Cherokee Health Systems

Addiction Medicine Clinic Operations Manual

1. Background. Cherokee Health Systems (CHS) is an innovator and nationally-recognized leader in integrated care, embedding behavioral health providers alongside primary care providers to provide the full range of patient care. In 2016, CHS took the next step in the evolution of the care model and embedded addiction medicine providers within the existing integrated care structure to offer comprehensive outpatient services, including medication and behavioral therapy, to patients suffering from the disease of addiction.

2. Issue. Patients with substance abuse disorders (SUDs) are unquestionably at increased risk for a number of behavioral and physical health problems; furthermore, substance misuse complicates and/or compromises the treatment of these co-morbid health conditions. There is a clear need for integrated primary and behavioral health service providers to incorporate the treatment of addictive diseases into everyday practice.

3. Overview. The addiction medicine service (AMS) at CHS operates within the framework of the integrated model of care, providing substance use disorder care up to the American Society of Addiction Medicine (ASAM) Level 2.1 treatment placement, intensive outpatient (IOP) with medication management. The clinic staff includes addiction medicine specialists, primary care providers (PCP), behavioral health consultants (BHC), registered nurses, community health coordinators (CHC), pharmacists, and certified peer recovery specialists (CPRS). The AMS provides behavioral therapy in group and individual encounters, management of acute and chronic medical conditions, psychiatric medication management, medication-assisted treatment (MAT) for substance use disorders, CHC support for addressing social determinants of health, and referrals to specialist healthcare providers internal and external to the organization as clinically indicated. The CHS AMS is not a licensed opioid treatment program (OTP) so, therefore, does not offer methadone maintenance therapy.

4. Procedures.

A. Referrals: most patients enter the AMS via referral; referrals may be self, from providers within CHS, or from healthcare providers/organizations external to CHS; a patient may also be seen at the point of care during a separate CHS visit when an immediate need is identified. The majority of patients referred to the AMS first undergo evaluation by a psychologist or social worker participating in the open intake clinic every Friday afternoon. The open intake clinic allows patients to present as a

walk-in, no appointment necessary, and receive a behavioral health intake by a licensed provider for diagnostic clarification and treatment planning. The provider will then recommend an appropriate level of care based upon the patient's presentation, level of motivation, and treatment goals; levels of care may include referral for inpatient/residential care, referral to the CHS AMS, referral for immediate medical withdrawal management ("detox"), or referral to CHS' non-MAT IOP program, a group therapy program for patients deemed to not be candidates for MAT. Referred patients may bypass the open intake clinic and be received directly into the AMS if meeting one of the priority criteria listed in section 4.A.2 below.

1) Immediacy of care: once a patient is assessed as having a SUD and is pending appointment with the AMS, it is recommended that addiction care begin immediately with the BHC offering behavioral interventions separately or in conjunction with the patient's primary care provider visit if the patient is established, or wishes to establish, with a PCP at CHS. The AMS operates on an open access model, with a goal of offering patients same day or next day appointments, to reduce the time between referral and appointment and effectively leverage the patient's motivation for treatment. However, when demand exceeds supply it is necessary to prioritize referrals for the patients at highest risk of adverse outcomes.

2) Referral Prioritization: specific populations of patients with SUDs warrant rapid intake to the AMS to promote reduction of elevated risk for morbidity and mortality associated with the addictive disease. The CHS AMS provides for the following prioritization of referrals and appointment time from receipt of referral:

a) Pregnancy – seen within 24 hours

b) Hospital discharge for a medical or psychiatric condition co-morbid with active SUD (e.g., endocarditis, overdose, suicidal ideation) – seen within 48 hours

c) Discharge from an inpatient withdrawal management or residential SUD treatment program – seen within 48 hours (although every attempt is made to see patient within 24 hours to reduce risk of relapse and promote continuity of care)

d) Co-habitant of patient currently enrolled in CHS AMS – seen within 72 hours

B. Intake Evaluations: every new patient undergoes a comprehensive medical and behavioral assessment in order to enable development of an appropriate, unified treatment plan. The intake appointment is conducted as follows:

1) Nursing staff calls patient from waiting area, provides an orientation to the clinic space, and instructs the patient on providing a urine specimen for point-of-care urine drug testing.

2) After collection of urine specimen, nurse collects vital signs (including behavioral health "vitals", e.g., the PHQ-2), performs medication review and reconciliation, identifies if patient has an acute complaint suggestive of a medical emergency or appears intoxicated/impaired, verifies contact

information in the electronic health record (EHR), rooms the patient, processes the urine drug screen (UDS), and reviews the collected information with the medical provider and BHC.

3) Once nursing has reviewed the patient's initial evaluation with the provider, the patient is seen by either the physician/nurse practitioner or the BHC depending upon provider availability; ultimately, the patient sees a medical and a behavioral provider in the same visit.

4) The medical provider conducts a comprehensive medical, legal, employment, family, and substance use history; a brief social and psychiatric history is obtained and then correlated with the more detailed psychosocial history obtained by the BHC to avoid significant duplication of effort. A targeted physical exam is conducted based upon the patient's medical history, any acute presenting complaints, and the substance use history (e.g., a reported history of intravenous use would prompt a more thorough examination of the skin to look for evidence of recent injection, injection scarring, and infection/abscess). An obstetrical history and inquiry regarding current manner of birth control are conducted for all female patients of childbearing age. The medical provider reviews the patient's laboratory testing history and, if not current within the past six months, orders hepatitis B and C studies, HIV, liver function panel, and a CBC; other labs may be ordered as clinically indicated. The actual construct of the medical provider portion of the intake is best performed based upon available documentation templates in the EHR to promote ease of recording the encounter. At CHS, the Addiction Severity Index (ASI) is incorporated into the EHR, allowing for the medical and behavioral health providers to record intake findings in a shared document. An abbreviated ASI template is used at CHS for the medical provider intake and is attached as Annex A to this operations manual. Based upon the history, exam, and after consultation with the BHC, the medical provider will establish an assessment of the patient using the ASAM Criteria Dimensions Assessment to help guide treatment team discussions and treatment planning. The Dimensions Assessment considers the areas of intoxication/withdrawal potential, medical conditions, psychiatric conditions, readiness to change, potential for relapse, and recovery environment. When assessing withdrawal, it is helpful to use a validated scale, such as the clinical opioid withdrawal scale (COWS) and the clinical institute withdrawal alcohol-revised (CIWA-Ar); examples of each are included in Annex B. A brief description of the ASAM Dimensions is available at http://www.asamcontinuum.org/knowledgebase/what-are-the-six-dimensions-of-the-asam-criteria/; more detail may be found on the ASAM website, www.asam.org, and in the textbook *THE ASAM CRITERIA, Treatment Criteria for Addictive, Substance-Related, and Co-Occurring Conditions*, Third Edition, published by ASAM. The CHS AMS uses the ASAM Dimensions as a helpful matrix through which to discuss treatment planning and the appropriate level of care for each individual patient.

5) The behavioral provider conducts a comprehensive diagnostic interview including psychosocial history; a brief family and substance use history is obtained and correlated with the more detailed interview conducted by the medical provider. Information obtained in the diagnostic interview is recorded as a behavioral health intake and can be shared on the ASI template in the EHR. The behavioral provider contributes to the ASAM Dimensions Assessment and guides treatment team discussions for each patient's behavioral services.

6) The CPRS conducts an orientation to services offered by the CPRS, assists patients with identifying individual treatment goals as well as patient perceptions/experience with potential recommended treatment plans, and helps identify barriers to care. The CPRS assists patients identified at the intake evaluation as candidates for immediate inpatient withdrawal management or residential care by helping arrange telephone interviews with potential receiving facilities, identifying appropriate locations for care, facilitating transportation when other resources are exhausted, and counseling the patient on procedures and expectations for this level of care. The CPRS also aids patients seeking support through community meetings such as Alcoholics or Narcotics Anonymous, Celebrate Recovery, or other venues.

7) Patients identified as having needs in areas such as housing, food security, clothing, legal, or employment are offered the assistance of a CHC. The CHC may see the patient during the intake evaluation or at a subsequent visit if it is not appropriate during the intake appointment (e.g., a patient in acute withdrawal may not be able/willing to engage with a CHC at intake).

8) Once all appropriate staff members have met with a new patient, they consult briefly as a team to review/corroborate data and develop an immediate unified treatment plan. Either the medical or behavioral provider, or both in select circumstances, will discuss treatment recommendations and options with the patient and agree upon a plan and follow-up schedule. All patients receiving medication will meet with the medical provider prior to departing clinic if the treatment planning discussion is performed by the behavioral provider. It is important to note that this is the initial treatment plan. Patients' treatment plans are further discussed during daily, scheduled treatment team meetings and plans may be modified after further discussion amongst the team and as clinically indicated during the patient's course of treatment.

C. Medications: the CHS addiction medicine service offers FDA-approved medications for the treatment of alcohol, opioid, and tobacco use disorders. These medications include disulfiram, acamprosate, naltrexone, buprenorphine, nicotine replacement therapies, bupropion, and varenicline. This manual will address the medications used for alcohol and opioid use disorders; the vast majority of primary care providers are very familiar with the use of medications in the treatment of tobacco use disorder. A note is made, however, that patients with any substance use disorder should be assessed for tobacco use and offered treatment for cessation; treatment for tobacco use may occur concurrently with treatment for other substance use disorders. Prescribers and staff are referred to the medication package insert and other reference material for full details on all medications, to include specific drug-drug interactions. The provision of medication treatment is always concurrent with behavioral and social support.

1) Disulfiram (generic, trade name Antabuse, available orally only) – used for the treatment of alcohol use disorder, is the only sensitizing agent available in the U.S., irreversibly inhibiting an enzyme involved in the metabolism of alcohol, aldehyde dehydrogenase, resulting in a significant, unpleasant physiological reaction if a patient consumes alcohol or contacts alcohol in other forms, including some cough medicines and mouthwashes; used when abstinence is the goal of treatment; common side effects include drowsiness, lethargy, fatigue and may rarely cause

hepatotoxicity; manufacturer recommendations include performing a hepatic function panel at baseline and 10-14 days after starting treatment; patients should abstain from all alcohol for forty-eight hours prior to initiating disulfiram therapy; typical dose is 250mg once per day, may titrate to 500mg per day in select patients although this is uncommon; upon initiating disulfiram treatment, the patient is usually seen 1-2 times in the first week of treatment to monitor for medication side effects and support abstinence/medication compliance with behavioral strategies; follow-up thereafter is clinically indicated as determined by the treatment team; patients are encouraged to enlist the support of a sober family member or friend to promote medication compliance (e.g., home-based directly observed therapy, DOT); disulfiram is pregnancy category C, is not recommended in breast feeding, and is approved for adult patients only.

2) Acamprosate (generic, trade name Campral, available orally only) – used for the treatment of alcohol use disorder, its mechanism of action is not completely understood but it is known to exert effects on GABA and glutamate transmission, resulting in increased time to relapse and reduced days of drinking/total intake during relapse (these effects were demonstrated in European trials but not reproduced in U.S. trials, although study parameters and patient demographics differed); may be used when either abstinence or harm reduction is the goal of treatment; most common side effects include diarrhea, bloating, and pruritus which are usually mild and transient; does not undergo hepatic metabolism which may make it the preferred agent for patients with severe hepatic compromise; excreted unmetabolized by the kidneys, baseline renal function testing is recommended; acamprosate is approved at a dose of 1998mg/day given as two 333mg capsules three times per day, which may make dosing compliance a concern with some patients; it is ideally initiated while a patient is abstinent from alcohol but may be started while there is active drinking as a harm reduction intervention; follow-up, the provision of behavioral and social support, and benefit of DOT are as listed above for disulfiram; acamprosate is pregnancy category C and there is little information regarding its use in breastfeeding mothers so caution is recommended.

3) Naltrexone (available orally generic and trade name ReVia, available intramuscularly trade only as Vivitrol) – used for the treatment of alcohol and opioid use disorders, its mechanism of action is as an opioid antagonist and in alcohol use disorder it has been shown to help reduce cravings, number of drinking days, relapse to heavy drinking and increased the rate of abstinence; in opioid use disorder naltrexone helps reduce cravings, increases rates of abstinence, and reduces incidence of relapse; may be used when either abstinence or harm reduction is the goal of treatment; most common side effects include nausea, headache, and dizziness and are usually transient; injection site pain and inflammation may occur with Vivitrol and is generally managed successfully with anti-inflammatory medication; while generally well tolerated, naltrexone, both orally and intramuscularly, may rarely cause severe hepatotoxicity but usually only in doses exceeding that which is recommended; hepatic function tests should be checked prior to naltrexone initiation and then only need to be checked if clinically indicated; initiation of naltrexone for alcohol use disorder should ideally occur during a time of abstinence, although there is no known harm of using alcohol while taking the medication; initiation of naltrexone for opioid use disorder must occur after a sustained period of opioid abstinence (including buprenorphine) due to the high opioid receptor binding affinity of naltrexone and the subsequent risk of

precipitated withdrawal with administration of the medication to a patient who has recently used opioids; the majority of patients will require 5-10 days of opioid abstinence based upon the type and pattern of opioid use; however, patients using methadone may require longer due to the unpredictability of methadone half-life and clearance; opioid abstinence may require inpatient "detox" to achieve the minimum days in order to start naltrexone or the patient may prefer a trial of outpatient management, in which case the provider may support with withdrawal symptom medications (see section 4.D); the recommended oral maintenance dose of naltrexone is 50mg/day for both disorders and the patient should begin at 25mg/day for the first 3-7 days to minimize the risk for side effects and then advanced to the maintenance dose; the intramuscular dose is 380mg administered every 28-30 days; while generally effective for the projected duration of the injection, some patients may experience an increase in cravings during the final few days preceding the next injection; if this occurs, supplementation with 25mg/day or oral naltrexone for those few days may be indicated but should not exceed 3-5 days to reduce the risk of hepatotoxicity; a significant concern with naltrexone therapy occurs at the cessation of treatment – patients who receive naltrexone rapidly lose opioid tolerance, leading to a risk for accidental overdose if the patient relapses following cessation of naltrexone treatment; while the specific amount of time needed to lose opioid tolerance is unclear, it is best to assume that any patient treated with naltrexone is at risk for overdose once treatment is withdrawn and should be appropriately counseled and monitored for this risk; all patients with opioid use disorder should be provided with naloxone (Narcan) as part of an overdose risk mitigation strategy; naltrexone is pregnancy category C and, while limited data exists regarding its use by breastfeeding women, the manufacturer recommends it not be used; a patient education handout is attached in Annex C.

4) Buprenorphine (available as mono-product or combination product with naloxone, generic and trade (Subutex) mono-product, generic and trade (Zubsolv) combination sublingual tablets, trade sublingual film (Suboxone), trade buccal film (Bunavail), trade six-month implantable mono-product rods (Probuphine), and trade mono-product monthly subcutaneous injection (Sublocade)) – used for the treatment of opioid use disorder, it is a partial opioid agonist and, due to its high binding affinity for the opioid receptor, also acts as an opioid antagonist; available as a mono-product or combined with naloxone to serve as an abuse deterrent – naloxone has poor oral bioavailability but when inappropriately injected or snorted is fully bioavailable and may precipitate acute opioid withdrawal symptoms; medical providers may only prescribe buprenorphine following training and certification (the "X" DEA number) from the DEA, state rules vary regarding the allowance of nurse practitioners and physician assistants to prescribe buprenorphine, more information may be found at https://www.samhsa.gov/programs-campaigns/medication-assisted-treatment/training-materials-resources/buprenorphine-waiver; through its actions, buprenorphine serves to reduce the symptoms of opioid withdrawal, reduce cravings for opioids, reduce the effect of other opioids taken concurrently with buprenorphine, and reduce relapse rates; the most common side effects of buprenorphine include nausea, dizziness, sedation, insomnia, and constipation as well as local side effects that may occur from placement of the implant or subcutaneous injection forms of buprenorphine; due to its partial agonist activity and ceiling effect, buprenorphine has a low risk for the serious side effects seen with full opioid agonists (e.g., respiratory depression, overdose death) however deaths have been reported with buprenorphine use when combined with other central nervous system depressants such as alcohol and,

in particular, benzodiazepines and with accidental ingestion by young children; initiation of buprenorphine typically occurs in one of two scenarios – a patient presenting in active full opioid agonist use or the patient presenting with a period of full opioid agonist abstinence/already using buprenorphine (illicitly or prescribed); the patient currently using buprenorphine is relatively straightforward – the provider should ascertain the current dose, assess for efficacy and side effects, confirm the presence of buprenorphine or other opioids with a urine drug test, check the state controlled substance monitoring database (CSMD), and consider assuming prescribing authority for the patient's use of buprenorphine in the context of an addiction treatment program; the patient who presents with a period of opioid abstinence that is long enough for withdrawal symptoms to have abated, should be interviewed for prior experience with buprenorphine including efficacy and side effects and whether use was illicit or prescribed, undergo urine drug testing and review of the CSMD, queried for indications to initiate buprenorphine in the face of opioid abstinence (e.g., patient is newly abstinent, craving, and high risk for relapse, or a change in recovery environment that has renewed or increased opioid cravings), and, if clinically appropriate, consideration be given to prescribing buprenorphine; the patient who has completed opioid withdrawal, remains abstinent, and not currently using buprenorphine may undergo buprenorphine induction, with the first day's dose not to exceed 8mg or equivalent of buprenorphine and dose adjustments over the first week of treatment to a maximum maintenance dose of 16mg, titrated to effect of reduced opioid cravings (see Annex D for induction handout); patients who present actively using full opioid agonists must be in mild-moderate withdrawal when initiating buprenorphine treatment to avoid precipitated withdrawal, the use of a validated withdrawal instrument such as the COWS is useful for assessing the intensity of symptoms at the start of therapy and for monitoring a patient's response to treatment; patients in active use may be inducted on buprenorphine in the office or at home with explicit instructions for dosing and follow-up, see Annex D for sample instructions; similar to abstinent patients, the first day's dose should not exceed 8mg and the maintenance dose should generally not exceed 16mg; dose titration for patients in active opioid use should address control of withdrawal symptoms as well as reduction in cravings; all patients receiving buprenorphine should also receive naloxone with the appropriate patient education; all patients receiving buprenorphine should undergo informed consent for the use of the medication, included on the consent should be requirements for diversion control of the medication, see Annex D for a sample consent form (includes addendum for buprenorphine consent in pregnancy); buprenorphine is approved for use in pregnancy as the mono-product and either formulation may be used in breastfeeding; much more detail regarding the use of buprenorphine and other medications in the treatment of opioid use disorder may be found in the ASAM *National Practice Guideline for the use of Medications in the Treatment of Addiction Involving Opioid Use* at https://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf?sfvrsn=24.

D. Withdrawal Management: the underlying theme to this topic is patient safety; all patients should undergo a detailed history regarding substance withdrawal, especially regarding alcohol and benzodiazepines given the potentially life-threatening reactions that may occur during withdrawal from those two substances; withdrawal from the majority of substances, including opioids, is often managed safely as an outpatient with symptomatic medications and close behavioral support (see Annex E); buprenorphine may also be utilized in the management of opioid withdrawal; providers should counsel

patients on substance-specific withdrawal syndromes, the natural course of the withdrawal, and include discussion regarding post-acute withdrawal syndrome (PAWS); behavioral therapy support is critical during withdrawal management given the high rate of relapse during this period; a medication frequently used off-label for the management of the hyperadrenergic state commonly seen in substance withdrawal is clonidine at doses ranging from 0.1mg to 0.2mg three to four times per day; promethazine or a comparable antiemetic is often used for nausea and vomiting as well as standard anti-diarrheal medications; symptomatic medications are typically used for the acute withdrawal phase, generally up to seven days; management of alcohol or benzodiazepine withdrawal may occur as an outpatient or require inpatient care; factors suggesting the need for a higher level of care include a history of severe withdrawal reaction (especially seizure), unstable serious co-morbid medical or psychiatric conditions, prolonged high levels of use, lack of social support and/or a poor recovery environment, elevated risk for rapid relapse, and an inability to access emergency medical care; outpatient benzodiazepine withdrawal is usually conducted through a slow, gradual taper of the medication being used by the patient – e.g., a sample protocol may involve a ten percent reduction per week until reaching 30% of the original dose, then decreasing the dose drop and/or lengthening the interval between dose changes until complete; another option for benzodiazepine withdrawal for patients using short-acting medications is to convert to a longer-acting benzodiazepine (e.g., chlordiazepoxide or clonazepam) or phenobarbital and then commencing a taper – several benzodiazepine taper protocols are available in the literature; outpatient alcohol withdrawal may be conducted using symptomatic medications, as indicated above, in low risk patients or accomplished with the use of benzodiazepines for patients without a history of misuse or addiction to this class of medication and with good social support; details regarding the risk assessment of patients in alcohol withdrawal and sample medication protocols may be found in Annex E.

E. Behavioral Therapy: as indicated above in section 4.B.5, all patients undergo a behavioral health intake during the process of referral to the AMS or during the initial AMS clinic appointment; the behavioral health consultant is responsible for developing the behavioral treatment plan and reviewing recommendations with the treatment team; patients in the addiction clinic may receive behavioral services that include any or all of the following: standard BHC care in conjunction with medication management or primary care encounters, traditional individual therapy (e.g., trauma-focused therapy), substance use disorder oriented group therapy, and other specified group therapy (e.g., dialectic behavioral therapy, family or couples therapy, anger management, etc.); the group therapy provided by the AMS is conducted in two phases, each led by a behavioral provider and co-facilitated by the CPRS; phase 1 group meets once per week for three hours per session and is designed for individuals in early recovery, employing a cognitive behavioral therapy based curriculum; a standard phase 1 group provides for one hour of patient check-in, during which the patient provides an update on substance use since the last visit, significant acute or on-going stressors/risks for relapse, any acute medical or behavioral health needs, and requests for assistance from the CHC; hours two and three of phase 1 group offer the curriculum-based topic(s) or other therapeutic intervention at the discretion of the behavioral provider; patients spend a minimum of eight weeks in phase 1 group (although practically the average is 15-25 weeks) and progress to phase 2 group only upon recommendation of the treatment team and patient concurrence; phase 2 group meets once per week for one and one-half hours and is

designed for individuals who have progressed through phase 1 group and/or present for care with a prolonged period of recovery and abstinence; a typical session for phase 2 group includes patient check-in as in phase 1 followed by open discussion led by the participants or a brief curriculum-based topic presented by the behavioral provider leading group; patients are required to attend a minimum of four consecutive groups at the onset, then may progress to attendance every 2-4 weeks based on recovery status; phase 2 group is open-ended, patients may attend as often and for as long as they desire; unlike phase 1 group which is only offered during standard daytime work hours, phase 2 offers an evening group in recognition of patients who obtain employment as a product of healthy lifestyle changes in recovery; patients are encouraged to identify and attend community support meetings such as AA, NA, Celebrate Recovery, Smart Recovery, or others and to consider obtaining a sponsor, if offered through the meeting; while community meeting attendance is not generally required as part of receiving care in the AMS, some patients do have required attendance if it is thought to be a necessary part of the individualized treatment plan; for patients with mandated community meeting attendance, a meeting log is provided and the patient required to bring the log to AMS appointments; all patients who participate in any AMS group therapy are required to sign a group participation agreement; a sample agreement and meeting log are attached as Annex F.

F. Integrated Medical and Behavioral Visits: in line with the CHS integrated model of care, patients in the AMS may receive primary care and behavioral services at every appointment; given that nearly all patients attending one of the AMS group therapy sessions are also receiving addiction medication, the medical provider visit for medication management is performed in conjunction with the group therapy visit to promote appointment compliance and reduce the frequency by which patients are required to travel to clinic; at a minimum of monthly intervals, patients are individually brought out of group for a brief medication management visit with the medical provider and then returned to group at the completion of the visit; patients with medical or psychiatric needs apart from the addiction medication management visit may be provided care “on the spot” or provided a separate appointment, depending upon the need and provider availability; patients who do not attend an AMS group receive individual visits with the medical provider and BHC at least monthly or more frequently as the treatment plan indicates; routine wellness visits are scheduled individually, although birth control may be provided at any visit to improve access and adherence; CHC support may be provided at any visit, to include during a group session, based upon the patient’s recovery environment needs.

G. A “Typical” Treatment and Recovery Course:

1) Referral is made to the AMS or patient is priority triage for services.

2) Patient undergoes intake evaluation and receives/agrees to recommended treatment plan.

3) Initiation of medication: for buprenorphine, induction or assumption of prescription occurs; for induction, patient is usually seen 3-4 times in the first week to allow for dose titration and assessment of efficacy of therapy, then 1-2 times per week once maintenance dose is reached to determine stability on medication and assess for abstinence/harm reduction; for naltrexone, the first

dose of medication is always delivered orally; depending upon availability of vivitrol, patient's insurance, need for prior approval, a patient may receive a 12.5mg oral dose in clinic, be observed for 1-2 hours to assess for significant adverse reaction to medication, and then immediately be offered vivitrol; an alternative is to provide a one week course of oral naltrexone, 25mg per day for the first 3-4 days then 50mg per day, and have patient return in one week to receive vivitrol if appropriate; if patient does not desire vivitrol, then he/she may be maintained on 50mg per day oral naltrexone for the duration of treatment.

4) Initiation of behavioral services: started at intake with assessment and development of treatment plan, patients receive behavioral interventions at all medication appointments during the medication initiation and stabilization period; once stable on medications, patients begin recommended behavioral plan, usually with phase 1 group but may also include or be replaced by individual therapy when clinically indicated.

5) Maintenance therapy: typically consists of weekly to monthly medication management visits (frequency depending upon phase of group being attended and overall treatment plan/progress in recovery) and behavioral visits at similar intervals, again depending upon the type of therapy and the treatment plan; patients remain in maintenance therapy for as long as needed and may cycle between levels of care (e.g., start at CHS, be referred for inpatient care, return to CHS AMS), phases of group (a patient in phase 2 group may be struggling in recovery and cycle back to phase 1 group for more support, then return to phase 2 when ready), and dose and type of medication management (e.g., patient may taper from original buprenorphine maintenance dose of 16mg/day to 12mg/day, convert from buprenorphine to naltrexone, or taper medications altogether and continue to receive other services from the AMS); the duration of maintenance therapy with medication is variable, based upon the intensity of the patient's disease, progress in recovery, and the overall treatment plan; when initially counseled regarding the use of buprenorphine or naltrexone, patients are advised that an expected minimum duration of therapy is one year to allow for the patient to achieve sustained remission of the substance use disorder(s) per the DSM 5 diagnostic criteria, however the duration may be longer or shorter based upon individual patient needs; it is, unfortunately, a common occurrence for a patient to withdraw from treatment services altogether – when this occurs, attempts are made to outreach the patient by phone, email (if patient is enrolled in this service through the electronic health record), and letter and, unless the patient was dismissed from care for violent or otherwise untoward behavior, is invited to return for a re-assessment and treatment plan recommendation.

6) Exit Strategy: patients frequently inquire regarding the "completion" of treatment and when medication such as buprenorphine and naltrexone can be stopped; patients are reminded that addiction is a chronic disease and requires lifelong monitoring and surveillance even in the face of prolonged abstinence and recovery; a collaborative plan for reducing the intensity of treatment, discontinuation of medications, and long term disease surveillance is critical to a successful recovery; medication discontinuation is considered for a patient in, preferably, sustained remission who has a supportive recovery environment (sober support friends/family, stable housing, legal source of income, reliable transportation, etc.) and any medical or psychiatric disorders are well managed; naltrexone discontinuation may be performed at the patient's discretion, usually by not providing the next

scheduled vivitrol injection or simply stopping the oral medication, and does not require taper given that the medication does not induce physical dependence; buprenorphine discontinuation, due to its partial opioid agonist activity, requires taper to minimize opioid withdrawal symptoms and the risk for relapse as a result of an uncomfortable withdrawal; a patient on the typical maintenance dose of 16mg of buprenorphine per day may usually be reduced to 12mg per day with minimal discomfort, although a medication such as hydroxyzine may be prescribed for as use needed should the patient develop anxiety or restlessness with the dose reduction; the subsequent dose reductions occur at 2mg intervals until reaching 4mg per day, then reducing the dose by 1mg intervals; during the final reduction, providing 1mg every other day may ease the completion of the taper; dose reduction may be implemented at 1-2 week intervals or at an interval agreed upon by the provider and patient; frequent appointments, generally weekly, with behavioral support should be employed throughout the buprenorphine taper process to promote continued abstinence; patients who elect to transition to naltrexone following a buprenorphine taper must wait 5-10 days to initiate naltrexone to minimize the risk of precipitated withdrawal and a urine drug screen should be performed to confirm the absence of buprenorphine and other opioids prior to the first dose of naltrexone; all patients should develop a disease surveillance plan while actively engaged in services with the addition clinic, especially critical after the discontinuation of medications that require a patient to present to clinic for refills and follow-up; the plan may include continued attendance at phase 2 group sessions at an agreed upon interval, attendance at community meetings and sustained engagement with a sponsor, routine follow-up during primary care visits with the patient's primary care provider (PCP), routine encounters with a BHC or other behavioral health provider, or a combination of these strategies; a patient may be re-referred to the AMS at any time during disease surveillance if relapse or other concerns are identified; this discussion does not include patients exiting care due to dismissal for aberrant or other behavior, see section 4.H.5.

H. Special Topics.

1) Urine Drug Screening (UDS): CHS utilizes a CLIA-waived, in-office urine test to perform drug screening for which nursing staff are trained and approved to perform; the CHS test provides a positive or negative qualitative result for fourteen substances, including buprenorphine; screening results that require confirmation or quantification are sent to a reference laboratory; a UDS is performed on all patients presenting for intake, on the first follow-up appointment after intake (especially important for patients undergoing buprenorphine induction to confirm the presence of the medication in the urine), prior to initiation of naltrexone therapy to confirm the absence of opioids, randomly (all AMS patients are numbered and listed alphabetically on a spreadsheet, a random number generator is used to select patients for random UDS), when presenting for a random medication count, or when clinically indicated (e.g., patients who present to re-engage in care after missed appointment(s), who report a significant psychosocial stressor that presents a high risk for relapse, who are identified on a routine CSMD screening to have received a controlled substance that was not self-reported); patients are informed of the UDS results at the time of testing and any discrepancy between the result, the patient's prescription medication profile, and the patient's self-report is explored for resolution, if resolution is not achieved the specimen may be sent for confirmatory testing; the urine specimen may be collected under direct observation by an appropriate-gender staff member; if not

directly observed, the patient is required to leave all belongings in the exam room prior to entering the restroom and may be asked to pat down and/or lift baggy clothing to reduce the risk of a patient providing a substituted specimen.

2) Buprenorphine Diversion Control: buprenorphine in any form is subject to diversion and misuse, occurring in spite of cautious prescribing and monitoring; the CHS AMS attempts to minimize diversion of buprenorphine through the following strategies: informed consent and treatment agreement for the use of buprenorphine, signed by the patient and provider, describing the proper use and accountability for the medication; performance of random medication counts in the interval between prescriptions; when appropriate, empty wrapper counts at random and scheduled visits; UDS that assesses for the presence of buprenorphine to provide evidence patient is using the medication; monitoring of the CSMD to assess for "doctor shopping" for buprenorphine as well as identifying receipt of other controlled substances by the patient; and acting upon reports of medication misuse (e.g., a patient may report that another patient is misusing the medication; subsequently, the patient on whom the report is made is notified that a concern has arisen about misuse or aberrant behavior and the patient may be subject to smaller, more frequent scripts and enhanced monitoring via increased UDS and medication counts). Medication and wrapper counts are also evaluated for pharmaceutical product lot number and compared to a list provided by the CHS pharmacy (given that the majority of patients use the in-house CHS pharmacy) to ensure that the counted product is consistent with that dispensed for that particular prescription. Patients who are found to have incorrect medication/wrapper counts are queried for the cause; often patients are found to have overused the medication in response to a medical or psychosocial stressor and require re-education regarding proper use of buprenorphine and consequences of misuse, in addition to addressing the given stressor(s); occasionally, the patient reports medication loss or theft and, while this may be a legitimate explanation, re-education is provided to include guidance that any further report of loss or theft may result in tapering of buprenorphine and transition to a non-controlled substance like naltrexone; at times, a patient report is clearly implausible and/or not consistent with the UDS (e.g., the UDS is negative for buprenorphine despite a patient's claim of using the medication appropriately) and may result in immediate initiation of buprenorphine taper when suspicion of diversion is significant.

3) CSMD Review: a review is conducted on every patient at intake, a minimum of every six months, and when indicated; examples of indicated CSMD reviews include patient reporting receipt of a controlled substance prescription, following a medical/surgical/dental procedure that would likely result in prescribing of opioid pain management, following an emergency room visit with a complaint likely to have associated pain, when a patient seeks to re-engage in care after an unanticipated absence from the program, and after hospital discharge.

4) Appointment attendance: patients are made aware through multiple forums of the importance of compliance and punctuality with scheduled appointments; patients missing an individual appointment, medical or behavioral, receive a call from AMS staff to determine the cause of the missed visit and offer the next available appointment to promptly reschedule; patients arriving significantly late (generally more than 20 minutes late for a 30 minute appointment) are offered the opportunity to be "worked in" based on the provider's availability or rescheduled for the next available time; a missed

group therapy session results in a call from the AMS staff to determine cause and offer the next available individual appointment – especially pertinent since the majority of patients receiving buprenorphine receive refills during the group session and would be abruptly without medication when group is missed; patients arriving more than fifteen minutes late to group or leaving more than fifteen minutes early are not considered as having attended group that day for tracking purposes but are welcome to participate for the time present – this policy is also included in the group participation agreement referenced above; recurrent missed or late appointments may result in the treatment team's recommendation for a change in the treatment plan.

5) Probation, Dismissal, and Reinstatement Criteria: noncompliance and violation of program requirements results in progressive remedial and disciplinary action; probation involves enforcing more strict requirements or a change in treatment plan on patients who demonstrate noncompliance with basic rules; probation may occur when a patient fails to respond or present for required random medication counts on two occasions(remedial action being that patient is then required to call the AMS clinic three times weekly to "check in" and see if he/she is on the medication count list that day, not calling on two occasions may result in withdrawal of the patient's medication, see Annex D for sample patient notification), is recurrently late for appointments (remedial action may include a strict requirement to arrive on time and, if late, the patient will not be seen or prescribed medication that day), and providing an adulterated or substitute urine for a UDS (often indicative of increasing disease severity, remedial action may be to offer assistance with obtaining residential care, withdrawal of buprenorphine therapy due to high diversion risk in patients who falsify urines, increasing intensity of behavioral interventions/supports, medication conversion to naltrexone); dismissal involves a discharge of the patient from the AMS and could also include discharge from all care at CHS depending upon the severity of the offense; all cases considered for dismissal are reviewed by CHS leadership for discussion/decision; dismissal may occur when a patient is violent, harassing, or threatening toward a staff member or another patient, when a patient is confirmed to be selling prescribed controlled substance medications or other illicit substances on CHS premises, and when a patient is identified as having forged or falsely obtained a prescription for a controlled substance; of note, patients who electively leave care during the course of treatment (e.g., a patient who relapses and does not return for treatment) are not identified as being on probation or dismissed and may return to the AMS for reevaluation when ready; any patient dismissed from care from either the AMS or CHS as a whole may petition in writing for reinstatement; all reinstatement requests are reviewed and acted upon by CHS leadership.

6) Program Metrics: AMS clinic specific performance and outcome measures are in addition to applicable measures identified by CHS for the provision of primary care; addiction specific measures include thirty-day treatment retention, tobacco use screening and cessation counseling, residential/inpatient readmission rate, and contraceptive use screening and counseling; a more detailed description of these measures and standards may be found in Annex G; a thorough discussion of standards of care for addiction medicine professionals and recommended metrics may be found in the applicable ASAM documents at https://www.asam.org/docs/default-source/practice-support/quality-improvement/asam-standards-of-care.pdf?sfvrsn=338068c2_10 and

https://www.asam.org/docs/default-source/advocacy/performance-measures-for-the-addiction-specialist-physician.pdf?sfvrsn=5f986dc2_0.

5. Staff Roles and Responsibilities and General Clinic Considerations.

A. Roles and Responsibilities. The addiction clinic operates using a medical home model; that is, incorporating a multi-disciplinary integrated team approach, a daily morning team huddle that includes all members, roles and responsibilities that provide each team member an opportunity to operate at "the top of his/her license or skill set" and empowerment to affect treatment team decisions. Team huddle is led by the addiction medicine physician, or lead BHC in that person's absence, and items discussed include a brief review of the established patients with appointments that day, focusing on each patient's status within his/her treatment plan; recommendations from team members regarding changes to treatment plans; identification of the day's patients who may be on the random UDS list, random medication count list, or be subject to indicated performance of those tasks; overview of the new, intake patients for the day; staffing assessment and assignment of tasks (e.g., staff member is out sick or on vacation); and open discussion time for any team member's comments. Time allotted for huddle each morning is thirty minutes. Team member roles are as follows:

1) Addiction Medicine Physician: overall responsibility for administrative and clinical operation of the AMS; reviews referrals; provide addiction medicine and primary care services; participates in treatment planning; possess DEA "X" number; consultant and educator for internal staff and external organizations; consultant for community organizations regarding prevention and treatment of substance use disorders; qualifications include board certification in a primary care specialty and addiction medicine.

2) Behavioral Health Consultant: lead BHC responsible for all behavioral treatment provided within the AMS; reviews referrals; provide individual BHC and group therapy services; participates in treatment planning; consultant and educator for internal staff, external organizations, and community groups; additional BHCs support the AMS and operate under guidance of the lead BHC; qualifications include licensed psychologist with clinical competencies in addiction treatment.

3) Primary Care Provider: physician, nurse practitioner, or physician assistant with lead responsibility for the provision of primary care services to AMS patients; train and maintain skills in addiction medicine; provide addiction medication services, within scope of license and State regulations, to select AMS patients and in absence of addiction medicine physician; conduct care coordination for patients receiving care outside of CHS; qualifications include board certified, or specialty equivalent, primary care physician, nurse practitioner, or physician assistant with possession of "X" number if allowed by State regulations.

4) Nurse: provides in-person and telephone clinical patient triage, screening for routine preventive health and primary care needs, administrative and logistical management of clinic, coordinate provider schedules, care coordination, patient education; qualifications include licensed registered nurse.

5) Pharmacist: provides medication profile and safety review, medication utilization data, assistance with clinical management of chronic health conditions and medication options, patient education, CSMD monitoring; qualifications include licensed clinical pharmacist.

6) Certified Peer Recovery Specialist: provides treatment engagement support, recovery navigation and goal planning, patient education, liaison services with residential treatment facilities, co-facilitation of group therapy sessions, orientation to community support meetings; qualifications include State certification as a peer recovery specialist.

7) Community Health Coordinator: provides review of recovery environment and education/services to address areas of risk, care coordination, facilitation of internal and external referrals to agencies that can assist patients with basic needs and address social determinants of health, co-facilitation of group therapy sessions as needed; qualifications include bachelor's degree and internal training/credentialing for the position.

8) Adjunct team members: CHS is actively engaged in education and supports APA-accredited internship and post-doctoral training as well as training of family medicine residents and pharmacy students, any of whom may observe/provide services in the addiction clinic within the scope of respective training agreements; AMS patients may also be co-managed with other primary care and specialty providers, especially obstetrics-gynecology, who may attend treatment team meetings and morning huddle as needed.

B. Schedule Management.

1) Medical providers typically operate using an open template of 30-minute appointment slots; new patients for intake receive two slots, or 60 minutes, and follow-up patients for addiction and/or primary care needs receive a single 30-minute slot. A medical provider conducting a medication management visit for a patient during the group therapy session is scheduled every ten to fifteen minutes with a prime focus on the addiction medication given that there may be as many as 15 patients in group who need to be seen within the three hour session; patients raising non-urgent, non-acute medical or behavioral complaints are offered an appointment following group that day or on another day based upon the triaged need of the complaint, provider availability, and patient discretion. Patients presenting with an acute, urgent need are seen that day or referred to an emergency room, if appropriate.

2) Behavioral providers operate on a schedule template that allows for scheduled and unscheduled appointment times. Scheduled times may be filled by an individual patient presenting solely for BHC services or be in conjunction with an addiction and/or primary provider visit. Unscheduled time allows the BHC to rapidly respond to same-day requests for consultation and care from medical providers as well as immediately address the urgent needs of a patient in crisis. Appointment times are typically 30-minute slots but retain flexibility based upon the needs of the patient. The BHC may also have scheduled time to serve as a phase 1 or phase 2 group facilitator.

3) Patient scheduling is managed by the clinic lead RN, utilizing an open access model of care. While patients needing follow-up appointments are scheduled in the future, patients scheduling intake or acute care appointments are offered same-day or next day visits. This practice allows the AMS to maintain ready access for high priority triage patients as outlined in section 4.A.2 above. The number of open access appointments per day may vary based upon the demand signal by patients, number of referrals, and seasonal variation (e.g., flu season with a higher demand for acute care).

4) Patient volume management is multifactorial. Federal prescribing limits for buprenorphine will dictate patient volume for that medication. Buprenorphine patient volume should not exceed the total capacity of all waivered providers and their ability to "cross-cover" should one provider suddenly become incapacitated or leave the organization. The Substance Abuse and Mental Health Services Administration (SAMHSA) does allow providers to request an emergency increase in prescribing limit but action on this request may take up to 45 days and only be approved for up to six months without a request for extension. Anticipating patient appointment utilization rate is also vital to volume management. A buprenorphine patient who undergoes induction on the medication and has an uneventful recovery course (e.g., no significant relapses, does not cycle through levels of care or back and forth between group phases) is expected to utilize 35-40 appointments in the first twelve months of care; a naltrexone patient will likely use 30-35 appointments. These appointments do not take into account patient time in clinic for events like random medication counts. Number of medical and behavioral providers, expected provider availability, nursing and other support staff capacity, patient acuity, and logistical requirements (e.g., clinic space and patient flow) are all considered when determining patient capacity; capacity will change as the status of these variables alters over time.

5) Documentation: Every effort should be made to maximize efficiency and avoid duplication of documentation. The NextGen EHR has resident the Addiction Severity Index (ASI) template which may be used for new patient intake appointments. The ASI allows for multiple providers to document parts, or all, of the template on the same day for the same patient (e.g., medical provider documents the medical, legal, and substance use histories, the BHC documents the family, social and psychiatric history) and facilitates communication between providers. The ASI then allows specific data to be mined from the EHR, permitting analysis, review, and quality improvement of the addiction program.

6) Patient Tracking. Real-time, readily accessible patient data is critical to day-to-day operations of the addiction clinic. While the EHR is the ultimate secure repository of patient information, it is necessary to have immediate access to patient variables such as date/duration of last buprenorphine prescription, dates of last UDS and medical provider visit, date of last substance use, and EHR record number and date of birth, information that is not always immediately accessible through data requests of the EHR. In particular, buprenorphine tracking is critical to ensure providers do not exceed federal limits and in the event of an unannounced audit by the DEA. The CHS AMS maintains two patient tracking spreadsheets, located on a secure/approved access only share drive on the CHS information system. One spreadsheet is used as a "daily tracker" and contains limited/most critically needed patient information (e.g., buprenorphine prescription data); the other is a more comprehensive medical provider tracker that includes information such as last laboratory testing results and date (e.g.,

hepatitis and HIV screening), current medications, and obstetrical/birth control history. The daily tracker is, of course, update daily and the medical tracker updated as needed. Examples of each are included in Annex H.

6. Review and Revision. This document shall be reviewed and updated accordingly at a minimum of annually within thirty days of its anniversary date. Updates will be distributed electronically to all applicable staff and select updates considered critical to ongoing operations may be distributed at any time. The CHS Director of Addiction Medicine is responsible for the content, review, and updates to this document; the CHS Chief Clinical Officer retains approval authority for dissemination and execution.

Table of Contents

SECTION 1

SECTION 2