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SECTION 1

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.

SECTION 2

ANNEX

A

Addiction Medicine Intake

Medical

1. Number of times hospitalized in life, for medical reasons: _____
2. How long ago was last hospitalization: _____
3. Any chronic medical problems, include obstetrical history and current birth control as applicable:

   _____
4. Current prescribed medications:

   _____
5. On disability: _____
6. Number of days with medical concerns in the past 30: _____
7. How bothered is patient by medical problems: 0-not at all, 1-slightly, 2-moderately, 3-considerably, 4-extremely, X-not answered

Employment/Support

1. Education completed: _____years (GED=12)
2. Driver's license: YES NO
3. Have a car: YES NO
4. Current (or most recent) occupation:_____
5. How bothered is patient by employment problems, scale 0-4:_____

Alcohol/Drug Use

1. Alcohol Use: Last 30 days_____; Lifetime Use_____; Comments, include withdrawal history and date last used_____
2. Heroin: Last 30 days_____; Lifetime Use_____; Route_____; Comments, include date last used, amount, overdose history_____

   _____
3. Methadone: Last 30 days_____; Lifetime Use_____; Route_____; Comments, include date last used, dose, and street vs prescribed_____
4. Other Opioids: Last 30 days_____; Lifetime Use_____; Route_____; Comments, include date last used, , types, overdose, amount_____

   _____
5. Barbiturates: Last 30 days_____; Lifetime Use_____; Route_____; Comments, include date last used, types (e.g. qualuudes), overdose, amount_____

   _____

6. Other sedatives (benzos): Last 30 days:_____; Lifetime Use_____; Route_____; Comments, include date last used, types, amount, overdose, withdrawal history_____
_____
_____
7. Cocaine/Crack: Last 30 days_____; Lifetime Use_____; Route_____; Comments, include date last used, forms, amount_____
8. Amphetamines/Meth: Last 30 days_____; Lifetime Use_____; Route_____; Comments, include date last used, forms, amount_____
9. Marijuana: Last 30 days_____; Lifetime_____; Comments, include date last used and amount_____
10. Hallucinogens: Last 30 days_____; Lifetime_____; Comments, include date last used and form_____
11. Inhalants: Last 30 days_____; Lifetime_____; Comments, include date last used and form_____
12. Tobacco: Age at onset_____; Current use and form_____; Comments, include previous quit attempts/use of NRT or medication _____
_____
13. Which substance(s) is the major current problem:_____
14. How long was the last voluntary abstinence from the major substance:_____
15. How many months ago did this abstinence end:_____
16. How many times have you had alcohol withdrawal/DTs:_____
17. How many time have you overdosed on drugs:_____
18. How many times have you been treated for alcohol use:_____
19. How many of these were detox only:_____
20. How many time have you been treated for drug use:_____
21. How many of these were detox only:_____
22. How many days in the last 30 have you been treated as an outpatient for alcohol or drug problems:_____
23. How many days in the last 30 have you experienced problems with alcohol:_____
24. How troubled or bothered are you by these alcohol problems:_____ (scale 0-4)
25. How many days in the last 30 have you experienced problems with drugs:_____
26. How troubled or bothered are you by these drug problems:_____ (scale 0-4)
27. How important is it for you to get treatment for alcohol problems, scale 0-4:_____
28. How important is it for you to get treatment for drug problems, scale 0-4:_____
29. Rate patient's need for alcohol treatment, 0-9 scale:_____
30. Rate patient's need for drug treatment, 0-9 scale:_____

Legal Status

1. Is your evaluation for this treatment program prompted or suggested by the criminal justice system (e.g., court ordered, requirement of parole/probation):_____
2. Are you on parole or probation:_____
3. How many times in your life have you been charged with disorderly conduct, public intoxication, possession of drugs/paraphernalia:_____
4. Have you ever had a DUI, if so how many and when:_____
5. How many months have you been incarcerated in your life:_____
6. Are you presently awaiting trial, sentence, or have pending charges:_____
7. If so, what for:_____
8. How serious do you feel your legal problems are, scale 0-4:_____
9. How important to you is counseling or referral for legal problems, scale 0-4:_____
10. Rate patient's need for legal services, scale 0-9:_____

Family History

Have any of your immediate family (include aunts/uncles), or the person(s) who primarily raised you, suffered from an alcohol, drug, or psychiatric problem:_____

Mother's Side:_____

Father's Side:_____

Family/Social Status

1. Marital Status:_____. Current partner/significant other:_____
2. How long have you been in this marital status:_____
3. Are you satisfied with this situation:_____
4. Usual living arrangements:_____. For how long:_____
5. Do you live with anyone who has a current alcohol problem:_____
6. Do you live with anyone who uses drugs, illicit or prescribed controlled substances:
   _____
7. How many children do you have, include ages:_____
8. What is your relationship with your children:_____
9. How bothered are you by family problems in the last 30 days:_____ (scale 0-4)
10. How important to you is treatment or counseling for family problems:_____ (scale 0-4)

Psychiatric Status

1. How many times have you been treated for a BH problem as an inpatient:_____
2. How many times have you been treated for a BH problem as an outpatient:_____

3. Do you receive a pension/disability for a BH problem:_____
4. Have you experienced thoughts of suicide in the past 30 days:_____ or in your lifetime:_____
5. Have you attempted suicide in the past 30 days:_____ or in your lifetime: _____
6. Have you been prescribed medication for a BH problem in the past 30 days: _____ _____ or in your lifetime:_____ _____
7. Is the patient obviously depressed or withdrawn:_____
8. Is the patient obviously hostile or agitated:_____
9. Is the patient obviously anxious or nervous:_____
10. Is the patient having trouble with reality testing, thought disorders, or paranoid: _____ _____
11. Is the patient having suicidal thoughts:_____
12. How would you rate the patient's need for mental health treatment:_____ (scale 0-9)

ANNEX

B

Clinical Opiate Withdrawal Scale

For each item, circle the number that best describes the patient's signs or symptom. Rate on just the apparent relationship to opiate withdrawal. For example, if heart rate is increased because the patient was jogging just prior to assessment, the increase pulse rate would not add to the score.

Patient's Name:_____ Date and Time ____/____/____:_____

Reason for this assessment:_____

Resting Pulse Rate: _____beats/minute *Measured after patient is sitting or 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	**GI Upset**: *over last ½ hour* 0 no GI symptoms 1 stomach cramps 2 nausea or loose stool 3 vomiting or diarrhea 5 Multiple episodes of diarrhea or vomiting
Sweating: *over past ½ hour not accounted for by room temperature or patient activity.* 0 no report of chills or flushing 1 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	**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
Restlessness *Observation during assessment* 0 able to sit still 1 reports 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	**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
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 the rim of the iris is visible	**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
Bone or Joint aches *If patient was having pain previously, only the additional component attributed to opiates 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	**Gooseflesh skin** 0 skin is smooth 3 piloerrection of skin can be felt or hairs standing up on arms 5 prominent piloerrection
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	Total Score _____ The total score is the sum of all 11 items Initials of person completing Assessment: _____

Score: 5-12 = mild; 13-24 = moderate; 25-36 = moderately severe; more than 36 = severe withdrawal

Alcohol Withdrawal Assessment Scoring Guidelines (CIWA - Ar)

Nausea/Vomiting - Rate on scale 0 - 7

0 - None
1 - Mild nausea with no vomiting
2
3
4 - Intermittent nausea
5
6
7 - Constant nausea and frequent dry heaves and vomiting

Tremors - have patient extend arms & spread fingers. Rate on scale 0 - 7.
0 - No tremor
1 - Not visible, but can be felt fingertip to fingertip
2
3
4 - Moderate, with patient's arms extended
5
6
7 - severe, even w/ arms not extended

Anxiety - Rate on scale 0 - 7
0 - no anxiety, patient at ease
1 - mildly anxious
2
3
4 - moderately anxious or guarded, so anxiety is inferred
5
6
7 - equivalent to acute panic states seen in severe delirium or acute schizophrenic reactions.

Agitation - Rate on scale 0 - 7
0 - normal activity
1 - somewhat normal activity
2
3
4 - moderately fidgety and restless
5
6
7 - paces back and forth, or constantly thrashes about

Paroxysmal Sweats - Rate on Scale 0 - 7.
0 - no sweats
1- barely perceptible sweating, palms moist
2
3
4 - beads of sweat obvious on forehead
5
6
7 - drenching sweats

Orientation and clouding of sensorium - Ask, "What day is this? Where are you? Who am I?" Rate scale 0 - 4
0 - Oriented
1 – cannot do serial additions or is uncertain about date

2 - disoriented to date by no more than 2 calendar days

3 - disoriented to date by more than 2 calendar days
4 - Disoriented to place and / or person

Tactile disturbances - Ask, "Have you experienced any itching, pins & needles sensation, burning or numbness, or a feeling of bugs crawling on or under your skin?"
0 - none
1 - very mild itching, pins & needles, burning, or numbness
2 - mild itching, pins & needles, burning, or numbness
3 - moderate itching, pins & needles, burning, or numbness
4 - moderate hallucinations
5 - severe hallucinations
6 - extremely severe hallucinations
7 - continuous hallucinations

Auditory Disturbances - Ask, "Are you more aware of sounds around you? Are they harsh? Do they startle you? Do you hear anything that disturbs you or that you know isn't there?"
0 - not present
1 - Very mild harshness or ability to startle
2 - mild harshness or ability to startle
3 - moderate harshness or ability to startle
4 - moderate hallucinations
5 - severe hallucinations
6 - extremely severe hallucinations
7 - continuous hallucinations

Visual disturbances - Ask, "Does the light appear to be too bright? Is its color different than normal? Does it hurt your eyes? Are you seeing anything that disturbs you or that you know isn't there?"
0 - not present
1 - very mild sensitivity
2 - mild sensitivity
3 - moderate sensitivity
4 - moderate hallucinations
5 - severe hallucinations
6 - extremely severe hallucinations
7 - continuous hallucinations

Headache - Ask, "Does your head feel different than usual? Does it feel like there is a band around your head?" Do not rate dizziness or lightheadedness.

0 - not present
1 - very mild
2 - mild
3 - moderate
4 - moderately severe
5 - severe
6 - very severe
7 - extremely severe

Procedure:

1. Assess and rate each of the 10 criteria of the CIWA scale. Each criterion is rated on a scale from 0 to 7, except for "Orientation and clouding of sensorium" which is rated on scale 0 to 4. Add up the scores for all ten criteria. This is the total CIWA-Ar score for the patient at that time. Prophylactic medication should be started for any patient with a total CIWA-Ar score of 8 or greater (ie. start on withdrawal medication). If started on scheduled medication, additional PRN medication should be given for a total CIWA-Ar score of 15 or greater.
2. Document vitals and CIWA-Ar assessment on the Withdrawal Assessment Sheet. Document administration of PRN medications on the assessment sheet as well.
3. The CIWA-Ar scale is the most sensitive tool for assessment of the patient experiencing alcohol withdrawal. Nursing assessment is vitally important. Early intervention for CIWA-Ar score of 8 or greater provides the best means to prevent the progression of withdrawal.

Assessment Protocol

a. Vitals, Assessment Now.
b. If initial score ≥ 8 repeat q1h x 8 hrs, then if stable q2h x 8 hrs, then if stable q4h.
c. If initial score < 8, assess q4h x 72 hrs.
If score < 8 for 72 hrs, d/c assessment.
If score ≥ 8 at any time, go to (b) above.
d. If indicated, (see indications below) administer prn medications as ordered and record on MAR and below.

Date												
Time												
Pulse												
RR												
O_2 sat												
BP												

Assess and rate each of the following (CIWA-Ar Scale): Refer to reverse for detailed instructions in use of the CIWA-Ar scale.												
Nausea/vomiting (0 - 7) 0 - none; 1 - mild nausea ,no vomiting; 4 - intermittent nausea; 7 - constant nausea , frequent dry heaves & vomiting.												
Tremors (0 - 7) 0 - no tremor; 1 - not visible but can be felt; 4 - moderate w/ arms extended; 7 - severe, even w/ arms not extended.												
Anxiety (0 - 7) 0 - none, at ease; 1 - mildly anxious; 4 - moderately anxious or guarded; 7 - equivalent to acute panic state												
Agitation (0 - 7) 0 - normal activity; 1 - somewhat normal activity; 4 - moderately fidgety/restless; 7 - paces or constantly thrashes about												
Paroxysmal Sweats (0 - 7) 0 - no sweats; 1 - barely perceptible sweating, palms moist; 4 - beads of sweat obvious on forehead; 7 - drenching sweat												
Orientation (0 - 4) 0 - oriented; 1 - uncertain about date; 2 - disoriented to date by no more than 2 days; 3 - disoriented to date by > 2 days; 4 - disoriented to place and / or person												
Tactile Disturbances (0 - 7) 0 - none; 1 - very mild itch, P&N, ,numbness; 2-mild itch, P&N, burning, numbness; 3 - moderate itch, P&N, burning ,numbness; 4 - moderate hallucinations; 5 - severe hallucinations; 6 – extremely severe hallucinations; 7 - continuous hallucinations												
Auditory Disturbances (0 - 7) 0 - not present; 1 - very mild harshness/ ability to startle; 2 - mild harshness, ability to startle; 3 - moderate harshness, ability to startle; 4 - moderate hallucinations; 5 severe hallucinations; 6 - extremely severe hallucinations; 7 - continuous.hallucinations												
Visual Disturbances (0 - 7) 0 - not present; 1 - very mild sensitivity; 2 - mild sensitivity; 3 - moderate sensitivity; 4 - moderate hallucinations; 5 - severe hallucinations; 6 - extremely severe hallucinations; 7 - continuous hallucinations												
Headache (0 - 7) 0 - not present; 1 - very mild; 2 - mild; 3 - moderate; 4 - moderately severe; 5 - severe; 6 - very severe; 7 - extremely severe												
Total CIWA-Ar score:												
PRN Med: (circle one) Diazepam Lorazepam — **Dose given (mg):**												
Route:												
Time of PRN medication administration:												
Assessment of response (CIWA-Ar score 30-60 minutes after medication administered)												
RN Initials												

Scale for Scoring:
Total Score =
0 – 9: absent or minimal withdrawal
10 – 19: mild to moderate withdrawal
more than 20: severe withdrawal

Indications for PRN medication:
a. Total CIWA-AR score 8 or higher if ordered PRN only (Symptom-triggered method).
b. Total CIWA-Ar score 15 or higher if on Scheduled medication. (Scheduled + prn method)
Consider transfer to ICU for any of the following: Total score above 35, q1h assess. x more than 8hrs required, more than 4 mg/hr lorazepam x 3hr **or** 20 mg/hr diazepam x 3hr required, or resp. distress.

Patient Identification (Addressograph)

Signature/ Title	Initials	Signature / Title	Initials

Alcohol Withdrawal Assessment Flowsheet (revised Nov 2003)

ANNEX

C

NALTREXONE

What is naltrexone? An opioid antagonist medication that works by acting on the opioid receptors in the brain.

What is naltrexone used for? Naltrexone is used for the treatment of addiction to alcohol and/or opioids. By acting on the opioid receptors, it helps to decrease cravings for alcohol and opioids, reduce the pleasure of drinking, and block the effects of opiates and opioid medications.

How is naltrexone used? Naltrexone is available as a pill and as a shot (known by its trade name of Vivitrol). The usual dose for the pill is one tablet per day, while the shot is given once per month. Naltrexone should be used exactly as directed by your provider. If taking the pills and you miss a dose, take it as soon as you remember. However, if it is close to your next dose DO NOT "double up"; just skip the missed dose and continue with your regular dosing schedule. The shot is given every 28-30 days. It should not be given any earlier but can be given later if you miss the 30-day point. If using naltrexone for alcohol addiction, it may be started whenever you and your provider are ready. If using it for opioid addiction, you must be off of all opioids (including methadone and buprenorphine products like Suboxone) for 5-10 days before starting the medicine. If you take naltrexone too soon after using an opioid, it may cause you to go into rapid withdrawal. Your provider will help you decide when to begin naltrexone.

What are the potential side effects? Naltrexone is usually very well tolerated, with few to no side effects in most people. However, side effects may occur and the most common include nausea, vomiting, stomach pain or cramps, and diarrhea; less common side effects include loss of appetite, headache, dizziness, and anxiety. If side effects do occur, most will go away within a couple of weeks. If they do not go away or become severe, let your provider know as soon as possible. Naltrexone may cause liver damage when taken in large doses. It is not likely to cause liver damage when taken in the dose directed by your provider. Be sure to tell your provider if you have or ever had hepatitis or other liver disease. Your provider will check liver blood tests while you take naltrexone to help make sure it does not cause liver damage.

What else do I need to know? If you are pregnant, plan to become pregnant, or are breast-feeding make sure you tell your provider to help decide if naltrexone is right for you. If using naltrexone for opioid addiction and you have a relapse after stopping the medicine you will be at high risk for overdose due to the loss of tolerance to opioids. Make sure you continue the other parts of your recovery program after stopping naltrexone and seek help immediately if you relapse. You should carry or wear a medical alert identification in case of an emergency so that emergency personnel will know you are on naltrexone. If you take too much naltrexone or suspect a naltrexone overdose, call the U.S. poison hotline at 1-800-222-1222 or go to the closest emergency room immediately.

ANNEX

D

Instructions for Buprenorphine Induction

Congratulations on your decision to improve your health and treat your opioid addiction with buprenorphine (also known by the names Suboxone, Subutex, and Bunavail). Here are some things you should know and do to prepare for the start of treatment:

1. If you are actively using opioids, you **MUST** be in withdrawal in order to begin treatment with buprenorphine. By being in withdrawal, it tells us that other opioids are out of your system and it is safe to begin treatment. If you are not in withdrawal and receive a dose of buprenorphine, there is a very good chance that you will experience something called precipitated withdrawal. This means that the buprenorphine will send you into immediate, and often severe, withdrawal. You know your body best – make sure your last use of opioids gives enough time for you to be in withdrawal by the time you arrive for your induction appointment.

2. If you are not actively using opioids and have not had a recent relapse, then you will be able to start buprenorphine treatment without worrying about a precipitated withdrawal. If you have had a recent relapse after time in recovery, then you should wait at least 48 hours before starting buprenorphine.

3. On the day of your induction, you should not drive to or from the clinic – have someone who can drive you or use public transportation. Note that you will be here on the first day for 3 to 6 hours, depending upon your response to the first doses of buprenorphine.

4. After the first day, you should expect to return to the clinic every day for the rest of the week. After the first week, you will likely need to be in clinic 2-3 times the following week and then weekly thereafter, based on how you are doing in your recovery.

5. Once you reach your maintenance dose and are stable on buprenorphine, you should plan to start attending the group therapy sessions. The actual start date will be set by you and your treatment team.

6. If you have any questions about your induction, need to reschedule, or feel you need to be seen sooner than your scheduled appointment please call 865-544-0406 and ask to leave a message for Dr. McGrail.

Instructions for Buprenorphine Home Induction

Congratulations on your decision to improve your health and treat your opioid addiction with buprenorphine (also known by the names Suboxone, Subutex, and Bunavail). Here are some things you should know and do to prepare for the start of treatment:

1. If you are actively using opioids, you **MUST** be in withdrawal in order to begin treatment with buprenorphine. By being in withdrawal, it tells us that other opioids are out of your system and it is safe to begin treatment. If you are not in withdrawal and receive a dose of buprenorphine, there is a very good chance that you will experience something called precipitated withdrawal. This means that the buprenorphine will send you into immediate, and often severe, withdrawal. You know your body best – make sure your last use of opioids gives enough time for you to be in withdrawal by the time you take your first dose of buprenorphine.

2. If you are not actively using opioids and have not had a recent relapse, then you will be able to start buprenorphine treatment without worrying about a precipitated withdrawal. If you have had a recent relapse after time in recovery, then you should wait at least 48 hours before starting buprenorphine. If you recently relapsed with methadone, please let us know as you may have to wait longer before starting buprenorphine.

3. On the day you start buprenorphine, you should not drive, work, or perform any other activities that could be negatively impacted if you were to experience a side effect of the medication. The most common side effects of buprenorphine are sleepiness, nausea, and constipation. Most of the time, if you experience a side effect it will go away within a few days of taking the medication. If not, please let us know.

4. You will likely start on a low dose of buprenorphine and then gradually increase the dose until you no longer experience any opioid withdrawal symptoms (pill sickness) and your cravings are reduced. Your specific dosing plan is outlined below. DO NOT take more medication than instructed. If you do, you will run out of medication early and may then experience withdrawal from buprenorphine, a process that could be as severe as withdrawing from other opioids. Also, if you run out of medication early, you cannot get an early refill – you will have to wait until your next scheduled visit to get more medicine.

5. Once you reach the dose of medication that is right for you, you will have reached your maintenance, or regular, dose. It may take up to one week on the maintenance dose before you feel "normal" – no withdrawal symptoms and reduced cravings. Once you are stable on your maintenance dose, you will begin your behavioral therapy program.

6. If you have any questions about your medication, please call 865-934-6748 to speak with one of the clinic staff. If you feel you are having a severe reaction to the medication, go directly to the nearest emergency room or call 911.

Dosing Instructions:

Day 1 –

Day 2 –

Day 3 –

Day 4 –

Day 5 –

Day 6 –

Day 7 –

Next Appointment:

Clinical Opiate Withdrawal Scale (COWS)

Flow-sheet for measuring symptoms over a period of time during buprenorphine induction.

For each item, write in the number that best describes the patient's signs or symptom. Rate on just the apparent relationship to opiate withdrawal. For example, if heart rate is increased because the patient was jogging just prior to assessment, the increase pulse rate would not add to the score.

Patient's Name:_____ Date: _____

Buprenorphine induction:

Enter scores at time zero, 30min after first dose, 2 h after first dose, etc.

	Times: _____	_____	_____	_____
Resting Pulse Rate: (record beats per minute) *Measured after patient is sitting or 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 or flushing 1 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 reports 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 the rim of the iris is visible				
Bone or Joint aches *If patient was having pain previously, only the additional component attributed to opiates 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 stool 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 piloerrection of skin can be felt or hairs standing up on arms 5 prominent piloerrection				
Total scores **with observer's initials**				

Score:
5-12 = mild;
13-24 = moderate;
25-36 = moderately severe;
more than 36 = severe withdrawal

Cherokee Health Systems

Patient Consent and Agreement for Buprenorphine Treatment

Buprenorphine, with or without the additional medication naloxone, is recommended to me as part of my treatment program for opioid addiction. My signature below indicates that I voluntarily agree to participate in buprenorphine treatment; understand the risks, benefits, and alternatives to buprenorphine; and will be an active partner in a comprehensive treatment plan.

Benefits and Risks. Buprenorphine is an opioid medication that acts in two ways. First, it acts on the same areas of the brain that morphine and heroin act upon but it does so with less potency. This means it has less potential to cause the severe side effects of stronger opioids, like trouble breathing, sedation, and overdose death. Secondly, it acts to block the effects of other opioids so that when another opioid drug is taken, it is less likely to have an effect on the person. When naloxone, which is only an opioid blocker, is added to the buprenorphine, it has no effect when the medication is used properly. It is only when a medication like buprenorphine/naloxone (Suboxone) is used improperly, for example dissolved and injected, that naloxone rapidly blocks the effects of all opioids (including buprenorphine) and causes the person to experience immediate withdrawal. The use of buprenorphine during treatment for opioid addiction has been shown to reduce the use of illicit opioids, reduce cravings, improve treatment compliance, and reduce the chance of relapse. The risks of buprenorphine use, with and without naloxone, include side effects such as allergy to the medication, constipation, sedation, nausea, and insomnia. The use of buprenorphine with other medications and drugs that cause sedation, especially alcohol and benzodiazepines (drugs like valium, xanax, and klonopin), or the use of additional opioids can be dangerous and lead to serious adverse effects like difficulty breathing and death.

Buprenorphine Induction. If I am currently using opioids at the time I start treatment with buprenorphine, I will need to go through induction for buprenorphine. The induction process will be explained in detail by my treating provider but will require me to be in moderate withdrawal at the time I start treatment; if I have recently used other opioids, starting this medication may cause me to rapidly experience withdrawal symptoms. I will then be given small doses of buprenorphine at regular time intervals until I reach the initial dose that is right for me. I will likely be in the clinic for 4-8 hours for the induction and need to return to the clinic every 1-3 days for at least the first couple of weeks of my treatment.

Buprenorphine Maintenance Therapy. After my induction and when I have reached a stable dose of buprenorphine, I will be on maintenance therapy for the medication. The dose of medication will depend upon my response to the treatment and will be decided upon by me and my provider. I will continue to actively participate in the other parts of my overall treatment program. Buprenorphine treatment may result in dependence on the medication. As a result, it should not be suddenly stopped as it may cause withdrawal symptoms similar to withdrawal from other opioids. If the decision is made to stop treatment with buprenorphine, by me and/or my provider, it should be stopped gradually to help reduce any withdrawal symptoms; abruptly stopping the medication will likely result in significant

withdrawal symptoms. Maintenance therapy may be continued as long as I need it and it is an agreed upon part of my treatment program.

Alternative Treatments. Treatment for opioid addiction is available that does not involve the use of buprenorphine. This includes programs that do not use any medications during the course of treatment; programs that use the medication methadone, which is also an opioid, as part of the treatment plan; and programs that use the medication naltrexone, an opioid blocker similar in effect to naloxone, as part of treatment. If I decide I do not want treatment with buprenorphine, my provider can give me information about these other options.

Agreements. Buprenorphine is an opioid and, as such, can be dangerous to other people (especially children) and some may want to steal or misuse my medication. Therefore, I agree to the following:

1. I will not sell, share, or give any of my medication to another person.
2. The medication is my responsibility and I will keep it in a safe and secure place. Lost or stolen medication will not be refilled early regardless of the reason.
3. I will not seek or obtain any medications from other providers without informing my buprenorphine provider.
4. I will take my medication the way I have been instructed and will not alter the way I take it or the amount I take without first asking my doctor.
5. Buprenorphine may only be prescribed to me during my office visits. If I miss an appointment, I will have to wait until the next visit to receive my medication.
6. I will provide urine specimens for drug testing as a way to help monitor the progress of my treatment; urine collection may be directly observed by a staff member.
7. I will comply with requests for medication counts; when asked, I will bring all unused medication to clinic in the original packaging provided by my pharmacy for pill or film count. I will also comply with medication packaging counts. If I am on a medication that comes in individual wrappers, I will bring all empty wrappers from each prescription to the appointment immediately following the date of the prescription.
8. If I violate any of these agreements, my addiction treatment may be stopped immediately. If so, I will be provided recommendations for other treatment options.

_____ _____

Patient Signature Date/Time

_____ _____

Provider Signature Date/Time

Cherokee Health Systems

Pregnancy Addendum to Consent and Agreement for Buprenorphine Treatment

Buprenorphine has been recommended to me as part of my treatment plan for opioid addiction while pregnant. This pregnancy addendum provides additional information regarding the use of buprenorphine that is pertinent to me, while pregnant, and my baby, during the pregnancy and at the time of birth. All of the information and agreements included in the regular Consent and Agreement for Buprenorphine Treatment still apply and I have already signed that document. My signature below indicates that I voluntarily agree to buprenorphine treatment while pregnant; understand the risks and benefits to me and the baby; and have been informed of the alternatives to buprenorphine treatment.

Benefits and Risks. Buprenorphine is FDA approved for the treatment of opioid addiction and it is considered Pregnancy Category C (which means there is not enough research and evidence to say whether it is safe or not safe to use during pregnancy). However, buprenorphine is used regularly to treat opioid addiction in pregnant women and is endorsed by several national and international organizations. Pregnant women who take buprenorphine and do well in their treatment program generally have healthier babies than women who stop treatment, relapse, or continue to use illicit opioids during pregnancy. Buprenorphine is also safe to use while breastfeeding. The risks to me are described in the regular consent that I signed and are the same while pregnant. While taking buprenorphine during pregnancy, the baby may also experience some sedation and not be as active as usual, especially when I first start the medication. The primary risk to the baby is a condition called Neonatal Abstinence Syndrome (NAS) or Neonatal Opioid Withdrawal Syndrome (NOWS). This means that the baby may experience withdrawal from buprenorphine after delivery and experience symptoms such as irritability, poor or difficult feeding, sleep disturbance, tremor, and vomiting. Babies who experience NAS/NOWS will often remain in the hospital for several days after delivery and may require treatment with small doses of an opioid or other medication to manage the withdrawal.

Alternative Treatments. The alternatives to buprenorphine treatment during pregnancy are the same as when not pregnant with the general exception of naltrexone. While there are no specific worries about naltrexone, there is not enough information or experience with using it during pregnancy to allow for recommending its use.

_____ _____

Patient Signature Date/Time

_____ _____

Provider Signature Date/Time

ANNEX

E

Alcohol Withdrawal Management

All providers, both primary care and behavioral health, and nursing staff should be familiar with the identification and management of alcohol withdrawal. Given the potentially life-threatening complications of alcohol withdrawal, it is imperative to readily and accurately estimate the level of risk for severe withdrawal and disposition the patient appropriately.

The American Society of Addiction Medicine (ASAM) recommends determining a risk rating for the patient in suspected alcohol withdrawal with subsequent assignment to a level of care based upon the rating. It is important to note that risk ratings may fluctuate based upon individual patient characteristics during withdrawal. Therefore, the rating and level of care must be considered fluid and subject to change based on continued reassessment. Also, the medical management of withdrawal should not occur in a vacuum. Perhaps with the exception of patients requiring Level 4 withdrawal management services (intensive care inpatient), the period of withdrawal is appropriate for assessment and initiation of comprehensive, integrated treatment for the individual's substance use disorder(s); early involvement of addiction medicine, primary care, and BHC providers is indicated in most cases.

The use of a validated clinical tool for assessing alcohol withdrawal is useful for guiding management of withdrawal symptoms. The recommended withdrawal scale is the Clinical Institute Withdrawal Assessment for Alcohol, revised – otherwise known as the CIWA-Ar. The CIWA-Ar, although not specifically validated for this purpose, is also helpful for determining the patient's risk rating for withdrawal severity. The CIWA-Ar, like any tool, is one part of the overall patient assessment and must be considered in the overall clinical context.

Alcohol withdrawal should be considered in any patient who reports daily heavy drinking with no reported abstinence over the preceding 48 hours. Alcohol withdrawal syndrome may be variable in presentation, typically intensifying over 6-24 hours with a peak at 36 hours after the last drink and diminishing symptoms by 72-96 hours. The CIWA-Ar should be the clinical tool for assessing the patient's intensity of withdrawal. Patients who have a CIWA-Ar score of 8 or less consistently throughout the first 24 hours of presentation are at little risk of severe withdrawal. However, even with a low score, concern for more severe withdrawal syndromes must be elevated if any of the following are present: past history of seizures or delirium tremens; frequent sleep disturbances or nightmares in the previous week; presence of sweating, tremor, or pulse greater than 100 in the setting of a blood alcohol more than 0.10mg/dl; serum chloride under 96mmol/l; or severe physical health problems, particularly acute systemic infection. While the blood alcohol and serum chloride values may not be readily available in an outpatient clinic setting, the total clinical presentation and patient history should be considered when assigning a risk rating and when making clinical care judgments.

The following is a description of the ASAM levels of care for withdrawal management (formerly known as "detox") and risk ratings for withdrawal severity.

ASAM Withdrawal Management (WM) Levels of Care

Level 1 WM: Ambulatory WM without extended on-site monitoring.

- low intensity withdrawal; may or may not involve medication management; provides for comprehensive physical and psychological assessment along with substance use disorder (SUD) treatment planning; usual maximum CIWA-Ar score of up to 8-10; appropriate for patients with risk rating of 0 and some with risk rating of 1; may be performed in a primary care setting with BHC support or referred to addiction medicine.

Level 2 WM: Ambulatory WM with extended on-site monitoring.

- low to medium intensity withdrawal; usually, but not always, involves medication management; provides for comprehensive physical and psychological assessment along with SUD treatment planning; usual maximum CIWA-Ar score of up to 18; generally patients at this level have a risk rating of 1 or 2; may be performed in a primary care setting with BHC support but more typically referred to addiction medicine.

Level 3.2 WM: Clinically managed residential WM

Level 3.7 WM: Medically monitored inpatient WM

Level 4 WM: Medically managed intensive inpatient WM

- while some patients with a risk rating of 1 or 2 may be candidates for Level 3.2, typically these levels are reserved for more seriously ill (medically and/or psychologically) patients and those with more significant risk of severe withdrawal syndromes, i.e., those with a risk rating of 3 or 4; CIWA-Ar score greater than 19 should prompt consideration for level 3 or 4 WM; since levels 3.2, 3.7, and 4 exceed Cherokee Health Systems' capabilities, patients requiring these levels of WM care should be promptly and safely transferred to another treatment provider.

ASAM Risk Ratings for Alcohol WM

Risk Rating 0: Minimal or No Risk

- patient is fully functioning and tolerant of any withdrawal discomfort; low, <8, CIWA-Ar score and no concerning withdrawal history; no concurrent withdrawal from other substances; no or well controlled, mild medical and psychiatric co-morbidities; no urgent needs and SUD level of care driven primarily by assessment of dimensions other than WM; appropriate for Level 1 WM care and immediate SUD treatment planning and implementation; follow-up visits based upon SUD treatment plan.

Risk Rating 1: Mild Risk

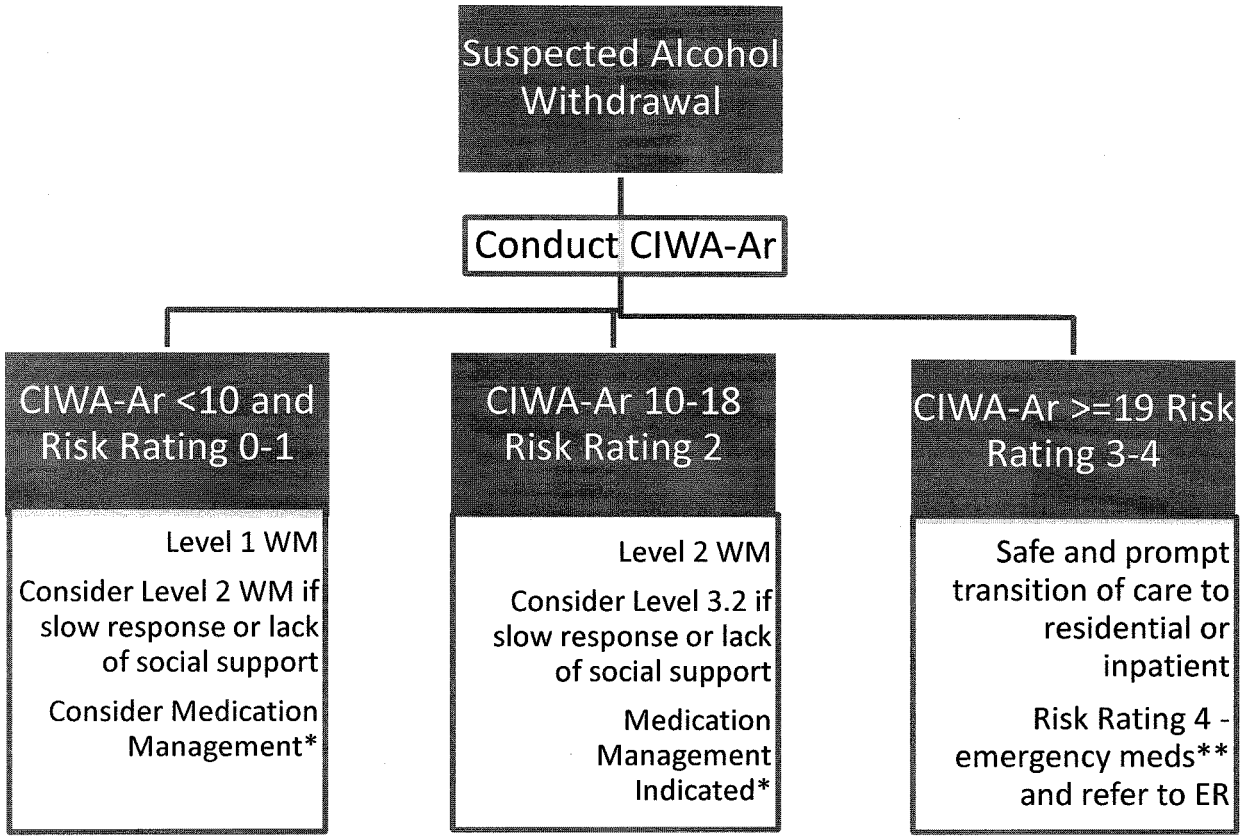
- mildly symptomatic with CIWA-Ar less than 10; no history in past year of severe withdrawal syndrome; no concurrent withdrawal from other substances; any medical or psychiatric problems are mild and/or well controlled; cognitively able to provide self care and understand treatment plan; may need medication for symptom management; appropriate for Level 1 WM care, especially with good social support structure and good response to medical and psychosocial interventions, or Level 2 WM care if inadequate social support or slow improvement in symptoms with medical and psychosocial treatment; generally have daily follow-up visits until acute withdrawal resolved and any withdrawal medications have been tapered and discontinued, subsequent visits based upon SUD treatment plan.

Risk Rating 2: Moderate Risk

- moderately symptomatic with CIWA-Ar usually 10-18; likely to exhibit moderate anxiety, sweating, insomnia, and mild tremor; if nausea/vomiting are present they are not serious enough to significantly affect treatment; no history of severe withdrawal syndromes and any active medical and psychiatric problems are stable; medication management is indicated at this risk rating; able to provide self care and understand treatment plan; appropriate for Level 2 WM with good social support and response to medical and psychosocial interventions or Level 3.2 if inadequate social support or insufficient improvement in symptoms with medical and psychosocial treatments; for Level 2 WM, follow-up is daily until acute withdrawal is resolved and withdrawal medications are tapered and discontinued, subsequent visits based upon SUD treatment plan.

Risk Rating 3, Significant Risk, and Risk Rating 4, Severe Risk

- exceed the risk rating 2 criteria; CIWA-Ar score 19 or greater; unstable, active medical and/or psychiatric problems exist; past episode(s) of severe withdrawal symptoms; occasionally a risk rating 3 patient with strong social support structure, relatively benign history, and a rapid, sustained response to office treatment may be treated at Level 2 WM; generally, though, risk rating 3 patients require Level 3.7 WM and all risk rating 4 patients (characterized by current seizures or delirium tremens or current severe symptoms with significant co-morbidities) require Level 4 WM; almost all risk rating 3 and 4 patients will be referred outside Cherokee Health Systems for care.



*Medication Management:

1. Symptom-triggered ("prn") dosing: Diazepam 10-20mg or Lorazepam 2-4mg; give every hour while CIWA-Ar>8-10; preferred route is oral but may be IM; caution for oversedation.
2. Fixed Dose: Diazepam 10mg every 6 hours for 4 doses then 5mg every 6 hours for 8 doses or Lorazepam 2mg every 6 hours for 4 doses then 1mg every 6 hours for 8 doses; must be able to tolerate oral meds; caution for oversedation.

**Emergency Medications:

1. Seizures: Lorazepam 4mg IV, may repeat in 10-15min or Diazepam 5-10mg IV every 10-15min up to 30mg maximum.
2. Delirium/Severe Agitation: Diazepam 5mg IV every 5 min x2, then 10mg IV every 5 min x2, then 20mg IV as needed; goal is light sedation, monitor for oversedation/respiratory depression. Alternate regimen is Haloperidol 1-5mg IM with or without Lorazepam 1-5mg IM every 5-10 min; start at low dose and titrate upward as needed.

Opioid Withdrawal from Chronic Opioid Therapy

Withdrawal from illicit or prescribed use of opioids may occur after as little as one week of use, with onset of the withdrawal depending upon pharmacokinetics of the drug and individual variation. For example, regular heroin users may experience withdrawal symptoms in as little as 6-12 hours following last use whereas 24-36 hours for users of oxycodone is common, while users of longer acting opioids like methadone or buprenorphine may not experience withdrawal symptoms for 2-3 days. While usually not life-threatening in persons without a serious, unstable medical or psychiatric co-morbidity, opioid withdrawal is often extremely uncomfortable and may lead to a patient "using anything" to alleviate the symptoms. Evidenced-based tools like the Clinical Opiate Withdrawal Scale (COWS) are used to assess the severity of opioid withdrawal and help to guide treatment (see attachment). Most opioid withdrawal may be managed in the outpatient setting with close medical and behavioral monitoring and support; however, clinician judgment regarding the impact of co-morbidities and the patient's capacity to perform outpatient management should take precedence over the severity of the withdrawal based upon a COWS score and referral for inpatient withdrawal management made when indicated. Outpatient management is generally indicated for a COWS score consistent with up to moderate to moderately-severe withdrawal; recommended steps for management include:

1. Obtain COWS score upon patient presentation along with routine vital signs and assessment.
2. Obtain urine drug screen to assess for presence/type of opioids and establish consistency, or resolve discrepancy, of result with patient report. Also assess for presence of other substance use that may complicate or pose a risk to opioid use and withdrawal, such as concomitant benzodiazepine use.
3. Obtain opioid use history – type, amount, duration, history of previous withdrawal, history of diagnosis and/or treatment of opioid use or other substance use disorder, history of opioid overdose.
4. Involve the BHC early! This is critical for diagnostic clarity regarding the presence of a substance use disorder, co-morbid psychiatric conditions, building patient motivation, and treatment planning.
5. Counsel the patient regarding alternate pain management options, including non-pharmacologic, non-opioid, and behavioral strategies. Also consider discussing with patients, when indicated, the possibility of opioid-induced hyperalgesia – the phenomenon through which many individuals on chronic opioids experience an increased sensitivity to pain and, when long term opioid therapy is ceased, the individual's pain spontaneously improves after several weeks of opioid abstinence. Informing the patient that his/her pain will not be ignored is important to build a therapeutic alliance and successfully navigate opioid withdrawal.
6. There are essentially three outpatient treatment plan options going forward. First, continue opioid therapy (either with you as the prescriber or with referral to a pain clinic for consideration). Second, assist the patient with acute opioid withdrawal (see below for symptomatic management). Third, conduct an outpatient opioid taper employing a slow, scheduled reduction in opioid dosing to minimize withdrawal symptoms and reduce the risk of return to opioid medications (see below for sample protocol).

7. The management of acute opioid withdrawal requires an integrated medical and behavioral approach. Regarding medication management, the following are helpful for withdrawal symptom control: promethazine 25mg every 4-6 hours as needed for nausea/vomiting; loperamide OTC as directed for diarrhea; and clonidine 0.1-0.2mg three times per day as needed for the hyperautonomic symptoms such as restlessness, anxiety, muscle cramps. Symptomatic medications are provided for a period of five days, enough for the majority of patients to progress through the most uncomfortable part of opioid withdrawal. Patients should undergo urine drug testing at least one week after reported opioid cessation and then 1-2 weeks later to assess for relapse. Patients are followed initially at least once or twice weekly for medical and behavioral support, then as indicated for ongoing management. Providers should be alert for post-acute withdrawal syndrome (PAWS), manifesting typically as mood and sleep disturbances, and in particular, with opioid withdrawal, as a transient increase in perceived pain. PAWS will often resolve spontaneously within 6-12 weeks but may last up to 12 months in some individuals. The presence of PAWS should not preclude the appropriate management of mood, sleep, and pain concerns as would otherwise be clinically indicated.
8. The conduct of a gradual outpatient opioid taper should be considered in the patient for whom acute withdrawal is not indicated or would be too risky (e.g., severe medical or psychiatric co-morbidities, unsupportive environmental factors, etc.). A sample protocol for outpatient opioid taper is suggested by the Mayo Clinic: taper 10% of the original opioid dose per week until reaching 30%, then taper 10% per week until done. For example, a patient using 100mg of oxycodone per day would be tapered 10mg per week until reaching 30mg, then would be tapered 3mg per week (10% of 30mg) until done. This gradual taper schedule serves to minimize withdrawal symptoms, risk of relapse, and allows time to implement alternate pain management strategies prior to completion of the taper. Patients are followed weekly for medication management and urine drug testing should be performed at least monthly, more often as indicated.
9. It is not uncommon for patients to cycle between treatment plans. For example, a patient managed as an outpatient may then need inpatient care before returning to outpatient services. Patients attempting an acute withdrawal may be unsuccessful and require a gradual opioid taper. All members of the treatment team, including the patient, are important toward determining the "right care at the right time".

Any questions regarding management of opioid withdrawal, or other substance use related concerns, may be directed to the CHS addiction medicine service at x6748 or email Dr. McGrail or Dr. Tenbarge.

ANNEX

F

Cherokee Health Systems Program
Group Treatment Program (GTP) for Substance Use Disorders
Participation Agreement

We are excited to partner with you to improve your health and quality of life. Our program is designed to give you the support and skills necessary to reduce any future impact your addiction may have on your life and provide a safe place for you to learn a drug and alcohol free lifestyle. As part of your treatment plan, you have accepted our recommendation to participate in our Group Treatment Program (GTP) for substance use disorders. GTP is conducted in a group session format and will cover many topics in the areas of behavioral health, physical health, and recovery from addiction. Your attendance in at all group sessions is *required*.

You can expect the following format for the GTP:

1. GTP will meet 1 time per week for 3 hours
2. GTP is a group medical visit, meaning that this 3 hour group visit is your medication management appointment. By attending group, you are attending your medication management appointment with your Addiction Specialist. If you miss group, you miss your medication management appointment as these will not be scheduled separately from group.
3. The treatment team will be present at the group medical visit. This includes your Addiction Specialist, a Behavioral Health provider, and Community Health Coordinator. You will be leaving the group for a brief period to discuss your medication privately with your provider at some point while the group medical visit is in session.
4. The pharmacy will fill medications during the group medical visit and will release prescribed medications after the group ends.
5. If something prevents you from arriving within the first 15 min of group or you request to leave more than 15 minutes before group has ended, you are welcome to stay and participate in the group but will not be counted as present. Arriving more than 15 minutes late or leaving more than 15 minutes early will mean you are unable to be seen regarding medication on that day and must schedule a follow up with your physician and behavioral health provider to discuss progress in the program. The day and time of that appointment will not be the same day as the missed group and will be up to the provider's discretion.
6. Please make efforts to schedule other responsibilities including other appointments in a way that does not conflict with your GTP attendance. Minor illnesses and non-court related appointments do not quality as an excused absence from group.

— quality

As always, throughout the program, you will meet with the Program staff to assess your treatment progress. If, together, we determine that you would benefit from continued participation in GTP, you will be given the opportunity to continue in the program. When you reach the point in your recovery that you are ready to move from the Phase I Group into the Program's Phase II (or "Aftercare") Group, you will be given that opportunity. This change in group will happen based upon your treatment progress.

We fully understand that addiction is a disease and that relapses do occur. If at any time during Phase I or Phase II Group, we feel that you need a different level of treatment for your disease, we will discuss it together and change your treatment plan as needed. Many patients find that treatment plans change often during recovery, to include remaining in or returning to GTP, medication changes, or referral to a higher level of care than is available at Cherokee. Everyone's course during recovery is different and change is OK – the important thing is that you receive the care that is right for you.

In addition to GTP, you will have other parts of your treatment plan in which you will participate. These may include the use of medications to help treat addiction; medical appointments for physical health issues; individual therapy for behavioral health concerns; meetings with a case manager to assist with housing, transportation, and other needs; and attendance at AA, NA, or other similar meetings. We will work with you to balance all of these requirements to help you develop a healthy lifestyle. Urine drug screens are also an important part of monitoring your treatment progress. Drug screen testing may occur during a GTP session or during one of your individual medical or behavioral health appointments. Drug screen results are used for treatment purposes and are not released outside of Cherokee unless you sign a written release requesting that your confidential health information be released.

If you are on medication for addiction treatment (such as Suboxone or Vivitrol), your medication will not abruptly be stopped if you are unable to continue participating in GTP. If this happens, you will meet with Program staff and develop a revised treatment plan for your recovery.

The Guidelines for GTP Participation

1. Everything that happens in group, including the identities of other group members, is confidential and must not be discussed outside of group – "what happens in group stays in group".
2. A participant who appears to be intoxicated during a session will be required to leave and obtain a safe way to get home. If the participant refuses and/or drives away, police will be notified.
3. Deferring your prescribed medications to others and/or selling any illicit substances on Cherokee property will result in dismissal from care.
4. No cell phone use during group.
5. Be respectful toward staff and other group participants.
6. Do not wear revealing clothing or clothing with references to drugs and alcohol.
7. Participate in group discussions to the best of your ability – group is better for everyone if all participants put forth a good effort.
8. Tobacco products and energy drinks of any kind are not allowed in group.
9. Follow all rules of Cherokee Health Systems, including no weapons in the building (including pocket knives).
10. Be honest.

I understand the requirements for GTP participation and agree to abide by the participation guidelines.

_____

Patient Signature

_____ _____

BHC Signature

Addiction Specialist Signature

Cherokee Health Systems

Cherokee Health Systems
Intensive Outpatient Alcohol and Drug Program
AA/NA Proof of Attendance

Name: _____

Date	Time	(AA/NA)	Location	Facilitator's Signature & Phone Number
1.				
2.				
3.				
4.				
5.				
6.				
7.				
8.				
9.				
10.				
11.				
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16.				

ANNEX

G

Addiction Clinic Performance Measures

1. Thirty-day treatment retention: treatment of substance use disorders requires consistent and sustained engagement by the patient in a treatment program; providers must make every reasonable effort to foster and sustain this engagement; one review article identified a national 30-day treatment retention rate average of approximately 68%, although with significant variability based on factors such as patient demographics, type of treatment, and substance(s) involved; patient outcomes improve the longer a patient remains in treatment; **recommendation – CHS addiction medicine providers achieve 65% or greater 30-day treatment retention**, with retention defined as patients returning for at least one appointment with any clinic provider within 30 days following the initial intake visit; excluded would be patients determined at intake to need a level of care not offered by CHS (e.g., referred for inpatient care), patients incarcerated or hospitalized following intake for more than seven days, and patients re-locating outside the CHS addiction clinic service area within 30 days of intake.

2. Tobacco use screening and cessation counseling: nicotine addiction is widespread in patients suffering from substance use disorders and requires assessment and treatment during the provision of services for addiction to other substances to reduce tobacco related morbidity; **recommendation – CHS addiction medicine providers provide tobacco use screening and cessation counseling to 90% or greater of patients within a twelve month period**, consistent with UDS measures and applicable to other CHS primary care providers.

3. Residential/inpatient readmission rate: patients successfully completing residential or inpatient treatment programs require timely and appropriate care plans following discharge to reduce substance use related morbidity and to promote the effective utilization of healthcare resources; rapid return to residential or inpatient care may indicate an ineffective outpatient treatment plan or change in disease severity; when possible and clinically appropriate, outpatient care should be optimized to reduce rapid return to more costly residential/inpatient care services; literature review identified readmission rates ranging from approximately 8% to 25% for periods of 30 to 180 days following discharge; **recommendation – CHS addiction medicine service achieve residential/inpatient readmission rates of 20% or less over the 90-day period following discharge**, with the measure applying to those patients referred by CHS for residential/inpatient care and successfully completing the prescribed length of the program; excluded would be patients presenting to CHS following residential/inpatient care not recommended/referred by CHS, patients who leave care AMA, and patients who do not attend at least one post-discharge visit at CHS to re-engage in outpatient care.

4. Contraceptive use screening and counseling: women with substance use disorders who become pregnant experience increased risk for maternal, fetal, and neonatal morbidity; identifying appropriate patients for use of contraception, particularly long-acting reversible contraception (LARC), is critical to reduce unintended pregnancy, associated risks, and the potential risk of neonatal abstinence syndrome in the babies of patients with an opioid use disorder; **recommendation – CHS addiction medicine providers annually screen 90% or greater of female patients of childbearing age for contraceptive needs and counsel appropriate patients on the use of LARC and other birth control methods**, with the measure applying to all female patients between the ages of 18 and 60 years.

ANNEX

H

DAILY TRACKER EXAMPLE

NAME	TB Screen	D.O.B.	Bup Stop Date	Pharmacy	CSMD DUE	Insurance	Vivitrol PAP ETOH	Last UDS	Last MD/NP visit	Comment
	yes		INACTIVE	Cherokee	NA	TNC		NA	NA	
			6/19/2018	Cherokee	10/19/2018	Grant/Self-pay		4/6/2018	5/29/2018	taper complete 6/19
			INACTIVE	Cherokee	8/13/2018	NEEDS GRANT, Self pay		2/13/2018	2/13/2018	

Legend

Bup Stop Date – date current buprenorphine prescription will be finished

CSMD – Controlled Substance Monitoring Database (the Tennessee State PDMP)

Vivitrol PAP ETOH – patients with an alcohol use disorder diagnosis and no opioid use disorder diagnosis may receive Vivitrol through the pharmaceutical company patient assistance program (PAP); this is the date the patient's PAP expires.

UDS – urine drug screen

MEDICAL TRACKER EXAMPLE

NAME	D.O.B.	SUD Dx	DOC	Last Use DOC	Last Use Any	MAT	LFTs	Hepatitis	HIV	PMH	Obstetric Hx	Psych Hx	Meds	IOP Start	Comments
Intake 2/21/2017		Opioids	Heroin	3/13/2017	Xanax 2/25/17, Marijuana 2/25/17	Bunavail 4.2/0.7	Norm 2/21/17	B Neg 2/21/17, Hep C pos, non-detect viral load 3/1/17	Neg 2/21/17	Fibromyalgia, Chronic fatigue, OA/DDD to back, neck, hips, ankles	G8P2242, youngest born in 2001, BTL	BPD, Anxiety	Celexa, Topamax, Hydroxyzine	3/8/2017	GF of another treatment participant, homeless - couch surfs
Intake 11/6/2017		Opioids	Opioids	Percocet 11/5/17	Xanax 11/27/17	Suboxone 2x8/2 mg	Norm 10/4/17	Hep B Surf Ab pos Hep B Ag neg 10/2017 Hep C RNA neg 11/6/17	Neg 11/6/17	Hep C s/p RBV/INF 2011, hypothyroid, osteoporosis, AI, RAD, HTN	G1P1001, 37yo	Bipolar	Gabapentin, Lisinopril, Fluoxetine, Rexulti, Synthroid, Proventil MDI, Vit D	Pending	Lives alone in Love Towers, currently in divorce proceedings, mult treatments in past for SUD

Legend

DOC – Drug of Choice

LFTs – Liver Function Tests

PMH – Past Medical History

Note – above document is usually printed on 8.5x14 paper allowing for improved legibility of the fields