” or “Substance Abuse Treatment” means a broad range of services intended to assess status, reduce symptoms, or mitigate the effects of substance misuse, substance use disorders, or co-occurring disorders; reduce risk of relapse and associated harm; or restore or establish well-being for individuals and families; provided, that said practice may include, but not be limited to, care coordination, case management, medical, pharmacological, psychological, psycho-educational, rehabilitative or social services, and therapies. The overall goals are to eliminate the substance abuse as a contributing factor to physical, psychological, and social dysfunction and to arrest or reverse the progress of any associated problems.

17. “Treatment Program” or “Substance Abuse Treatment Program” means an organized system of services containing a mission, philosophy, and model of substance use disorder treatment designed to address the needs of clients.

## APPENDIX B - DSM-5 Diagnosis Chart for Opioid Use Disorder

*Source: Adapted from DSM-5*

| Diagnostic Criteria | Meets criteria? Yes | No | Notes |
|---|---|---|---|
| Opioids taken over a longer time period than was intended and/or in larger amounts. | | | |
| Unsuccessful efforts or persistent desire to cut down or control opioid use. | | | |
| Great deal of time spent in activities necessary to obtain or use the opioid or recover from its effects. | | | |
| Strong desire or urge (craving) to use opioids. | | | |
| Recurrent opioid use resulting in a failure to fulfill major role obligations at home, school, or work. | | | |
| Continued opioid use despite recurrent or persistent interpersonal or social problems exacerbated by the substance. | | | |
| Important social, recreational, or occupational activities reduced or given up because of opioid use. | | | |
| Recurrent opioid use in situations in which it is physically hazardous. | | | |
| Continued opioid use despite knowledge of recurrent or persistent psychological or physical problem that is likely to have been exacerbated or caused by the substance. | | | |
| Tolerance*, defined by markedly diminished effect with continued use of same amount of an opioid or need for markedly increased amounts of opioids to achieve desired effect or intoxication. | | | |
| Withdrawal*, manifested by opioids (or closely related substance) taken to avoid or relieve withdrawal symptoms or characteristic opioid withdrawal syndrome. | | | |

*This criterion is not considered to be met for those individuals taking opioids solely under appropriate medical supervision.

### Illness Severity

| | *Number of Symptoms* |
|---|---|
| Mild | 2-3 |
| Moderate | 4-5 |
| Severe | 6+ |

## APPENDIX C - Clinical Opiate Withdrawal Scale (COWS)

*Source: Wesson, D. R., & Ling, W. (2003). The Clinical Opiate Withdrawal Scale (COWS). J Psychoactive Drugs, 35(2), 253–9.*

| | DATE/TIME: | DATE/TIME: | DATE/TIME: |
|---|---|---|---|
| **Resting Pulse Rate**: (record beats per minute) *Measured after patient is sitting/lying for one minute.*<br>0 pulse rate 80 or below 1 pulse rate 81-100<br>2 pulse rate 101-120 4 pulse rate greater than 120 | | | |
| **Sweating:** *Over past ½ hour not accounted for by room temperature or patient activity.*<br>0 no report of chills of flushing 1 one subjective report of chills or flushing 2 flushed or observable moistness on face 3 beads of sweat on brow or face 4 sweat streaming off face | | | |
| **Restlessness:** *Observation during assessment.*<br>0 able to sit still 1 report difficulty sitting still, but is able to do so<br>3 frequent shifting or extraneous movements of legs/arms<br>5 unable to sit still for more than a few seconds | | | |
| **Pupil Size:**<br>0 pupils pinned or normal size for room light 1 pupils possibly larger than normal for room light 2 pupils moderately dilated 5 pupils so dilated that only rim of the iris is visible | | | |
| **Bone or Joint aches**: *If patient was having pains previously, only the additional component attributed to opiate withdrawal is scored.*<br>0 not present 1 mild diffuse discomfort 2 patient reports severe diffuse aching of joints/muscles 4 patient is rubbing joints or muscles and is unable to sit still because of discomfort | | | |
| **Runny nose or tearing:** *Not accounted for by cold symptoms or allergies.*<br>0 not present 1 nasal stuffiness or unusually moist eyes<br>2 nose running or tearing 4 nose constantly running or tears streaming down cheeks | | | |
| **GI Upset:** *Over last ½ hour*<br>0 no GI symptoms 1 stomach cramps 2 nausea or loose stools<br>3 vomiting or diarrhea 5 multiple episodes of diarrhea or vomiting | | | |
| **Tremor:** *Observation of outstretched hands*<br>0 no tremor 1 tremor can be felt, but not observed 2 slight tremor observable 4 gross tremor or muscle twitching | | | |
| **Yawning:** *Observation during assessment*<br>0 no yawning 1 yawning once or twice during assessment<br>2 yawning three or more times during assessment<br>4 yawning several times/minute | | | |
| **Anxiety or Irritability**<br>0 none 1 patient reports increasing irritability or anxiousness<br>2 patient obviously irritable, anxious 4 patient so irritable or anxious that participation in the assessment is difficult | | | |
| **Gooseflesh skin**<br>0 skin is smooth 3 piloerection of skin can be felt or hairs standing up on arms 5 prominent piloerection | | | |
| **Total Score** | | | |
| **Observers Initials** | | | |
| **Blood Pressure/Pulse** | | | |
| **Dose of Buprenorphine/naloxone Given** | | | |

Note: Give first dose when COWS score ≥ 7

Score: 5-12 = MILD
13-24 = MODERATE
25-36 = MODERATELY SEVERE
More than 36 = SEVERE WITHDRAWAL

## APPENDIX D – Sample Physical Exam Form

*Adapted from:* Permitted use of internal form used by Behavioral Health Group, 2017

### PHYSICAL EXAM

Date: _____

Patient Name:_____ Age:_____ DOB:_____ Patient ID:_____


Height: _____ Weight: _____ Temperature: _____ Pulse: _____

Respiration: _____ Blood Pressure: _____

**Patient Clinical and Medical History:**

Dose: _____ mg(s) Code: _____

*Check all that apply:*

☐ HTN ☐ Hyperlipidemia ☐ Asthma ☐ AIDS / HIV ☐ Stomach ulcers/Reflux

☐ CAD ☐ Hepatitis ☐ Cancer ☐ Other>>> _____

**Allergies:** _____

**Current Medication:** _____

**Surgeries:** _____

**Abnormal Labs:** _____

**Skin:** General Appearance ☐ Normal ☐ Abnormal [If Abnormal List Referral(s):]

☐ Normal ☐ Abnormal

Check if present, and describe in IV Track Record:

☐ Tattoos/Distinguishing Marks: ☐ Thrombosis Veins ☐ Subcutaneous Abscesses: [Select One] ☐ Puffy Hand

Tracks ☐ New ☐ OI ☐ None

**See IV TRACK RECORD**

| | Left | Right | | Left | Right |
|---|---|---|---|---|---|
| Arm | ☐ | ☐ | Antecubital fossa | ☐ | ☐ |
| Forearm | ☐ | ☐ | Hand | ☐ | ☐ |

**Eyes:** ☐ Normal ☐ Abnormal [If Abnormal List Referral(s):]

EOM: ☐ Normal ☐ Abnormal

Fundi: ☐ Normal ☐ Abnormal

*Check Findings:* Sclera: ☐ Normal ☐ Icteric

Nystagmus: ☐ Absent ☐ Present

Pupil Size ☐ Normal ☐ Myotic ☐ Mydriatic ☐ Reactive ☐ Nonreactive

| | | | | | | |
|---|---|---|---|---|---|---|
| **Ear Canal and Drums:** | | | Normal | Abnormal | [If Abnormal List Referral(s):] | |
| **Nose:** | | | Normal | Abnormal | | |
| **Mouth and Throat:** | | | Normal | Abnormal | | |
| **Teeth:** | | | Normal | Abnormal | | |
| **Neck, including Thyroid:** | | | Normal | Abnormal | | |
| **Lymph Nodes:** | Cervical | | Normal | Abnormal | [If Abnormal List Referral(s):] | |
| | Axillary | | Normal | Abnormal | | |
| | Epitrochlear | | Normal | Abnormal | | |
| | Inguinal | | Normal | Abnormal | | |
| **Heart:** | | Normal | Abnormal | Referral needed for ECG? | [If Abnormal List Referral(s):] | |
| **Peripheral Pulses:** | | Normal | Abnormal | Yes | No | |
| **Lungs:** | | | Normal | Abnormal | [If Abnormal List Referral(s):] | |
| **Abdomen** | | | Normal | Abnormal | | |
| *Check Findings:* | Liver: | | Palpable | Not Palpable | Non-tender | Tender Enlarged |
| | Spleen: | | Palpable | Not Palpable | | |
| | Kidney: | | Palpable | Not Palpable | | |
| **Joints:** | | | Normal | Abnormal | [If Abnormal or Yes List Referral(s):] | |
| **Spine:** | | | Normal | Abnormal | | |
| **Extremities:** | | | Normal | Abnormal | | |
| **Herniations:** | | | Yes | No | | |
| **Edema:** | | | Yes | No | | |
| **Varicosities, Thrombophlebitis** | | | Yes | No | | |
| **Neurological:** | | | | | | |
| (DTR's, Babinski, Romberg): | | | Normal | Abnormal | [If Abnormal List Referral(s):] | |
| | Cranial Nerves | | Normal | Abnormal | | |
| | Gait | | Normal | Abnormal | | |
| | Balance | | Normal | Abnormal | | |
| | Coordination | | Normal | Abnormal | | |
| | Motor Strength | | Normal | Abnormal | | |
| *Check Findings:* | Mental Status: | | Alert | Somnolent | Noticeably High | |
| | | | Does not report any danger to self/others | | | |
| | Speech: | | Clear | Slurred | | |

## SUMMARY DOCUMENTATION OF CURRENT PHYSIOLOGICAL ADDICTION

☐ **Not Applicable for ANNUAL PHYSICAL - ONLY complete this section during ADMISSION PHYSICAL EXAMINATION or if**

**Addictive Drug**

- ☐ Heroin
- ☐ Prescription Opiate Narcotics
- ☐ Street Opiate Narcotics

Daily Consumption:

Time last used: _____

**Toxic State**

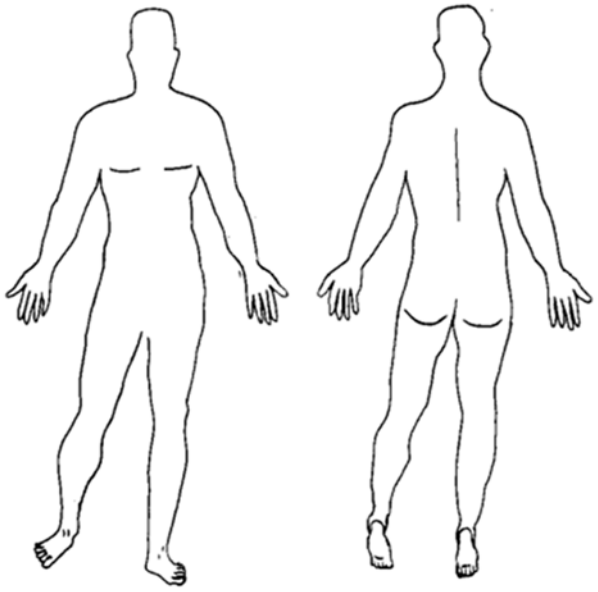
- ☐ New Tracks
- ☐ Contracted Pupila
- ☐ Constipation
- ☐ Slurred Speech
- ☐ Nystagmus
- ☐ Staggering Gait

**Withdraw State (Check if present)**

- ☐ Dilated Pupils
- ☐ Rhinorrhea
- ☐ Lacrimation
- ☐ Nausea/Vomiting
- ☐ Positive Romberg
- ☐ Orthostatic Hypotension
- ☐ "Gooseflesh"
- ☐ Diarrhea
- ☐ Tremulousness
- ☐ Delirium
- ☐ Diaphoresis
- ☐ Other (specify)> _____
- ☐ Fever
- ☐ Anxiety
- ☐ Insomnia
- ☐ Convulsions

Provider Signature _____ Date: _____

## IV TRACK RECORD



**Describe Tracks/Tattoos/ Distinguishing Marks:**

**X = Recent Tracks** **0 = Old Tracks**

**PAIN**

Patient complaint of current pain: Yes No Patient complaint of recent pain: Yes No

Patient complaint of **CHRONIC PAIN** Yes No

If the patient answers yes to either of these questions, then answer the following:

What is the location of the pain?

On a scale of 0 to 10 (0 being no pain and 10 being the worst pain imaginable), please rate the following:

Current pain intensity _____ Worst pain in few days _____ Least pain in past few days ____

Average pain over the past few days

What is the sensory quality of the pain: Stabbing Throbbing Aching Burning Shooting

Is the pain currently being treated? Yes No by whom : Clinic Private Doctor

Other (specify)

**IMPRESSION:** Pain is associated with substance abuse or Pain is medically based

**Further action needed to address pain related problems?** Yes No **Referral needed?** Yes No

Referral:

**LABORATORY**

**Laboratory Test Ordered:** CBC with Diff Liver Profile RPR Urine Drug Screen

TB Skin Test Biological Pregnancy Test Micro UA

**PHYSICAL EXAMINATION SUMMARY**

**Overall Impression of Addiction:**

Provider Signature: _____ Date: _____

**RECOMMENDATION**

**Recommendation Based on Examination:**

Provider Signature: _____ Date: _____

**COMMENTS**

**General Impression of Patient:**

Physical Completed [**Date**]

Provider Signature: _____ Date: _____

## APPENDIX E - Special Populations

*Source: Adapted from TIP 40 with contributions from the Buprenorphine Treatment Guidelines Committee*

### E.1. ADOLESCENT TREATMENT (UNDER 18)

- Not all adolescents who use substances are, or will become, dependent. Programs and counselors must be careful not to prematurely diagnose or label adolescents or otherwise pressure them to accept that they have a disease: This may do more harm than good in the long run.
- Programs should make every effort to involve the adolescent client's family due to its possible role in the origins of the problematic behavior and its importance as an agent of change in the adolescent's environment.
- Using adult programs for treating adolescents is ill-advised. If this must occur, it should be done only with great caution and with alertness to the inherent complications that may threaten effective treatment for these young people.
- This treatment should include family therapy, vocational and education support, and an assessment of causative factors.
- The ASAM National Practice Guidelines for the Treatment of Opioid Use Disorder recommend that clinicians consider treating adolescents with opioid use disorder using the full range of treatment options, including medication.
- The ASAM National Practice Guidelines for the Treatment of Opioid Use Disorder acknowledge the importance of and recommend psychosocial treatment of adolescents with opioid use disorder while advising that appropriate management of opioid use disorder with medication not be delayed or precluded in the absence of the availability of these important resources or in the absence of the adolescent's consent to participate in these additional elements of treatment.
- The ASAM National Practice Guidelines for the Treatment of Opioid Use Disorder caution against the utilization of group therapy in the adolescent population due to the risk of iatrogenic effects as group members may reinforce the substance use behaviors among the milieu and acknowledgment is provided that additional research is needed to determine which psychosocial interventions are most beneficial in the adolescent population.

### E.2. BUPRENORPHINE AND PAIN

According to Tennessee Code 53-11-311(a), "*Any product containing buprenorphine, whether with or without naloxone, may only be prescribed for a use recognized by the Federal Food and drug Administration (FDA). This subsection (a) shall not apply to a person: (1) Who has a documented diagnosis of opiate addiction as shown in their medical record; (2) Who receives treatment from a provider practicing under 21 U.S.C. § 823(g)(2); and (3) Who is counted against the total number of patients allowed to the provider as set forth in 21 U.S.C. § 823(g)(2).*" (See **APPENDIX H)**

- Chronic pain and substance use disorders have similar physical, social, emotional, and economic effects on health and well-being. Patients with one or both conditions may report insomnia, depression, impaired

functioning, and other symptoms. Effective chronic pain management in patients with, or in recovery from, substance use disorders must address both conditions simultaneously.

- For all patients with pain, it is important that the correct diagnosis of pain etiology be made and that a suitable treatment be identified. Nonpharmacological treatments have been shown to be effective for pain (e.g., physical therapy) and may be considered.
- If pharmacological treatment is considered, then nonnarcotic medications such as acetaminophen and nonsteroidal anti-inflammatory drugs (NSAIDs) should be tried first. Adjunctive medications, including anticonvulsants, may be useful. Tricyclic antidepressants or combined norepinephrine-serotonin reuptake inhibitors may also be considered.
- For patients taking buprenorphine for the treatment of opioid use disorder, temporarily increasing the frequency of administration of buprenorphine, or temporarily increasing the dose may be effective for pain management.
- Should the above strategies be inadequate in the treatment of pain, the ASAM National Practice Guidelines for the Treatment of Opioid Use Disorder advise that the addition of a short-acting full agonist opioid to the patient's regular buprenorphine regimen can be effective for treatment of severe acute pain in a supervised setting, such as during hospitalization, and acknowledge higher than typical doses may be necessary to achieve adequate analgesia than that of the opioid-naïve patient.

## E.3. BUPRENORPHINE AND SURGERY

*Source: Adapted from the ASAM National Practice Guidelines for the Treatment of Opioid Use Disorder (2020).*

- Discontinuation of buprenorphine before surgery or elective cesarean section is not required.
- Research has demonstrated the addition of full-opioid agonists can be effective for the treatment of pain in surgical patients taking buprenorphine.
- Collaboration between the addiction treatment provider and surgical team is recommended when making decisions regarding reducing or discontinuing the dose of buprenorphine prior to surgery.
- In cases where the dose is reduced or discontinued prior to surgery a patient may be able to resume their pre-surgery daily dose when withheld or adjusted for a short time (1-3 days).
- For longer periods of time the dose may require gradual initiation back to the prior maintenance dose to reduce risk for respiratory depression, sedation, or adverse side effects.
  For acute post operative pain increasing and/or splitting the buprenorphine dose may adequately address acute pain (referred to 'Buprenorphine and Pain' of Special Populations).

## E.4. WOMEN WHO ARE PREGNANT OR BREASTFEEDING

According to the ASAM National Practice Guideline for the Treatment of Opioid Use Disorder (2020), pregnant women who are physically dependent on opioids should receive either methadone or buprenorphine treatment rather than withdrawal management or counseling alone. Treatment with these agents should be initiated as early as possible during pregnancy. Potential for adverse effects with initiation of buprenorphine is mostly seen in the third trimester. Consider hospitalization for treatment initiation in this subpopulation.

- The ASAM National Practice Guidelines for the Treatment of Opioid Use Disorder state that more research is needed regarding the safety of the combined product in pregnant and nursing women, however, it is generally accepted that buprenorphine, with or without naloxone, is safe and effective in pregnant and nursing women and although the Tennessee statute allows for the utilization of the mono-product in pregnant and breastfeeding patients, it does not require the utilization of the mono-product. The determination to use the combined or mono-product buprenorphine during the peri and postpartum or breastfeeding period is an individual decision that should be made collaboratively between the clinician and patient with considerations for coordination of care with the OB/GYN. The utilization of the combination product is not contraindicated in pregnancy or nursing. A decision based on the risks verses benefits of either formulation should be made based on the providers clinical judgement and knowledge of the individual patient. Clear documentation in the patient's chart of the patient's awareness of the risks and benefits of buprenorphine in the treatment of pregnant or breastfeeding women is essential. The benefits of treatment include preventing withdrawal, reducing cravings, and blocking the effects of other opioids in the pregnant mother. Treatment with buprenorphine or methadone makes it more likely that the fetus will grow normally and not be born too early. The services received with medication, such as counseling and prenatal care, can help the pregnant mother have a healthier pregnancy. The risks of treatment include the baby experiencing temporary withdrawal symptoms following birth. Swaddling, breastfeeding, and sometimes medication can be used to help ease these symptoms in babies. Sometimes additional care is needed in the neonatal intensive care unit following birth. Monthly drug screens, or more frequently if clinically indicated, should be performed during pregnancy. Emphasis should be made on maintaining documentation of drug screens in the patient's record. Testing should be used to monitor for adherence to medication and for the use of illicit and controlled substances. This should be done with informed consent from the mother.
- It is recommended that care is co-managed by a clinician experienced in obstetrical care and a clinician experienced in the treatment of OUD; coordination of care with OB/GYN, if different from the buprenorphine provider, should be made. The buprenorphine provider should have documentation in the patient's chart documenting this coordination of care.
- Consider consulting the patient's pharmacist to determine that patients are picking up their medications, including those for prenatal care (e.g. prenatal vitamins, etc.), to determine adherence to their treatment regimen and making progress in their individualized treatment plan.
- Should a provider decide to not serve a pregnant patient, the provider should make every reasonable effort to refer the patient to available treatment resources keeping in mind the ASAM guidance that pregnant women should receive buprenorphine or methadone as opposed to withdrawal management or counseling alone.
- Treatment with buprenorphine while pregnant is a decision between the patient and provider and should be made with the agreement and signed understanding that the patient will be treated at the lowest effective dose through pregnancy.
- Breastfeeding: Sufficient evidence exists that buprenorphine products with or without naloxone are safe in breastfeeding. Medication selection for a nursing mother should be made that considers all patient-specific factors, including risk of diversion of buprenorphine mono product.

- Providers should be aware the Safe Harbor provision pursuant to TCA § 33-10-104(f), regarding treating pregnant women prior to end of the 20th week of pregnancy and interactions with the Tennessee Department of Children's Services.

## E.5. CO-OCCURRING PSYCHIATRIC DISORDERS

- Deliberation about what medications to prescribe to patients with active substance use disorders requires a careful consideration of their psychiatric diagnoses, their medical co-morbidities and overall health status, and how the specific substances they are using might interact with the medications being considered.

- In the case of opioid use disorder, the most dangerous medications to recommend or prescribe are those that depress respiratory drive, such as benzodiazepines. However, the use of alcohol, cannabis, stimulants, benzodiazepines, sedative-hypnotics, and/or other addictive drugs or substances should not be the sole reason to withhold or suspend needed treatment but shall be assessed and considered when developing the patient's individualized treatment plan.

## E.6. PATIENTS WITH SIGNIFICANT MEDICAL COMORBIDITIES

Patients who have unstable or very severe cardiovascular disease, such as advanced heart failure or angina/coronary artery disease, may have difficulty tolerating the stress of induction onto buprenorphine. The same may be true for patients with severe lung disease, such as COPD. For this reason, these patients should be monitored very carefully throughout their treatment for any substance use disorder.

- These patients may need to undergo induction in an inpatient setting to allow for close monitoring or may be better served by methadone treatment.
- Patients who have underlying conditions that increase somnolence, such as sleep apnea or narcolepsy, need close monitoring during early treatment to evaluate the effects of buprenorphine.

## E.7. BUPRENORPHINE AND LIVER DISEASE (INCLUDING HEPATITIS C)

Current SAMHSA guidelines recommend that patients with severe liver impairment may not be candidates for buprenorphine treatment if their transaminases (AST or ALT) are elevated more than five times the upper limit of normal. Patients infected with hepatitis C may need to be maintained on buprenorphine in order to withstand the stress of hepatitis C treatment. Studies have shown that these patients may do extremely well on treatment, particularly if they receive daily, directly observed treatment with buprenorphine.

- The ASAM National Practice Guidelines for the Treatment of Opioid Use Disorder point out that there is not evidence to suggest methadone or buprenorphine significantly increase elevated liver enzymes during the first six months of treatment.
- The decision of which medication for opioid use disorder to utilize should thus be made based on the patient's individual needs and clinicians best clinical judgement.
- It is recommended that regular monitoring of liver enzymes in the patient with elevated transaminases be considered when buprenorphine treatment is prescribed.

## E.8. BUPRENORPHINE AND HIV

Treatment with methadone or buprenorphine has been shown to reduce frequency of drug use and to reduce HIV risky behaviors; and methadone has been shown to reduce rates of HIV infection in those with injection drug misuse. Adherence to buprenorphine treatment is associated with greater likelihood of viral suppression and higher CD4 counts. Treatment of HIV infected patients with buprenorphine is associated with an approximately 50% decrease in opioid injection drug use, and this use decreases with increasing time on treatment.

- The addition of nontraditional treatment components--such as nutritional counseling, exercise regimens, education about testicular self-examination (for men), breast exams (for women), and ways to lower cholesterol--will greatly enhance the mental and physical health of persons with HIV/AIDS.
- Many HIV-infected substance users are unable to maintain total abstinence from substance use after the abrupt discontinuation at the start of treatment. In dealing with clients' ongoing substance use, treatment programs must find a balance between abstinence and public health approaches to substance abuse treatment.
- Buprenorphine is metabolized to norbuprenorphine by cytochrome CYP3A4. Medications that inhibit CYP3A4, such as HIV protease inhibitors, may require that one or both medication doses be adjusted.
- Buprenorphine providers should establish a coordination of care with the patient’s HIV provider to ensure the safe and effective use of both buprenorphine and HIV medications.

## APPENDIX F – Adverse Childhood Experiences (ACEs)

*Source: For additional information about ACEs, please visit: https://www.cdc.gov/violenceprevention/acestudy/about_ace.html*

### Finding Your ACE Score

**While you were growing up, during your first 18 years of life:**

1. Did a parent or other adult in the household **often or very often**…
   Swear at you, insult you, put you down, or humiliate you?
   **or**
   Act in a way that made you afraid that you might be physically hurt?
   Yes No If yes enter 1 _____

2. Did a parent or other adult in the household **often or very often**…
   Push, grab, slap, or throw something at you?
   **or**
   **Ever** hit you so hard that you had marks or were injured?
   Yes No If yes enter 1 _____

3. Did an adult or person at least 5 years older than you **ever**…
   Touch or fondle you or have you touch their body in a sexual way?
   **or**
   Attempt or actually have oral, anal, or vaginal intercourse with you?
   Yes No If yes enter 1 _____

4. Did you **often or very often** feel that …
   No one in your family loved you or thought you were important or special?
   **or**
   Your family didn't look out for each other, feel close to each other, or support each other?
   Yes No If yes enter 1 _____

5. Did you **often or very often** feel that …
   You didn't have enough to eat, had to wear dirty clothes, and had no one to protect you?
   **or**
   Your parents were too drunk or high to take care of you or take you to the doctor if you needed it?
   Yes No If yes enter 1 _____

6. Were your parents **ever** separated or divorced?
   Yes No If yes enter 1 _____

7. Was your mother or stepmother:
   **Often or very often** pushed, grabbed, slapped, or had something thrown at her?
   **or**
   **Sometimes, often, or very often** kicked, bitten, hit with a fist, or hit with something hard?
   **or**
   **Ever** repeatedly hit at least a few minutes or threatened with a gun or knife?
   Yes No If yes enter 1 _____

8. Did you live with anyone who was a problem drinker or alcoholic or who used street drugs?
   Yes No If yes enter 1 _____

9. Was a household member depressed or mentally ill, or did a household member attempt suicide?

Yes No If yes enter 1 _____

10. Did a household member go to prison?

Yes No If yes enter 1 _____

**Now add up your "Yes" answers: _____ This is your ACE Score.**

## APPENDIX G – Treatment Planning and Therapies

*Source: Deborah Hillin & Dr. Richard Soper*

### Treatment Plans

Treatment plans need to utilize assessment information, describe client problems in behavioral terms, and specify in measurable steps the objectives that have been individually selected to help clients reach identified goals.

Treatment plans should assess the severity of the substance use disorder as well as any co-occurring disorders; should identify the client's goals for treatment in measurable, time sensitive steps toward achieving the goals; address the motivation and readiness for change; and should incorporate a strength-based approach.

Use a Problem List to formulate treatment plans and develop:
–**Problem Statements -** information gathered from the assessment
–**Goals** based on Problem Statements
–**Objectives** based on Goals and specific to what the client will do
–**Interventions** based on Objectives and what the staff will be doing with client
These components need to reflect action steps of the client in measurable activities, etc.

Treatment plans should reflect the client's strengths and active participation in the treatment planning.

### Therapies

Therapies, including individual, family and group therapy, help people learn to increase their coping skills, manage high-risk situations, avoid substance-use triggers and control cravings. Therapies that have demonstrated effectiveness may include, but are not limited to:

- **Motivational interviewing and motivational enhancement therapy:** bolsters motivation to change substance use behaviors
- **Cognitive behavioral therapy:** helps identify, recognize and avoid thought processes, behaviors and situations associated with substance use; manage cravings and negative emotions; and develop better problem-solving and coping skills
- **Community reinforcement approach:** focuses on improving family relations, acquiring job skills, and developing alternative activities and associates to minimize substance use
- **Contingency management:** alters behavior by rewarding constructive behaviors and discouraging unhealthy behaviors
- **Behavioral couples/family therapy:** improves communication and support and reduces conflict between couples and families that have a member with a substance problem
- **Family therapy for adolescents:** addresses adolescent substance use and related problem behaviors in relation to individual, family, peer and community-level influences (examples include multidimensional family therapy, functional family therapy, multi-systemic therapy, brief strategic family therapy, integrated/combined treatments)
- **12-Step facilitation approach (Not the same as, but used in conjunction with, AA, NA, fellowship meeting):** Therapy sessions are highly structured, following a similar format each week that includes symptoms inquiry, review and reinforcement for AA participation, introduction and explication of the week's theme, and setting goals for AA participation for the next week. Material introduced during treatment sessions is complemented by reading assignments from AA literature.
- **Acceptance and commitment therapy:** increases psychological flexibility, or the ability to enter the present moment more fully and either change or persist in behavior when doing so serves valued ends

## APPENDIX H – Tennessee Code Annotated § 53-11-311

*Tenn. Code Ann. § 53-11-311*

*** Current through 2023 Regular Session ***
Title 53 Food, Drugs and Cosmetics Chapter 11 Narcotic Drugs and Drug Control Part 3 Regulations and Registration
Tenn. Code Ann. § 53-11-311 (2023)

**53-11-311. Use of buprenorphine products.**

**(a)** Any product containing buprenorphine, whether with or without naloxone, may only be prescribed for a use recognized by the federal food and drug administration. This subsection (a) shall not apply to a person:

**(1)** Who has a documented diagnosis of opiate addiction as shown in their medical record;

**(2)** Who receives treatment from a provider practicing under 21 U.S.C. § 823(g)(2); and

**(3)** Who is counted against the total number of patients allowed to the provider as set forth in 21 U.S.C. § 823(g)(2).

**(b)**

**(1)** Any prescription for buprenorphine mono or for buprenorphine without use of naloxone for the treatment of substance use disorder shall only be permitted to a patient who is:

**(A)** Pregnant;

**(B)** A nursing mother;

**(C)** Has a documented history of an adverse reaction or hypersensitivity to naloxone; or

**(D)** Directly administered the buprenorphine mono or buprenorphine without use of naloxone by a healthcare provider, acting within the healthcare provider's scope of practice, for the treatment of substance use disorder pursuant to a medical order or prescription order from a physician licensed under title 63, chapter 6 or 9; provided, however, that this subdivision (b)(1)(D) does not permit buprenorphine mono or buprenorphine without use of naloxone to be dispensed to a patient in a manner that would permit it to be administered away from the premises on which it is dispensed.

**(2)** If the prescriber of buprenorphine mono or buprenorphine without use of naloxone for a patient under subdivision (b)(1)(A) or (b)(1)(B) is not the patient's obstetrical or gynecological provider, the prescriber shall consult with the patient's obstetrical or gynecological provider to the extent possible to determine whether the prescription is appropriate for the patient.

**(c)**

**(1)** Notwithstanding any other provision of this title, and except as otherwise provided in subdivision (c)(2), a physician licensed under title 63, chapter 6 or 9, is the only healthcare provider authorized to prescribe any buprenorphine product for any federal food and drug administration approved use in recovery or medication-assisted treatment.

**(2)** Healthcare providers not licensed pursuant to title 63, chapter 6 or 9, and who are otherwise permitted to prescribe Schedule II or III drugs under this title, are prohibited from prescribing any buprenorphine product for the treatment of opioid use disorder unless the provider:

**(A)** Is licensed and has practiced as a family, adult, or psychiatric nurse practitioner or physician assistant in this state;

**(B)** Has had no limitations or conditions imposed on the provider's license by the provider's licensing authority within the previous three (3) years;

**(C)** Is employed by a community mental health center, as defined in § 33-1-101, or a federally qualified health center, as defined in § 63-10-601(a), that employs one (1) or more physicians and has adopted clinical protocols for medication-assisted treatment;

**(D)** Is employed at a facility at which healthcare providers are contracted and credentialed with TennCare and TennCare's managed care organizations to treat opioid use disorder with buprenorphine products for use in recovery or medication-assisted treatment;
**(E)** Is employed at a facility at which healthcare providers are accepting new TennCare enrollees or patients for treatment of opiate addiction;
**(F)** Is employed by a facility that requires patients to verify identification;
**(G)** Does not write any prescription for a buprenorphine product that exceeds a sixteen-milligram daily equivalent;
**(H)** Does not prescribe or dispense a mono product or buprenorphine without naloxone;
**(I)** Works under the supervision of a physician who holds an active federal Drug Addiction Treatment Act of 2000 (DATA 2000) waiver registration from the federal drug enforcement agency that authorizes the physician to prescribe buprenorphine products and is actively treating patients with buprenorphine products for recovery or medication-assisted treatment;
**(J)** Obtains a waiver registration pursuant to the federal Drug Addiction Treatment Act of 2000 (DATA 2000) from the federal drug enforcement agency that authorizes the provider to prescribe buprenorphine products under federal law;
**(K)** Prescribes buprenorphine products only to patients who are treated through the organization that employs the provider;
**(L)** Is supervised by or collaborates with a physician who is limited to the supervision of, or collaboration for, a maximum of four (4) licensed nurse practitioners or physician assistants;
**(M)** Is supervised by or collaborates with a physician who reviews one hundred percent (100%) of the charts of the patients being prescribed a buprenorphine product;
**(N)** Weighs the risk of relapse with the benefit of tapering down or off of buprenorphine when, similar to other disease states, tapering from the treatment medication is clinically appropriate and in agreement with the patient and tapering schedules and durations are patient specific. Providers shall initiate and lead a discussion regarding patient readiness to taper down or taper off treatment medications employed in the patient's treatment with each patient at any time upon the patient's request but no later than one (1) year after initiating treatment and then every six (6) months thereafter;
**(O)** Writes prescriptions that can only be dispensed by a licensed pharmacy to ensure entry into the controlled substance database; and
**(P)** Writes prescriptions of buprenorphine products to fifty (50) or fewer patients at any given time.

**(d)**

**(1)** A prescriber who treats a patient with more than sixteen milligrams (16 mg) per day of buprenorphine or its therapeutic equivalent for more than thirty (30) consecutive days for treatment of opioid dependence shall clearly document in the patient's medical record why the patient needs the higher dosage amounts of buprenorphine. A prescriber who does not meet the requirements established in the manner described in subdivision (d)(2) and treats a patient with more than twenty milligrams (20 mg) per day of buprenorphine or its therapeutic equivalent for more than thirty (30) consecutive days for treatment of opioid dependence shall, to the extent possible, either consult with an addiction specialist meeting the requirements established in the manner described in subdivision (d)(2) or refer the patient to the addiction specialist for management of the patient's treatment plan. If a prescribing physician cannot make the required consultation or referral as outlined in this subsection (d), the reasons shall be set out in the medical record.
**(2)** The board of medical examiners and the board of osteopathic examination shall promulgate rules establishing the requirements for licensees to qualify as addiction specialists.

**(e)** This section shall not apply to perioperative surgery or ventilator sedation that is performed in a licensed healthcare facility set forth in § 68-11-201(3) or (26).

**(f)** When patients are admitted as inpatients of a hospital, or registered as outpatients of a hospital, prescribers may continue orders for these drug products as part of a medication reconciliation process to continue home medications as previously prescribed and without restrictions pertaining to the use of the product until the patient is discharged from the facility. However, prescriptions written upon discharge from the facility and intended to be filled by the patient at a retail pharmacy and consumed post-discharge shall follow the requirements of this section.

**(g)**

**(1)**

**(A)** Notwithstanding any other law, the dispensing of buprenorphine products is prohibited by any person or entity unless the dispensing is done by a nonresidential office-based opiate treatment facility, as defined in § 33-2-402, with approval from the department of mental health and substance abuse services, a nonresidential substitution-based treatment center for opiate addiction as defined in § 33-2-402, a pharmacy licensed under title 63, chapter 10, or a hospital licensed under title 33, or title 68, chapter 11. This subsection (g) does not apply to the administering of buprenorphine products as otherwise permitted by law.

**(B)** A pharmacy and a distributor, as defined in § 63-10-204, shall report to the department of health the quantities of buprenorphine that the pharmacy or distributor delivers to nonresidential office-based opiate treatment facilities in this state.

**(2)** The department of mental health and substance abuse services shall promulgate rules to establish requirements for approval of dispensing of buprenorphine products at a nonresidential office-based opiate treatment facility as defined in § 33-2-402. These rules shall include a requirement that a provider who dispenses buprenorphine products at a nonresidential office-based opiate treatment facility must report the fact that the provider dispenses buprenorphine products to the provider's licensing board, check the controlled substance database prior to dispensing, and enter the amounts dispensed into the controlled substance database, to the extent permitted by 42 CFR part 2.

**(h)**

**(1)** Notwithstanding subsection (c), this subsection (h) controls the prescription of buprenorphine products by any healthcare provider licensed under title 63, chapter 7 or 19, who is employed by or contracted with a nonresidential office-based opiate treatment facility, as defined in § 33-2-402.

**(2)** A healthcare provider licensed under title 63, chapter 7 or 19, may prescribe a buprenorphine product, as approved by the federal food and drug administration for use in recovery or medication-assisted treatment if:

**(A)** The provider works in a nonresidential office-based opiate treatment facility, as defined in § 33-2-402, that is licensed by the department of mental health and substance abuse services and that does not have authority to dispense buprenorphine products;

**(B)** The provider practices under the direct supervision of a physician who is licensed under title 63, chapter 6 or chapter 9; holds an active Drug Addiction Treatment Act of 2000 (DATA 2000) waiver from the United States drug enforcement administration; and is actively treating patients with buprenorphine products for recovery or medication-assisted treatment at the same nonresidential office-based opiate treatment facility, as defined in § 33-2-402, as the provider;

**(C)** The facility and its healthcare providers are contracted and credentialed with TennCare and TennCare's managed care organizations to treat opioid use disorder with buprenorphine products for use in recovery or medication-assisted treatment;

**(D)** The facility or its healthcare providers are directly billing TennCare and TennCare's managed care organizations for the services provided within the facility;

**(E)** The facility or its healthcare providers are accepting new TennCare enrollees or patients for treatment of opiate addiction;

**(F)** The provider does not write any prescription for a buprenorphine product that exceeds a sixteen-milligram daily equivalent;

**(G)** Except as provided in subdivision (h)(2)(H), the provider does not prescribe or dispense a mono product or buprenorphine without naloxone;
**(H)** The provider uses injectable or implantable buprenorphine formulations in accordance with subdivision (b)(1)(D);
**(I)** The provider has practiced as a family, adult, or psychiatric nurse practitioner or physician assistant in this state;
**(J)** The provider obtains a waiver registration from the United States drug enforcement administration that authorizes the provider to prescribe buprenorphine products under federal law and regulations;
**(K)** The provider prescribes buprenorphine products only to patients who are treated through a nonresidential office-based opiate treatment facility, as defined in § 33-2-402, that employs or contracts with the provider;
**(L)** The provider writes prescriptions of buprenorphine products that can only be dispensed by a licensed pharmacy to ensure entry into the controlled substance monitoring database;
**(M)** The provider writes prescriptions of buprenorphine products to one hundred (100) or fewer patients at any given time;
**(N)** When providing direct supervision, the physician does not oversee more than two (2) providers licensed under title 63, chapter 7 or 19, at one (1) time during clinical operations; and
**(O)** The supervising physician ensures all rules of operation for a nonresidential office-based opiate treatment facility, as defined in § 33-2-402; the Tennessee Nonresidential Buprenorphine Treatment Guidelines as established by the department of mental health and substance abuse services and the department of health; and all other state laws, rules, and guidelines regarding use of buprenorphine products for medication assisted treatment are followed.

History

Acts 2015, ch. 396, § 3; 2018, ch. 674, § 1; 2018, ch. 978, § 7; 2020, ch. 761, § 1; 2020, ch. 771, § 1.

## APPENDIX I – Tennessee Code Annotated § 53-11-312

*Tenn. Code Ann. § 53-11-312*

*** Current through 2023 Regular Session ***
Title 53 Food, Drugs and Cosmetics Chapter 11 Narcotic Drugs and Drug Control Part 3 Regulations and Registration
Tenn. Code Ann. § 53-11-312 (2023)

**53-11-312. Educational materials for providers and facilities where medication assisted treatment is prescribed or provided.**

(a) No later than January 1, 2021, the departments of health and mental health and substance abuse services, and the bureau of TennCare shall collaborate to develop educational materials for providers and facilities where medication assisted treatment including treatment involving controlled substances is prescribed or provided. The educational materials shall include the following:

(1) Access to and availability of family planning services and contraception;
(2) Risks and effects of neonatal abstinence syndrome; and
(3) Approaches to client-centered counseling.

(b) The departments of health and mental health and substance abuse services and the bureau of TennCare shall make the educational materials available to prescribers of medication assisted treatment and facilities that use medication assisted treatment for the treatment of substance use disorder.

History

Acts 2020, ch. 747, § 1.

## APPENDIX J– Tennessee Code Annotated § 53-11-313

*Tenn. Code Ann. § 53-11-313*

*** Current through 2023 Regular Session ***
Title 53 Food, Drugs and Cosmetics Chapter 11 Narcotic Drugs and Drug Control Part 3 Regulations and Registration
Tenn. Code Ann. § 53-11-313 (2023)

**53-11-313. Payment for buprenorphine products.**

(a) Except as provided in subsection (b), a healthcare prescriber of a buprenorphine product for use in recovery or medication-assisted treatment, or a nonresidential office-based opiate treatment facility, as defined in § 33-2-402, shall only accept a check, money order, or debit card or credit card that is linked to a bank or credit card account from a financial institution, in payment for services provided by the healthcare prescriber or facility. Use of prepaid debit cards, prepaid credit cards, gift cards, or any other card not linked with a bank or credit card account from a financial institution is prohibited. As used in this subsection (a), "financial institution" means a state or national bank, a state or federally chartered credit union, or a savings bank.

(b) A healthcare prescriber or facility described in subsection (a) may accept payment for services provided to a patient by the prescriber or facility in cash for a co-pay, coinsurance, or deductible if the prescriber or facility submits the remainder of the bill for the services provided to the patient's insurance plan for reimbursement. If the patient does not have an insurance plan, then the healthcare prescriber or facility shall not accept cash as payment for services provided.

(c) No healthcare provider, licensed by title 63, chapter 6, 7, 9, or 19, shall be compensated or receive payment for services related to buprenorphine treatment:

(1) By which the provider receives an amount per patient that is treated within the office or other setting; or

(2) By any means by which the provider receives a percentage of a payment that is directly received by a patient to the office, nonresidential office-based opiate treatment facility, as defined in § 33-2-402, or other provider.

(d) A healthcare provider licensed under title 63, or a nonresidential office-based opiate treatment facility, as defined in § 33-2-402, shall not knowingly treat any TennCare enrollee with buprenorphine products for use in recovery or medication-assisted treatment unless that provider directly bills or seeks reimbursement from TennCare or TennCare's managed care organizations for services provided to the TennCare enrollee. A person is required to disclose to the healthcare provider or nonresidential office-based opiate treatment facility, as defined in § 33-2-402, that the person is a TennCare enrollee seeking treatment with buprenorphine products for use in recovery or medication-assisted treatment.

History

Acts 2020, ch. 771, § 2.

**APPENDIX K.1. – Public Chapter No. 112 of 2017**

# State of Tennessee

## PUBLIC CHAPTER NO. 112

### SENATE BILL NO. 709

**By Yager, Crowe, Briggs, Massey, Haile**

Substituted for: House Bill No. 746

By Powers, Staples, Dunn, Zachary, Ramsey, Smith, Ragan, Daniel

AN ACT to amend Tennessee Code Annotated, Title 63, Chapter 1, relative to treatment guidelines for the nonresidential use of buprenorphine.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 63, Chapter 1, Part 4, is amended by adding the following as a new section:

(a) As used in this section:

(1) "Commissioners" means the commissioner of mental health and substance abuse services and the commissioner of health; and

(2) "Nonresidential buprenorphine treatment guidelines" means systematically developed standards to assist any practitioners authorized by the state to prescribe buprenorphine-containing products for the treatment of opioid use disorder as defined in the latest version of the Diagnostic and Statistical Manual of Mental Disorders.

(b)(1) By January 1, 2018, the commissioner of mental health and substance abuse services, in collaboration with the commissioner of health, shall develop recommended nonresidential treatment guidelines for the use of buprenorphine that can be used by prescribers in this state as a guide for caring for patients. This subsection (b) shall only apply to practitioners prescribing buprenorphine-containing products for the treatment of opioid use disorder in a nonresidential setting. The guidelines must be consistent with applicable state and federal laws.

(2) Guidelines from nationally recognized organizations, such as the American Society of Addiction Medicine, Substance Abuse and Mental Health Services Administration, and the American Board of Preventative Medicine, must serve as resources in the development of

guidelines under this section.

(3) The commissioner of mental health and substance abuse services shall consult with appropriate physicians, alcohol and substance abuse counselors, and other experts to serve as resources in the development of guidelines under this section.

(c) Beginning in 2019, the commissioners shall review the nonresidential buprenorphine treatment guidelines by September 30 of each year and shall cause these guidelines to be posted on both the department of mental health and substance abuse services and the department of health's websites.

(d)(1) The commissioner of mental health and substance abuse services shall submit the nonresidential buprenorphine treatment guidelines to each health-related board that licenses any practitioner authorized by the state to prescribe buprenorphine- containing products for the treatment of an opioid use disorder as defined in the Diagnostic and Statistical Manual of Mental Disorders and to the board of pharmacy.

(2) Each board shall review the nonresidential buprenorphine treatment guidelines and determine how the nonresidential buprenorphine treatment guidelines should be used by that board's licensees.

(3) Each board shall post the nonresidential buprenorphine guidelines and standards on the licensing board's website.

(e) The commissioner of mental health and substance abuse services shall provide a copy of any guidelines developed pursuant to this section and any revision to those guidelines developed pursuant to this section to the chairs of the health committee of the house of representatives and the health and welfare committee of the senate at the time the guidelines or the revisions are posted on websites of the department of mental health and substance abuse services and the department of health.

SECTION 2. This act shall take effect upon becoming a law, the public welfare requiring it.

**APPENDIX K.2. – Public Chapter No. 978 of 2018**

# State of Tennessee

## PUBLIC CHAPTER NO. 978

### SENATE BILL NO.777

**By Jackson, Yager**

Substituted for: House Bill No.717

By Johnson. Cameron Sexton, Eldridge, Powers

AN ACT to amend Tennessee Code Annotated , Title 4; Title 33; Title 49;Title 53;Title 56;Title 63; Title 68 and Title 71, relative to substance abuse.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Section 33-2-402(10)(A), is amended by deleting the language "to fifty percent (50%) or more of its patients and to one hundred fifty (150) or more patients" and substituting instead the language "to twenty-five percent (25%) or more of its patients or to one hundred fifty (150) or more patients".

SECTION 2. Tennessee Code Annotated, Section 33-2-402(10), is amended by adding the following as a new subdivision (C):

(C) "Nonresidential office-based opiate treatment facility" does not include any facility that meets the definition of a nonresidential substitution-based treatment center for opiate addiction;

SECTION 3. Tennessee Code Annotated, Section 33-2-403, is amended by adding the following new subsections:

(h) By January 1, 2019, the commissioner of mental health and substance abuse services shall revise rules for nonresidential office-based opiate treatment facilities to be consistent with state and federal law and to establish:

(1) Standards for determining what constitutes a high dose of the opioid employed in treatment at a nonresidential office-based opiate treatment facility;

(2) Protocols for initiating or switching a patient at a nonresidential office- based treatment facility to a high dose of the opioids employed in treatment; and

(3) Protocols for initiating periodic prescriber-initiated-and-led discussions with patients regarding patient readiness to taper down or taper off the opioids employed in treatment.

(i) The commissioner is authorized to use emergency rulemaking under §4-5-208 to promulgate the rules pursuant to subsection (h). The rules must be promulgated in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5.

(j)(1) Beginning in 2020, the commissioner of mental health and substance abuse services shall review the rules for nonresidential office-based opiate treatment facilities by September 30 of each even-numbered year.

(2) The commissioner of mental health and substance abuse services shall submit the rules for nonresidential office-based opiate treatment facilities to each health-related board that licenses any practitioner authorized by the state to prescribe the products for the treatment of an opioid use disorder as defined in the Diagnostic and Statistical Manual of Mental Disorders and to the board of pharmacy.

(3)(A) Each board shall review the rules and enforce the rules with respect to that board's licensees.

(B) When a board's licensees are subject to the rules for nonresidential office-based opiate treatment facilities, the definition of "enforce" for purposes of this subdivision (j)(3) means referring any complaints or information regarding those licensees to the department.

(4) Each board shall post the rules on the licensing board's website.

(k)(1) The commissioner of mental health and substance abuse services shall provide a copy of any emergency rule developed pursuant to subsection (h) or (i) and any revision to a rule developed pursuant to subsection (j) to the chairs of the health committee of the house of representatives and the health and welfare committee of the senate at the same time the rules are submitted to the licensing boards pursuant to subdivision (j)(2).

(2) The commissioner of mental health and substance abuse services shall provide a copy of any rule developed pursuant to subsection (h) or (j) and any revision to a rule developed pursuant to subsection (j) to the chairs of the health committee of the house of representatives and the health and welfare committee of the senate at the same time the text of the rule is made available to the government operations committees of the senate and the house of representatives for purposes of conducting the review required by § 4-5-226 in order for the health committee of the house of representatives and the health and welfare committee of the senate to be afforded the opportunity to comment on the rule.

(l) A violation of a rule described in subsection (h) and (j) is grounds for disciplinary action against a practitioner licensed under title 63 by the board that licensed that practitioner.

SECTION 4. Tennessee Code Annotated, Section 33-2-406(h), is amended by designating the existing language as subdivision (h)(1) and adding the following as a new subdivision (h)(2):

(2)(A) Notwithstanding this part, beginning July 1, 2018, the licensing fee for a nonresidential office-based opiate treatment facility is one thousand five hundred dollars ($1,500) per year. On or after July 1, 2019, the department may revise the fee by rule as otherwise permitted by law.

(B) Notwithstanding this part, beginning July 1, 2018, the department shall apply a reinspection fee of five hundred dollars ($500) to a nonresidential office- based opiate treatment facility. On or after July 1, 2019, the department may revise the fee by rules as otherwise permitted by law.

SECTION 5. Tennessee Code Annotated, Section 63-1-403, is amended by adding the following as subsection (c) and redesignating existing subsection (c) and remaining subsections accordingly:

(c) By July 1, 2019, the commissioner of mental health and substance abuse services, in collaboration with the commissioner of health, shall revise the nonresidential buprenorphine treatment guidelines to be consistent with state and federal law and establish protocols for initiating periodic prescriber-initiated-and-led discussions with patients regarding patient readiness to taper down or taper off opioids employed in treatment. The commissioner of mental health and substance abuse services shall consult with appropriate physicians, alcohol and substance abuse counselors, and other experts to serve as resources in the development of guidelines under this subsection (c).

SECTION 6. Tennessee Code Annotated, Sect on 53-10-304, is amended by adding the following as a new subsection (e):

(e) Notwithstanding subsection (c) or (d), a healthcare practitioner shall submit the dispensing of buprenorphine products in accordance with this part. However, this subsection (e) does not apply to a practitioner when reporting the dispensing of buprenorphine products would conflict with 42 CFR part 2.

SECTION 7. Tennessee Code Annotated, Section 53-11-311, is amended by adding the following as a new subsection:

( )(1)(A) Notwithstanding any other law, the dispensing of buprenorphine products is prohibited by any person or entity unless the dispensing is done by a nonresidential office-based opiate treatment facility, as defined in §33-2-402, with approval from the department of mental health and substance abuse services, a nonresidential substitution-based treatment center for opiate addiction as defined in § 33-2-402, a pharmacy licensed under title 63, chapter 10, or a hospital licensed under title 33, or title 68, chapter 11. This subsection ( ) does not apply to the administering of buprenorphine products as otherwise permitted by law.

(B) A pharmacy and a distributor, as defined in § 63-10-204, shall report to the department of health the quantities of buprenorphine that the pharmacy or distributor delivers to nonresidential office-based opiate treatment facilities in this state.

(2) The department of mental health and substance abuse services shall promulgate rules to establish requirements for approval of dispensing of buprenorphine products at a nonresidential office-based opiate treatment facility as defined in § 33-2-402. These rules shall include a requirement that a provider who dispenses buprenorphine products at a nonresidential office-based opiate treatment facility must report the fact that the provider dispenses buprenorphine products to the provider's licensing board, check the controlled substance database prior to dispensing, and enter the amounts dispensed into the controlled substance database, to the extent permitted by 42 CFR part 2.

SECTION 8. Tennessee Code Annotated, Section 68-1-128(a)(1), is amended by deleting the language "controlled substances in the previous calendar year" and substituting instead the language "controlled substances, other than buprenorphine formulations that have not received approval for pain applications from the federal food and drug administration, in the previous calendar year".

SECTION 9. Tennessee Code Annotated, Section 68-1-128(a)(1), is amended by designating the existing language as subdivision (a)(1)(A) and adding the following as a new subdivision (a)(1)(B):

(B) Identify the top twenty (20) prescribers who have unique DEA numbers of buprenorphine products or equivalent products in the previous calendar year, or if implemented more frequently for the relevant time period as determined by the department, from the data available in the controlled substances database established pursuant to title 53, chapter 10, part 3. The department may organize the list of prescribers required by this subdivision (a)(1)(8) in any manner as may be appropriate to reflect levels of service, training, or other relevant factors by a healthcare provider. These factors may include, but not be limited to, whether the provider is board-certified.

SECTION 10. Tennessee Code Annotated, Section 68-1-128(a)(3), is amended by deleting the language "list" and substituting the language "lists".

SECTION 11. Tennessee Code Annotated, Section 68-1-128(b)(1)(A), is amended by deleting the language "on the top fifty (50) prescribers of controlled substances in the state and the top ten (10) prescribers" and substituting instead the language "on the lists of the top twenty (20) prescribers of buprenorphine products, the top fifty (50) prescribers of controlled substances in the state, and the top ten (10) prescribers".

SECTION 12. Tennessee Code Annotated, Section 68-1-128, is amended by adding the following as new subsections:

(h)(1) After the completion of the study provided for in subdivision (i)(1), and no later than July 31 of each subsequent year, in consultation with the controlled substance database, the department of health shall identify licensed prescribers whose prescribing patterns of controlled substances represent statistical outliers in addition to top prescribers and high-risk prescribers identified pursuant to this section.

(2) The department of health shall inquire of the appropriate licensing board concerning any action taken against a prescriber identified by the department pursuant to subdivision (h)(1). Each board shall respond within thirty (30) days concerning the status of any action or lack of action against an identified prescriber.

(3) Each board shall also report on the total numbers of prescribers disciplined each year and the general categories of discipline imposed on the prescribers, including consent agreements, as well as reasons for declining to exercise discipline.

(4) The commissioner of health shall report a summary of the data concerning prescribers identified under this subsection (h), including a summary of any disciplinary action taken or pending by a licensing board against a prescriber, to the chairs of the health and welfare committee of the senate and the health committee of the house of representatives.

(i)(1) On or before January 1, 2020, the comptroller of the treasury shall complete a study of the incidence of significantly statistically abnormal prescribing patterns by prescribers licensed under title 63 and the disciplinary response of the licensing boards to those prescribers. The comptroller shall report findings and recommendations of the study to the chairs of the health and welfare committee of the senate and the health committee of the house of representatives.

(2) Notwithstanding any other state law, the department of health, the controlled substance database, and a licensing board of any prescriber of opioids shall disclose to the comptroller of the

treasury any relevant information in order for the comptroller to complete this study from July 1, 2018, through June 30, 2020. Any record that personally identifies a patient or a healthcare practitioner that is disclosed to the comptroller shall be confidential and shall not be disclosed as a public record at any time and shall not be subject to a subpoena.

SECTION 13. Tennessee Code Annotated, Title 63, Chapter 1, Part 1, is amended by adding the following as a new section:

(a) If a healthcare practitioner treats a human patient with an opioid and that healthcare practitioner's licensing board or agency finds that the healthcare practitioner engaged in a significant deviation or pattern of deviation from sound medical judgment, the minimum disciplinary action that a healthcare practitioner's licensing board or committee must take shall be established and promulgated by rule by a task force composed of representatives from:

(1) The board of medical examiners;

(2) The board of osteopathic examination;

(3) The board of dentistry;

(4) The board of podiatric medical examiners;

(5) The board of optometry;

(6) The board of nursing; and

(7) The board of medical examiners' committee on physician assistants.

(b) The task force must create a uniform minimum disciplinary action pursuant to this section, which shall be binding on each board and committee listed in subsection (a).

(c) The task force is authorized to establish minimum disciplinary actions pursuant to this section by emergency rule in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5. The rule promulgated by the task force shall be codified and published by the secretary of state in each of the chapters for the boards and committee listed in subsection (a).

(d)(1) Each board and committee listed in subsection (a) must select and appoint by majority vote one (1) member of their respective board or committee to serve on the task force before September 1, 2018.

(2) The task force shall select and appoint a member to serve as chair of the task force.

(3) A majority of the task force shall constitute a quorum, and a majority vote of the task force members present is required for any action.

(4) Notwithstanding any provision of the Uniform Administrative Procedures Act to the contrary, the task force shall hear public comment at any required hearing on behalf of all boards listed in subsection (a) when a hearing is required. The task force is authorized to vote to promulgate the rule to establish the uniform minimum disciplinary action for each board and committee listed in subsection (a).

(e) In the event that the task force has not promulgated uniform minimum disciplinary actions by April 1, 2019, then the minimum disciplinary action that a healthcare practitioner's licensing board or agency must take is a removal of the healthcare practitioner's right to prescribe controlled substances for no less than five (5) years.

(f) The task force shall terminate upon the later of July 1, 2019, or the effective date of a permanent rule establishing the uniform minimum disciplinary action pursuant to this section. The procedures of this section must be followed to amend, repeal, or otherwise revise the uniform minimum disciplinary action established pursuant to this section. In such case, the task force may be reconvened by the commissioner of health or a majority of the boards and committees listed in subsection (a).

(g) Nothing in this part shall be construed to prohibit the licensing boards and committee listed in subsection (a) from promulgating rules regarding other minimum disciplinary actions that will be taken against their licensees.

SECTION 14. Section 13 of this act shall terminate on July 1, 2023, and the law in effect prior to this act's effective date shall be restored.

SECTION 15. For rulemaking purposes, this act shall take effect upon becoming a law, the public welfare requiring it. For all other purposes, this act shall take effect July 1, 2018, the public welfare requiring it.