Tennessee Nonresidential Buprenorphine Treatment Guidelines

(Fall 2021 Update)

TN Department of Mental Health & Substance Abuse Services

TN Department of Health

(MONTH AND DAY), 2021

Dear Friends and Colleagues,

We are pleased to share with you the Fall 2021 update of the Tennessee Nonresidential Buprenorphine Treatment Guidelines.

Working collaboratively the Tennessee Department of Mental Health and Substance Abuse Services (TDMHSAS) along with the Tennessee Department of Health (TDOH) developed these guidelines in response to the enactment of Public Chapter 112 in 2017. Since that time the chronic, relapsing disease of opioid use disorder (OUD) has continued to be a prevalent health concern effecting Tennesseans. Conclusive evidence shows that medications are the gold standard of treatment for OUD. Buprenorphine continues to be an important mainstay of recovery for many individuals in Tennessee. The TDMHSAS and TDOH continue to acknowledge the importance of treatment guidelines to promote the highest standard of care for individuals pursuing medication as part of their recovery journey. Additionally, practice guidelines seek to reduce the risk of diversion associated with buprenorphine.

To ensure that these Guidelines continue to incorporate the most current evidence, a group of clinical experts, policy makers, and other esteemed stakeholders met on September 1st of 2021 to review the national guidelines published in the Spring of 2020 by the American Society of Addiction Medicine (ASAM). These individuals formed the third generation of the Buprenorphine Treatment Guidelines Committee. Thoughtful consideration was given to how these national changes should be incorporated into the Tennessee Nonresidential Buprenorphine Treatment Guidelines. The culmination of the Committee's hard work is this Fall 2021update to the Guidelines.

We thank you for your support as we continuously aim to improve these Guidelines. We appreciate your willingness to provide hope through evidence-based care in your individual communities across Tennessee. We continue to recommend that as you provide care using buprenorphine-containing products to treat individuals with an OUD in a nonresidential setting that you closely regard these Guidelines. Together, we can ensure that all patients using medications in their recovery process from OUD receive the best quality of care.

Sincerely,

Marie Williams, LCSW
Commissioner
TDMHSAS

Lisa Piercey, MD, MBA, FAAP
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 2021 review meeting of these guidelines:

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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 (i.e. driver's license, state-issued identification, etc.).

2. All prospective patients must be given an 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 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. Document the prospective patient's process addictions, if any, and document how they can interfere with the prospective patient's recovery from substance use.
    e. Assess comorbid medical and psychiatric conditions and disorders and to determine how, when, and where they will be addressed.
    f. Screen prospective patient for communicable diseases and address them as needed.
    g. Evaluate the prospective patient's level of physical, psychological, and social functioning or impairment.
    h. Assess the prospective patient's social supports, such as family and friends, employment status, housing status, financial status, and any legal issues.
    i. Determine the prospective patient's readiness to participate in treatment (See **APPENDIX D.1** as an example).
    j. Determine the prospective patient's wishes with respect to pregnancy.

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 a drug test for the prospective patient prior to initiating buprenorphine treatment and the results of this test shall be documented.

B. PATIENT SELECTION

1. Buprenorphine treatment may be appropriate for individuals meeting the following:
    a. Interested in opioid use disorder treatment (See **Appendix D.1** as an example).
    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 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 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.

2. See **APPENDIX H** for sample consent to release information document.

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 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.

2. See **APPENDIX G** for sample buprenorphine consent to treatment form.

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 child-bearing 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 to become 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, 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.

F. REQUIREMENTS FOR BENZODIAZEPINE CO-PRESCRIBING

1. Benzodiazepines should only be prescribed to a patient after careful evaluation while utilizing caution and good judgement. 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 by a DATA waived prescriber. 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 with a DATA 2000 waiver 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.

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 T.C.A. § 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. The consensus of the Buprenorphine Treatment Guidelines Committee is that 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.
    c. If the prescriber of buprenorphine without naloxone is treating a patient that is pregnant or nursing and 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.

B. SELECTING A THERAPY

1. When to start buprenorphine, whether with or without naloxone.
    a. Patient will likely feel he/she is in early stages of withdrawal. Prescriber may consider suggesting that the patient return during opioid 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 (See **APPENDIX I**).
    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 **APPENDICES R and S.2**.) 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.

C. GENERAL DOSING GUIDELINES

1. For offices offering in-office induction: Induction should be conducted according to standards established by the American Society of Addiction Medicine and using the buprenorphine-containing product package insert (See **APPENDIX I**). Target buprenorphine dose range should be 4 mg to 16 mg (or equivalent) per day (See **APPENDIX O**).

D. PATIENT MANAGEMENT

1. Assessment of a patient
    a. An assessment of a patient shall include documentation of a physical exam by an appropriate provider (See **APPENDIX J** as an example). 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.
    b. Patient 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. An assessment of a patient shall include an evaluation of the need for trauma-informed care, including obtaining an Adverse Childhood Experiences (ACEs) score (See **APPENDIX M**).
    d. 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 soon thereafter.

2. Provider shall obtain a signed individualized treatment plan upon initiation of treatment, which shall be documented in the patient's medical record.

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 N**).
    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 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 education 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 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 child-bearing 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. Patient 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 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.

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 semi-synthetic opioid.

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. "DATA 2000 Waiver" means the registered authority given to a qualified health care professional by the U.S. Drug Enforcement Administration to prescribe FDA-approved narcotic medication for opioid detoxification or maintenance treatment pursuant to 21 U.S.C. §823(g).

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

7. "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.

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

9. "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.

10. "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.

11. "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.

12. “Patient” shall refer to an individual receiving treatment for opioid use disorder by a licensed provider.

13. “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).

14. “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.

15. “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.

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

17. “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.

18. “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.* 0 pulse rate 80 or below 1 pulse rate 81-100 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.* 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.* 0 able to sit still 1 report difficulty sitting still, but is able to do so 3 frequent shifting or extraneous movements of legs/arms 5 unable to sit still for more than a few seconds			
Pupil Size: 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.* 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.* 0 not present 1 nasal stuffiness or unusually moist eyes 2 nose running or tearing 4 nose constantly running or tears streaming down cheeks			
GI Upset: *Over last ½ hour* 0 no GI symptoms 1 stomach cramps 2 nausea or loose stools 3 vomiting or diarrhea 5 multiple episodes of diarrhea or vomiting			
Tremor: *Observation of outstretched hands* 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* 0 no yawning 1 yawning once or twice during assessment 2 yawning three or more times during assessment 4 yawning several times/minute			
Anxiety or Irritability 0 none 1 patient reports increasing irritability or anxiousness 2 patient obviously irritable, anxious 4 patient so irritable or anxious that participation in the assessment is difficult			
Gooseflesh skin 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.1. - SOCRATES: Patient Readiness Assessment

Source: TIP 35: Enhancing Motivation for Change in Substance Abuse Treatment. SAMHSA

INSTRUCTIONS: Please read the following statements carefully. Each one describes a way that you might (or might not) feel about your drug use. For each statement, circle one number from 1 to 5, to indicate how much you agree or disagree with it right now. Please circle one and only one number for every statement.

	Strongly Disagree	Disagree	Unsure	Agree	Strongly Agree
1. I really want to make changes in my use of drugs.	1	2	3	4	5
2. Sometimes I wonder if I am an addict.	1	2	3	4	5
3. If I don't change my drug use soon, my problems are going to get worse.	1	2	3	4	5
4. I have already started making some changes in my use of drugs.	1	2	3	4	5
5. I was using drugs too much at one time, but I've managed to change that.	1	2	3	4	5
6. Sometimes I wonder if my drug use is hurting other people.	1	2	3	4	5
7. I have a drug problem.	1	2	3	4	5
8. I'm not just thinking about changing my drug use; I'm already doing something about it.	1	2	3	4	5
9. I have already changed my drug use, and I am looking for ways to keep from slipping back to my old pattern.	1	2	3	4	5
10. I have serious problems with drugs.	1	2	3	4	5
11. Sometimes I wonder if I am in control of my drug use.	1	2	3	4	5
12. My drug use is causing a lot of harm.	1	2	3	4	5
13. I am actively doing things now to cut down or stop my use of drugs.	1	2	3	4	5
14. I want help to keep from going back to the drug problems that I had before.	1	2	3	4	5
15. I know that I have a drug problem.	1	2	3	4	5
16. There are times when I wonder if I use drugs too much.	1	2	3	4	5
17. I am a drug addict.	1	2	3	4	5
18. I am working hard to change my drug use.	1	2	3	4	5
19. I have made some changes in my drug use, and I want some help to keep from going back to the way I used before.	1	2	3	4	5

APPENDIX D.2. - SOCRATES Scoring Form - 19-Item Versions 8.0

Source: TIP 35: Enhancing Motivation for Change in Substance Abuse Treatment. SAMHSA

SOCRATES Scoring Form - 19-Item Versions 8.0

Transfer the client's answers from questionnaire (see note below):

Recognition	Ambivalence	Taking Steps
1 _____	2 _____	
3 _____		4 _____
		5 _____
	6 _____	
7 _____		8 _____
		9 _____
10 _____	11 _____	
12 _____		13 _____
		14 _____
15 _____	16 _____	
17 _____		18 _____
		19 _____
TOTALS		
Re_____	Am_____	Ts_____
Possible Range:		
7-35	4-20	8-40

INSTRUCTIONS: From the SOCRATES Scoring Form (19-Item Version) transfer the total scale scores into the empty boxes at the bottom of the Profile Sheet. Then for each scale, CIRCLE the same value above it to determine the decile range.

DECILE SCORES	Recognition	Ambivalence	Taking Steps
90 Very High		19-20	39-40
80		18	37-38
70 High	35	17	36
60	34	16	34-35
50 Medium	32-33	15	33
40	31	14	31-32
30 Low	29-30	12-13	30
20	27-28	9-11	26-29
10 Very Low	7-26	4-8	8 - 25
RAW SCORES (from Scoring Sheet)	Re =	Am =	Ts =

APPENDIX D.3. - Guidelines for Interpretation of SOCRATES-8 Scores

Source: TIP 35: Enhancing Motivation for Change in Substance Abuse Treatment. SAMHSA

Using the SOCRATES Profile Sheet, circle the client's raw score within each of the three scale columns. This provides information as to whether the client's scores are low, average, or high relative to people already seeking treatment for alcohol problems. The following are provided as general guidelines for interpretation of scores, but it is wise in an individual case also to examine individual item responses for additional information.

RECOGNITION

HIGH scorers directly acknowledge that they are having problems related to their drinking, tending to express a desire for change and to perceive that harm will continue if they do not change.

LOW scorers deny that alcohol is causing them serious problems, reject diagnostic labels such as "problem drinker" and "alcoholic," and do not express a desire for change.

AMBIVALENCE

HIGH scorers say that they sometimes wonder if they are in control of their drinking, are drinking too much, are hurting other people, and/or are alcoholic. Thus a high score reflects ambivalence or uncertainty. A high score here reflects some openness to reflection, as might be particularly expected in the contemplation stage of change.

LOW scorers say that they do not wonder whether they drink too much, are in control, are hurting others, or are alcoholic. Note that a person may score low on ambivalence either because they "know" their drinking is causing problems (high Recognition), or because they "know" that they do not have drinking problems (low Recognition). Thus a low Ambivalence score should be interpreted in relation to the Recognition score.

TAKING STEPS

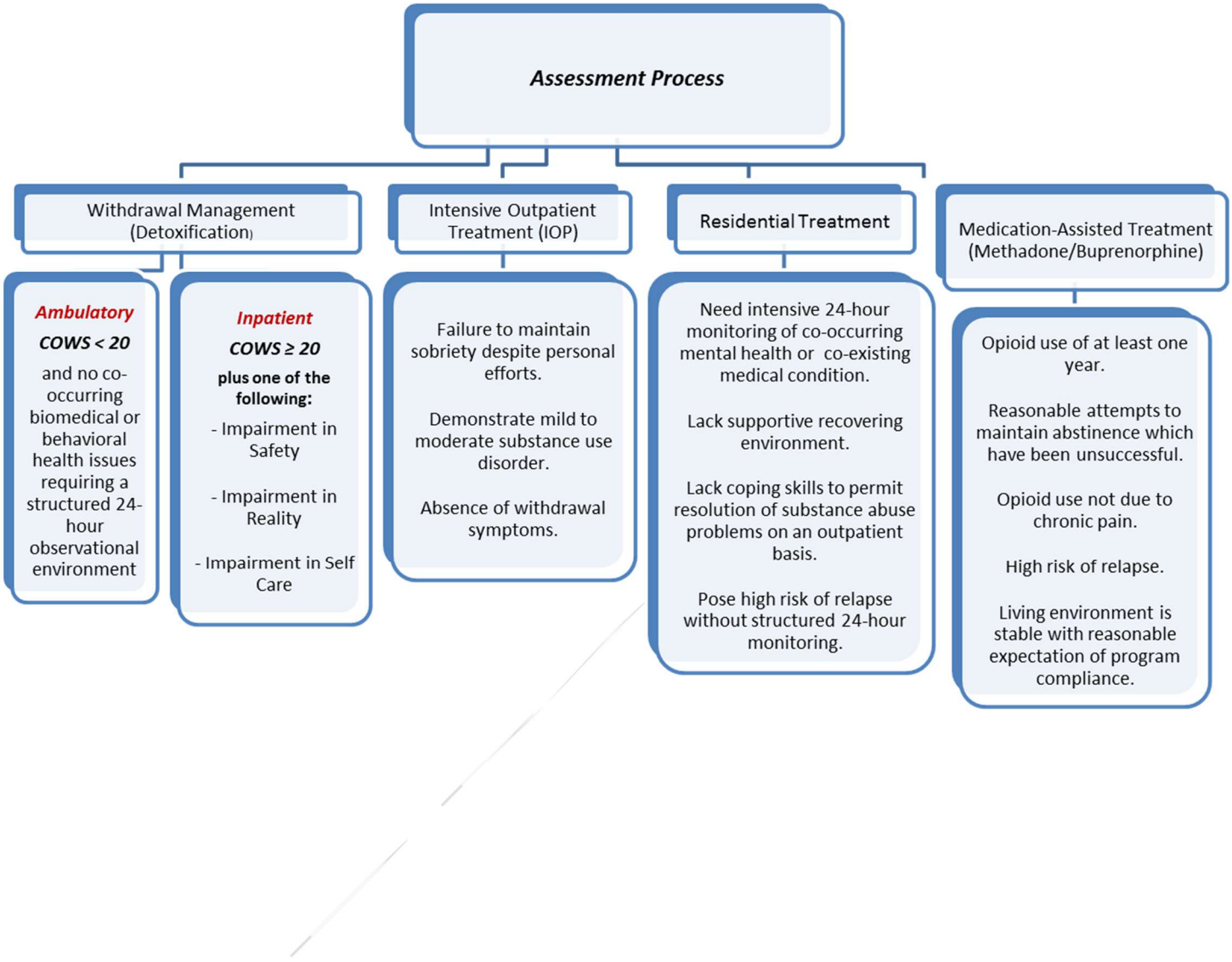
HIGH scorers report that they are already doing things to make a positive change in their drinking, and may have experienced some success in this regard. Change is underway, and they may want help to persist or to prevent backsliding. A high score on this scale has been found to be predictive of successful change.

LOW scorers report that they are not currently doing things to change their drinking, and they have not made such changes recently.

APPENDIX E - Assessment Process Chart

Provided by: Dr. Burley, Dr. Carter, and Dr. Villanueva - TDMHSAS

Disclaimer: The below chart is to be used as a general guide and not dictate patient placement criteria.



APPENDIX F – Sample Patient Agreement

Source: Dr. Richard Soper

PATIENT NAME: _____

PRIMARY CARE PHYSICIAN/SITE: _____

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

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

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

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

  _____

  _____

- The daily dose may not be changed without my (insert name of medical group) primary care physician's consent. This includes either increasing or decreasing the daily dose.
- Prescription refills will not be given prior to the planned refill date determined by the dose and quantity prescribed. I will accept generic medications.
- Accidental destruction, loss of medications or prescriptions will not be a reason to refill medications or rewrite prescriptions early. I will safeguard my controlled substance medications from use by family members, children or other unauthorized persons.

- You may be referred to an appropriate specialist to evaluate your physical condition.
- You may be asked to have an evaluation by either a psychiatrist or psychologist to help manage your medication needs.
- If your physician determines that you are not a good candidate to continue with the medication, you may be referred to a detoxification program or evaluation by a pain management center.
- These medications may be discontinued or adjusted at your physician's discretion.
- I understand that it is my physician's policy that all appointments must be kept or cancelled at least 2-working days in advance. I understand that the original bottle of each prescribed controlled substance medication must be brought to every visit.

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

Patient's Signature	Witness' Signature
Date	Date

APPENDIX G - Sample Buprenorphine Consent to Treatment Form

Source: Dr. Richard Soper

Buprenorphine is a medication approved by the Food and Drug Administration (FDA) for treatment of people with opioid dependence. Qualified physicians can treat up to 30 patients for opiate dependence. Buprenorphine can be used for detoxification or for maintenance therapy. Maintenance therapy can continue as long as medically necessary.

Buprenorphine itself is an opioid, but it is not as strong an opioid as heroin or morphine. Buprenorphine treatment can result in physical dependence of the opiate type. Buprenorphine withdrawal is generally less intense than with heroin or methadone. If buprenorphine is suddenly discontinued, some patients have no withdrawal symptoms; others have symptoms such as muscle aches, stomach cramps, or diarrhea lasting several days. To minimize the possibility of opiate withdrawal, buprenorphine should be discontinued gradually, usually over several weeks or more.

If you are dependent on opiates, you should be in as much withdrawal as possible when you take the first dose of buprenorphine. It you are not in withdrawal, buprenorphine may cause significant opioid withdrawal. For that reason, you should take the first dose in the office and remain in the office for observation. Within a few days, you will have a prescription for buprenorphine that will be filled in a pharmacy.

Some patients find that it takes several days to get used to the transition from the opioid they had been using to buprenorphine. During that time, any use of other opioids may cause an increase in symptoms. After you become stabilized on buprenorphine, it is expected that other opioids will have less effect. Attempts to override the buprenorphine by taking more opioids could result in an opioid overdose. You should not take any other medication without discussing it with me first.

Combining buprenorphine with alcohol or some other medications may also be hazardous. The combination of buprenorphine with medication such as Valium, Librium, Ativan has resulted in deaths.

The form of buprenorphine you may be taking is a combination of buprenorphine with a short-acting opiate blocker (naloxone). If the Buprenorphine tablet were dissolved and injected by someone taking heroin or another strong opioid, it could cause severe opiate withdrawal.

Buprenorphine tablets must be held under the tongue until they dissolve completely. Buprenorphine is then absorbed over the next 30 to 120 minutes from the tissue under the tongue. Buprenorphine will not be absorbed from the stomach if it is swallowed.

_____

Signature Print Name Date

APPENDIX H - Sample Consent for Release of Information

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

CONSENT FOR RELEASE OF CONFIDENTIAL INFORMATION

Patient Name: _____ Patient ID: _____

I,_____,_____-_____-_____ , _____/_____/ _____
(name of patient) (Social security number) (date of birth)

Authorize **To release to and obtain from:** (name/address/phone # of receiving agency)

_____ _____
_____ _____
_____ _____
_____ _____

The information listed below is being released for the following purpose: _____

Release/Discharge Summary	**After Care**	**Medications**
Assessments:	**Billing Records**	**Progress Notes**
Nursing	**Discharge Plans**	**Treatment Plans**
☐ Physical	**Doctor Orders**	**X-Rays**
☐ Psychiatric	**Lab Reports**	
☐ Psychosocial	**Letter of Admits And Release Dates**	
☐ Psychology	**Other –** [List Specific Document(s)]	

Date, Event, or Condition when Consent expires: _____

I understand that treatment services are NOT contingent upon or influenced by my decision to permit the release of information. I also understand that I, or my legally authorized representative, may revoke this consent in writing at any time unless action has already been taken based upon it. I freely and voluntarily give this consent.

I understand the records requested may be protected under 42 C.F.R. Part 2, governing Alcohol and Drug Abuse patient records, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), 45 C.F.R. pts. 160 & 164, State Confidentiality laws and regulations and cannot be released without my consent unless otherwise provided for by regulations. State and Federal law regulations prohibit any further disclosure of such records without my specific written consent or when otherwise permitted by such regulation.

THE INFORMATION I AUTHORIZE TO RELEASE MAY INCLUDE RECORDS WHICH MAY INDICATE THE PRESENCE OF A COMMUNICABLE OR VENEREAL DISEASE WHICH MAY INCLUDE, BUT IS NOT LIMITED TO DISEASES SUCH AS SYPHILIS, GONORRHEA, AND THE HUMAN IMMUNODEFICIENCY VIRUS, ALSO KNOWN AS ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS).

Patient Signature: _____ Date: _____

Witness Signature: _____ Date: _____

CONSENT FOR RELEASE OF CONFIDENTIAL INFORMATION

Patient Name: _____ Patient ID: _____

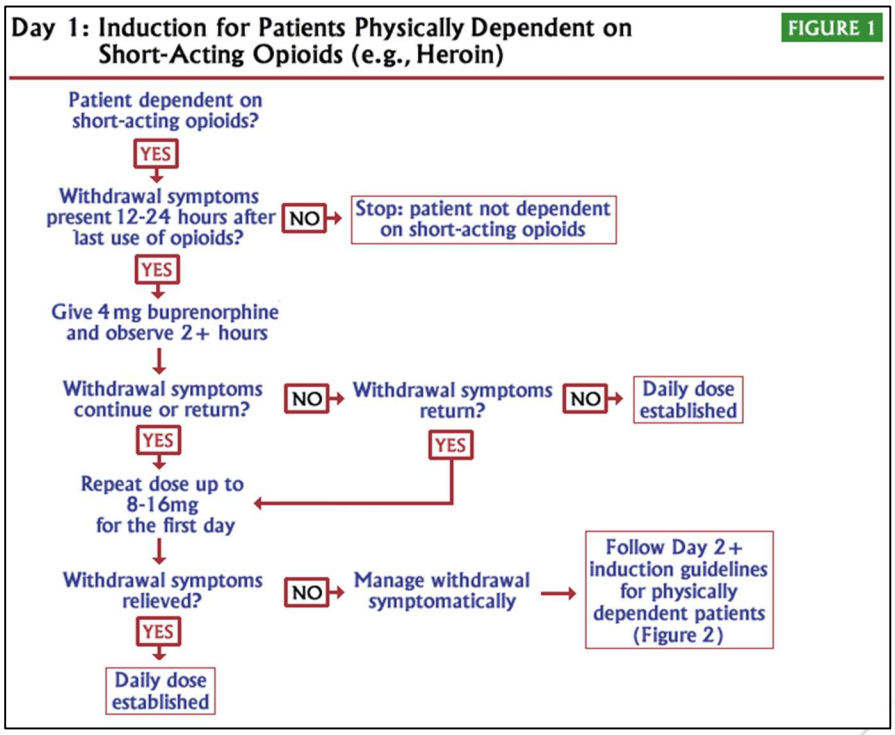
Revocation:

Patient Signature: _____ Date: _____

Witness Signature: _____ Date: _____

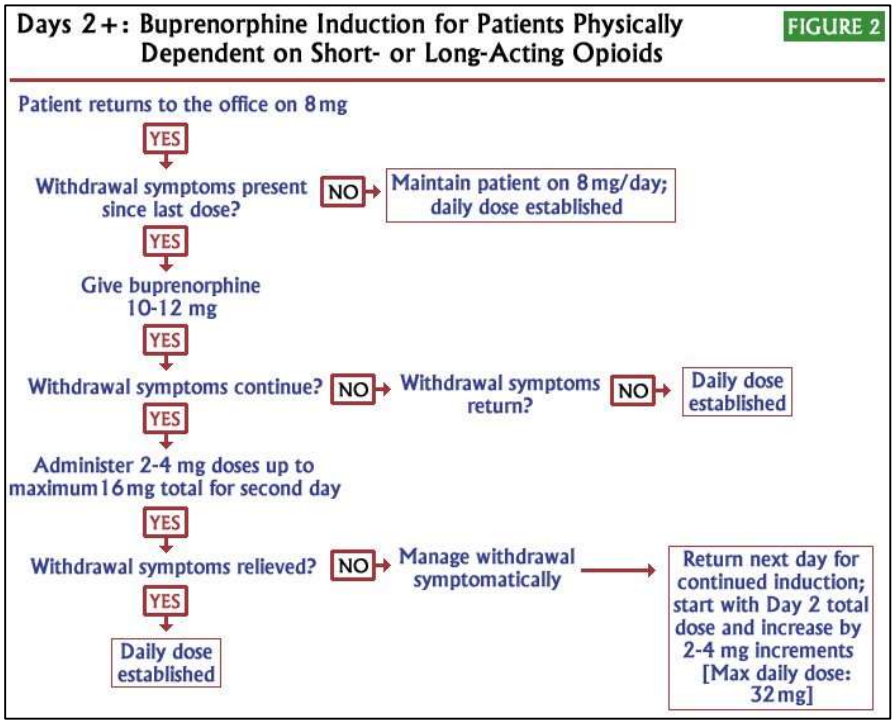
APPENDIX I - Sample Induction for Patients Dependent on Short or Long-Acting Opioids

Source: Buppractice



Patient should not have had Methadone > 35 mg per day in the last week or ≤ 35 mg per day in the last 48 hours, or longer. Patient should be exhibiting withdrawal symptoms before dosing with buprenorphine.

Patient should not have taken benzodiazepines (BDZ) in the last 12-24 hours.



Patients on methadone should be tapered down to ≤ 30 mg per day for at least 1 week. Buprenorphine can be started ≥ 24 hours, or longer, after patient's last methadone dose. Patient should be exhibiting withdrawal symptoms before dosing with buprenorphine.

Per the ASAM National Practice Guideline for the Treatment of Opioid Use Disorder: 2020 Focused Update, it is recommended to initiate buprenorphine at a dose of 2 mg to 4 mg. This dosage may be increased in increments of 2 mg to 8 mg to a dose of 4 mg to 16 mg per day to suppress withdrawal.

APPENDIX J – 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

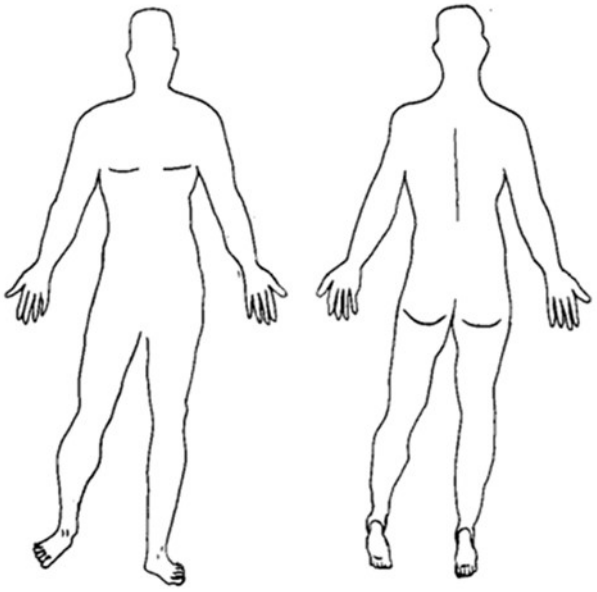
- ☐ New Tracks
- ☐ Contracted Pupila
- ☐ Constipation
- ☐ Slurred Speech
- ☐ Nystagmus
- ☐ Staggering Gait

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 K - Suggested Sleep Hygiene

The relationship between Sleep Disturbances & Substance Use Disorders

Guidance on how to assess and treat sleep problems for patients in recovery

- Sleep problems vary by substance used & can include insomnia, sleep latency (the time it takes to fall asleep) disturbances in sleep cycles, or daytime sleepiness.
- People detoxing from opioids often report symptoms of insomnia, and 25-75% of people with alcohol use disorder (AUD) have symptoms before even entering treatment.
- Marijuana users may experience trouble sleeping from the first few days of withdrawal, up to weeks afterwards.
- In a study of college students, users of stimulants reported increased sleep disturbances & worse sleep quality.
- A study that objectively measured sleep in abstaining cocaine users found their sleep quality to be deteriorating, despite their perception that it was improving.
- Sleep loss can interfere with substance use treatment and have significant negative effects on the physical, mental, and emotional well-being of people in recovery.

What Providers Can Do:

- Screen for insomnia among people in recovery from substance use disorder (SUD). Rule out causes of sleep problems such as stress, mental and medical disorders, nicotine use, and medications that disturb sleep.
- Educate patients on good sleep hygiene & keeping a sleep diary.
- Conduct careful evaluations prior to prescribing sedative-hypnotic medications. Benzodiazepines and non-benzodiazepines have the potential for abuse and can interfere with SUD recovery.
- Medications without known abuse potential should be the first treatment option when drug therapy is necessary to treat insomnia during recovery. This includes the dietary supplement melatonin, as well as ramelteon and doxepin, the only unscheduled prescription medications approved by the FDA for the treatment of insomnia.
- Off-label meds without known abuse potential include trazodone, amitriptyline, mirtazapine, nefazodone, & nortriptyline.

:)

GOOD SLEEP HYGIENE

Go to bed & get up at the same times each day. Use natural light to remind yourself when it's time to be asleep & awake. Exercise regularly. Do not take naps after 5 PM. Do not eat or drink too much at bedtime. Avoid caffeine, nicotine, TV, and phones before bedtime. Try winding down before bed with a bath

Zzz

NON-DRUG THERAPY

- Mindfulness meditation
- Muscle relaxation
- Biofeedback practice
- CBT for insomnia
- Stimulus control exercises
- Sleep restriction therapy
- Bright light therapy
- Dental devices and continuous positive airway pressure machines for obstructive sleep apnea

Adapted from *Treating Sleep Problems of People in Recovery from Substance Use Disorders*. For more information, visit www.samhsa.gov.

Sleeping pills digital image.; 2015. Available at: https://speedsleep.com/wp-content/uploads/2012/05/Prescription-drugs.jpg. Accessed September 15, 2017.

APPENDIX L - Special Populations

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

L.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.
- Treatment should include family therapy, a twelve-step based program, and assessment of causative factors.

L.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 R)**

Chronic pain and substance use disorders have similar physical, social, emotional, and economic effects on health and well-being. Patients with one or both of these 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.

L.3. WOMEN WHO ARE PREGNANT OR BREASTFEEDING

According to the ASAM Guidelines, 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.

- Buprenorphine should be considered when the prescriber believes the benefits outweigh the risks.
- Patients already maintained and stable on buprenorphine who become pregnant probably should continue it with close monitoring.
- Clear documentation in the patient's chart of the patient's awareness that there is insufficient data about the safety of buprenorphine in pregnancy is essential.
- Monthly drug screens should be performed during pregnancy. Emphasis should be made on maintaining documentation of drug screens in the patient's record.
- Coordination of care with OB/GYN, if different from buprenorphine provider, should be made. Buprenorphine provider should have documentation in patient's chart documenting this coordination of care.
- Patient's pharmacist should be consulted to determine that patients are picking up their medications, including those for prenatal care (i.e. prenatal vitamins, etc.), to determine adherence to their treatment regimen.
- 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.
- 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 (See Subsection A.1.b. of Section II).
- 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.

L.4. 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 the 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.

L.5. 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.

L.6. BUPRENORPHINE AND LIVER DISEASE (INCLUDING HEPATITIS C)

Current guidelines recommend that patients not be offered buprenorphine treatment if their transaminases (AST or ALT) are elevated more than three to 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.

L.7. BUPRENORPHINE AND HIV

Treatment with methadone or buprenorphine has been shown to reduce frequency of drug use and to reduce HIV risk 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 abusers are unable to maintain total abstinence from substance abuse after the abrupt discontinuation at the start of treatment. In dealing with clients' ongoing substance abuse, treatment programs must find a balance between abstinence and public health approaches to substance abuse treatment.

APPENDIX M – 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 N – 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 O - Suggested Dosing for In-Office Induction

Source: Adapted from Vermont Buprenorphine Guidelines.
http://dvha.vermont.gov/for-providers/buprenorphine-practice-guidelines-revised-final-10-15.pdf

1. These general guidelines should be followed for patients physically dependent on opioids. Patient-specific factors such as: age, co-morbidities, other risks, etc. must be considered when dosing buprenorphine.
    a. Begin induction early in the week.
    b. Plan on a time table of 3-5 days for stable dosing.
    c. Patient's last reported use should have been at least 6 hours prior to induction.
    d. Make sure the patient is not on methadone or other long-acting opioids as buprenorphine may precipitate withdrawal if it too closely follows long-acting opioids. (If patient is on methadone, see Subsection 2 below).
    e. Day 1: Give the patient a prescription for 2 doses of 2 mg (or equivalent) of buprenorphine with naloxone.
    f. Patient takes the prescription to the pharmacy and returns to the office with the medication.
    g. Patient self-administers the medication according to physician's guidance and product instruction in office.
    h. Target buprenorphine dose range should be 6 mg to 12 mg (or equivalent) per day, with a recommended maximum of 16 mg daily.
    i. If more than an 8 mg (or equivalent) dose is needed, gradually increase the dose in 2 mg (or equivalent) increments over the next several days.
    j. The patient's severity of withdrawal symptoms before the next scheduled dosing time is one of the best ways to assess adequacy of the dose. (See **APPENDIX C**).

2. For a more detailed regimen for patient's dependent on short or long acting opioids, see **APPENDIX I**.

Per the ASAM National Practice Guideline for the Treatment of Opioid Use Disorder: 2020 Focused Update, it is recommended to initiate buprenorphine at a dose of 2 mg to 4 mg. This dosage may be increased in increments of 2 mg to 8 mg to a dose of 4 mg to 16 mg per day to suppress withdrawal.

APPENDIX P – Guidelines for Pharmacists

Sources: College of Psychiatric & Neurologic Pharmacists, guideline, opioid use disorder, Suboxone® Medguide

Background

Being recognized by the American Psychiatric Association (APA) in their most recent Diagnostic and Statistical Manual of Mental Disorders, DSM-5, Opioid Use Disorder (OUD) should be recognized and treated as any other disorder. Community pharmacists have the responsibility of providing safe and appropriate access to treatment, while also protecting against misuse and abuse. One of the best methods for distinguishing legitimate use is by collaboration with prescribers.

Buprenorphine is the only opioid agonist medication in the United States that can be prescribed to treat OUD outside of an opioid treatment program. The Drug Addiction Treatment Act of 2000 (DATA 2000), limits prescriptive authority to prescribers that have obtained a waiver, distinguished by an "X" preceding their DEA number. This number along with their regular DEA number must be on the prescription.

Medication-assisted treatment encompasses opioid agonist treatment and opioid antagonist treatment. Buprenorphine can be prescribed to alleviate symptoms of opioid withdrawal, block opioid use, and allow the patient to begin to focus on improving their overall health. Relapse rates without MAT are substantial for opioid use disorder; therefore, long-term treatment may be the goal. Unlike other maintenance medications, buprenorphine may be prescribed in very limited quantities to ensure close follow up, particularly during the induction and stabilization phase. These frequent refills provide a high level of contact at the pharmacy and the opportunity for the pharmacist to actively participate in the patient's treatment. Concerns, progress, and missed doses should be clearly communicated with the provider. Some patients may require more intensive monitoring including provider request for supervised dosing at the pharmacy. It is recommended for the pharmacist to record in the patient's chart a note to prevent them from receiving other opioids without direct permission from their provider. This high level of care can make a significant difference in keeping patients engaged in treatment and achieving remission from OUD.

Pharmacists should review the following resource and incorporate these guidelines into their everyday practice:
http://cpnp.org/guideline/opioid

APPENDIX Q - Available Buprenorphine Formulations

Note: The following list of buprenorphine-containing products are only those that are approved by the Food and Drug Administration for the treatment of an opioid use disorder and may not be a complete list.

Buprenorphine Oral Products

Name	Dosage Forms	Strengths Available (mg)	Manufacturers Available
Zubsolv	Sublingual Tablet	0.7/0.18, 1.4/0.36, 2.9/0.71, 5.7/1.4, 8.6/2.1, 11.4/2.9	Orexo
Suboxone	Sublingual Film	2.0/0.5, 4.0/1.0, 8.0/2.0, 12.0/3.0	Indivior
Buprenorphine/ Naloxone	Sublingual Tablet	2.0/0.5, 8.0/2.0	Actavis, Amneal, Ethypharm, Kremers, Sun, TEVA, West-Ward
Buprenorphine HCL	Sublingual Tablet	2mg, 8mg	Actavis, Barr, Mylan, Sun, West-Ward, Rhodes Pharmaceuticals

Buprenorphine Injectable Products

Name	Dosage Forms	Strengths Available	Manufacturers Available
Sublocade	Monthly Injection (SQ)	100 mg/0.5 ml, 300mg/1.5 ml	Indivior

Buprenorphine Implantable Products

Name	Dosage Form	Strengths Available	Manufacturers Available
Probuphine	Implant (6 months)	74.2mg (4 implants)	Braeburn, USA

References:

LexiComp Drug Reference
Micromedex Drug Reference
Orange Book Drug Reference
Drugs@FDA: FDA Approved Drug Products

APPENDIX R – Tennessee Code Annotated § 53-11-311

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 S.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 S.2 – Public Chapter No. 674 of 2018

State of Tennessee

PUBLIC CHAPTER NO. 674

HOUSE BILL NO.2002

By Representatives Terry, Hawk, Cameron Sexton, Kumar, Favors, Ragan, Powers

Substituted for: Senate Bill No. 2099

By Senators Dickerson, Haile, Crowe, Bowling, Gardenhire

AN ACT to amend Tennessee Code Annotated, Title 53, Chapter 10; Title 53, Chapter 11 and Title 63, relative to buprenorphine.

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

SECTION 1. Tennessee Code Annotated, Section 53-11-311(b)(1) , is amended by adding the following as a new subdivision:

(D) Directly administered the buprenorphine mono or buprenorphine without use of naloxone by a healthcare provider, acting within the healthcare provide(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.

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

APPENDIX S.3 – 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.