



RCHC Clinical Guideline for Buprenorphine/Naloxone Treatment for Opioid Use Disorder

I. Purpose: To assist in the evaluation and treatment of opioid use disorder using buprenorphine/naloxone.

II. Scope of protocol: Office-based opioid treatment (OBOT) using buprenorphine/naloxone combination (Suboxone) for induction and maintenance.

III. Prerequisite Elements for Successful Medication Assisted Treatment (MAT) programs

- Engaged leadership
- Administrative and clinical champions
- Qualified providers - obtain waiver authorized through Drug Addiction Treatment Act of 2000 (DATA 2000)
 - MD/DO must have completed 8 hour waiver course; may prescribe up to 100 patients; after one year may apply for a *Patient Limit Increase* to treat up to 275 patients
 - NPs and PAs must complete 24 hours of education to qualify for waiver; may prescribe for up to 30 patients for one year; then may apply to prescribe for up to 100 patients
 - Additional 16 hours of training are needed (available in 2017)
- A minimum of two waiver providers; mentoring support is advised
- Adequate staffing for administrative activities to ensure the health center can follow waiver requirements and can meet audit requirements
- Team-based approaches enable clinics to provide patients with needed wraparound support services without overburdening physicians. Models may include nurse practitioners, physician assistants, behavioral health providers, certified addiction counselors, social workers, and/or health educators.
- Capacity to provide behavioral health services including counseling and support groups
- Pharmacists willing to partner
- Sustainable financing, or financing acceptable to the sponsoring organization.

Sources: Substance Abuse and Mental Health Services Administration (SAMHSA); California Health Care Foundation

IV. Patient criteria for medication assisted treatment with buprenorphine

Patient must meet the diagnosis of *opioid use disorder* using “DSM-V worksheet criteria for diagnosis of opiate use disorder” (see Appendix A). In addition, the patient must desire treatment, understand its risks/ benefits and have no contra-indications to MAT.

Source: SAMHSA: Treatment Improvement Protocols (TIP) 40 Buprenorphine Treatment checklist

https://www.ncbi.nlm.nih.gov/books/NBK64245/pdf/Bookshelf_NBK64245.pdf

V. Treatment considerations (see Appendix B)

- Inductions may be done in a primary care office, through a specialty clinic model, or as home inductions.
 - Office inductions have low complication rates and allow staff to begin building a therapeutic relationship with patients.
 - Specialty clinic models enable health centers that don't have the capacity to provide inductions maintain patients on Suboxone (“hub-spoke”).
 - Limited data is available on home inductions (Lee 2009; Gunderson 2010). Careful patient selection is required to ensure patients are able to manage at home and are not at risk for diversion. Health centers should have sufficient staff in place to support patients needing assistance.



- OBOT is not suitable for patients with active ETOH use or a sedative, hypnotic or anxiolytic use disorder. Risks, benefits and alternatives for each patient must be considered including tapering from other medications (e.g. benzodiazepines) or referral to an opioid treatment program (OTP).
- Buprenorphine/naloxone combination (Suboxone) is recommended for most patients because of its reduced potential for abuse compared to use of buprenorphine alone.
 - Monotherapy is recommended for pregnant women, patients with hepatic impairment and patients who desire to change from long-acting opioids to buprenorphine.
 - Methadone is recommended for patients who would benefit from daily dosing and close supervision of an OTP. Due to poor medication adherence, naltrexone is usually reserved for observed dosing.
- Patients must come in already experiencing some degree of opioid withdrawal syndrome. The period of time they must abstain will depend on the half-life of the opioid being used.
 - While they may be dependent or experiencing cravings, patients who are not actively using opioids or in danger of withdrawal patient do not need induction.
- Behavioral health support is an essential component of care. This may include individual treatment and/or attending structured groups that reinforce MAT.

VI. Pre-visit and Counseling

- Diagnose opioid use disorder using the DSM-V (see Appendix A).
- Triage for urgent or emergent medical or psychiatric problems including drug-related impairment or overdose.
- Complete medical history including screening for concomitant medical conditions and infectious disease (HIV, hepatitis & TB), acute trauma and pregnancy. Review medications for allergies and drug-drug interactions. Rule out pregnancy and confirm effective contraception.
- Evaluate past and current substance use: alcohol, sedatives, hypnotics, anxiolytics, and tobacco.
- Perform or have evidence of current physical examination including a mental status assessment.
- Initial laboratory tests: CBC, LFT, Hepatitis B&C, and HIV. All women of childbearing age should receive a pregnancy test.
- A urine drug test (UDS) should be done to identify use of opioids and other psychoactive medications at the initial visit and each subsequent visit.
- Immunize for Hepatitis B if indicated.
- Assessment of social and environmental factors to identify facilitators and barriers to treatment.
- Counsel and educate patient on how the medication works, required period of abstinence, risks/benefits associated with MAT, alternatives (methadone maintenance, naltrexone), how to deal with short-term pain relief (e.g. dental procedures, surgery) and plan for safe storage and overdose prevention.
 - Pros: safe/proven medication, suppression of opioid withdrawal
 - Possible benefits: improved pain control, anti-depressant effect
 - Cons: have to go through withdrawal before starting medication, does not give "high"
 - Potential risks: dangerous if combined with alcohol or benzodiazepines, liver toxicity
- Develop a treatment plan in coordination with the patient. Outline expectations and requirements for participation in the health center's program including appointments, fees, behavioral health sessions,



urine toxicology screening, and indications for dismissal from the program. Have patient sign a care agreement (see Appendix D).

- Obtain written consent to treatment with buprenorphine (see Appendices D-III).
- Provide a prescription for the naloxone with education regarding its use.

VII. Inductions

Inductions are for patients actively using opioids who have experienced mild to moderate opioid-related withdrawal effects (Clinical Opiate Withdrawal Scale score = 12-16).

- A period of abstinence is required: 6-16 hours for short-acting opioids, 17-24 hours intermediate-acting opioids, and 24-72 hours for methadone.

A. In-office

- Pre-visit assessment and counseling; patient provided education materials (see Appendices A - D).
- Day 1 – Patient presents to clinic:
 - Vital signs are checked
 - Urine toxicology obtained to determine presence of opioids or other drugs.
 - Physician assessment for withdrawal symptoms using the *Clinical Opiate Withdrawal Scale* (COWS) (Appendix C).
 - Administer a 2-4 mg dose (2-0.5mg #8); patient waits 30-90 minutes then is re-evaluated using COWS. Depending on the score, an additional 2-4mg is administered and the patient is re-evaluated; a maximum of 16 mg on day one.
 - Patient is linked with behavioral health services.
- Days 2 & 3 – Patient meets with physician for withdrawal evaluation and dosed as needed. Follow-up with behavioral health services (group/individual). MD re-evaluates before patient leaves at mid-day.
- After day 3, patient attends behavioral health appointments to help manage cravings, reduce likelihood of relapse and assist with emotional and social challenges. This may include individual sessions or groups using contingency management, cognitive behavioral therapy and other interventions.

B. Unobserved Home Induction

- Pre-visit for assessment and counseling; patient provided education materials (Appendices A - D).
 - Prescription – call-in or write prescription
 - Day 1: 4-16 mg; NTE 16mg; Schedule 3 medications, formulations:
 - 2/0.5, 4/1, 8/2, and 12/3mg SL strip
 - 2/0.5, 8/2 SL tab
 - Ancillary medications
 - Zofran 4-8 mg po TID PRN nausea
 - Prochlorperazine 10 mg po TID PRN nausea/vomiting
 - Clonidine 0.1mg po BID-TID agitation (caution hypotension)
 - Hydroxyzine 25-5 mg po q bedtime PRN insomnia
- Patient induces her/himself at home with close follow-up by phone over the next few days.
- An office visit is scheduled in the next week to check symptoms, dose, urine drug screen, including buprenorphine.
- Patient attends behavioral health appointments



VIII. Maintenance

Buprenorphine dose after induction and titration is usually at least 8mg per day; typically 8-16mg daily. US FDA approves dosing up to 24mg per day. Increasing the frequency of dosing rather than the dose of buprenorphine can be more effective for pain relief. While buccal film is not FDA approved for induction, it may be used for maintenance.

Weekly visits with UDS are recommended until patient is stable evidenced by abstinence from illicit drugs, participation in psychosocial treatment, and demonstration of good occupational and social functioning. While the waiver provider is responsible for addiction diagnosis, prescription management and periodic follow-up visits, a nurse care manager or other staff member can be the main point of contact and manage the program details. Once stable, the patient can move to semi-weekly, then monthly visits for regular evaluation and urine toxicology screening. Ongoing behavioral health support should also continue as relapse-prevention.

IX. Discontinuation of Medication

There is no recommended time limit for buprenorphine treatment. While tapering is possible, it is a slow process over several months. Successful termination of treatment will depend on multiple factors including the patient's involvement in meaningful activities and adequate behavioral support. Patients who have relapsed after termination should be returned to treatment.

X. Administrative Issues

- Privacy and Confidentiality: Individually identifiable drug or alcohol treatment information is protected by SAMHSA confidentiality regulation Title 42, Part 2 of the Code of Federal Regulations (42 C.F.R. Part 2). This regulation mandates that addiction treatment information in the possession of substance use disorder treatment providers be handled with a greater degree of confidentiality than general medical information. Among other stipulations, regulation 42 C.F.R. Part 2 requires that physicians providing opioid addiction treatment obtain signed patient consent before disclosing individually identifiable addiction treatment information to any third party. MAT programs should have patients sign a consent prior to beginning treatment that explicitly explains the exchange of information between medical providers, behavioral health clinicians and pharmacies involved.
- Buprenorphine supplies must be stored safely and have a procedure to ensure restricted access.
- Records must be kept current documenting patients, dates & amounts of medication received to confirm that providers are not exceeding limit of patients.
- U.S. Drug Enforcement Agency conducts random site visits to physician offices that have Buprenorphine waivers to monitor compliance.
- Financing – OBOT is a covered benefit under Partnership HealthPlan of California for patients with opioid use disorder (ICD-10 code F11.20). One visit is reimbursable per day at the primary care provider capitated rate for assigned members and *fee for service* for outside referrals (non-assigned members). No TAR is required. The medication is carved out, so is reimbursed by State Medi-Cal and not through the managed care plan.
- Workflow – various models have been shown to be effective
 - Individual visit model: see sample workflow Appendix E.
 - Group visits: Orientation and pre-induction steps can be done in a group to explain the process and sign consents. Ten to twelve patients can then be seen as a group led by a behavioral health



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staff member. During the sessions the X license provider will see each participant for an individualized check-in visit during which medication dosages can be adjusted.



Sources

American Society of Addiction Medicine (June 2015): <http://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf?sfvrsn=24>

- Summary: Kampman, K and Jarvis, M. 2015. American Society of Addiction Medicine (ASAM) National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use. *J Addict Med*; 9:358-367. <http://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-jam-article.pdf>

California Health Care Foundation

- <http://www.chcf.org/~media/MEDIA%20LIBRARY%20Files/PDF/PDF%20P/PDF%20PCBuprenorphinePrograms.pdf>

Centers for Medicare and Medicaid Services (CMS) Buprenorphine – A Primer for Prescribers and Pharmacists (December 2015): <https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/drugdiversion-buprenorphine-booklet.pdf>

Lee, J., Grossman, E., DiRocco, D, and M. Gourevitch. 2009. Home Buprenorphine/Naloxone Induction in Primary Care. *J of General Internal Medicine*, 24(2): 226-32.

Gunderson, E., Wang, X., Fiellin, D., Bryan, B., and F. Levin. 2010. Unobserved versus observed office buprenorphine/naloxone induction: a pilot randomized clinical trial; *Addiction Behavior*. May; 35(5): 537-540.

Substance Abuse and Mental Health Services Administration (SAMHSA)

- SAMHSA Medication Assisted Treatment webpage: <http://www.samhsa.gov/medication-assisted-treatment>
- Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction; A Treatment Improvement Protocol TIP 40 (2004): https://www.ncbi.nlm.nih.gov/books/NBK64245/pdf/Bookshelf_NBK64245.pdf
- Buprenorphine treatment checklist: http://www.integration.samhsa.gov/clinical-practice/mat/MAT_Implementation_Checklist_FINAL.pdf
- Waiver information: <https://www.samhsa.gov/medication-assisted-treatment/qualify-nps-pas-waivers>; <http://buprenorphine.samhsa.gov/forms/select-practitioner-type.php>; <https://www.samhsa.gov/medication-assisted-treatment/buprenorphine-waiver-management>; <https://www.samhsa.gov/medication-assisted-treatment/training-resources/buprenorphine-physician-training>
- *Decisions in Recovery*: <http://archive.samhsa.gov/MAT-Decisions-in-Recovery/Default.aspx>
- MAT pocket guide: <http://store.samhsa.gov/shin/content/SMA16-4892PG/SMA16-4892PG.pdf>
- Practitioner App to support MAT for Opioid Use Disorder: <http://www.integration.samhsa.gov/news/articles/2016/10/28/new-app-to-support-mat-for-opioid-use-disorder>
- Women Matter (gender specific resources on working with women who have substance use disorders): <https://www.samhsa.gov/women-children-families/trainings/women-matter>



- Substance Abuse Confidentiality Regulations (42 CFR Part 2) <http://www.samhsa.gov/about-us/who-we-are/laws/confidentiality-regulations-fags>

Wesson, D.R. & Ling, W. 2003. The Clinical Opiate Withdrawal Scale. Journal Psychoactive Drugs, April-June; 35 (2): 253-9.

http://www.researchgate.net/profile/Donald_Wesson2/publication/10608525_The_clinical_opiate_withdrawal_scale_COWS/links/571957a408ae30c3f9f2c232.pdf

Resources

Billing and Office Reimbursement: <http://www.buppractice.com/node/1437>

Clinical Pathway for Buprenorphine Treatment for Opioid Dependence:
<http://docs.clinicaltools.com/pdf/Buppractice/pathway.pdf>

National Alliance of Advocates for Buprenorphine treatment: <https://www.naabt.org/index.cfm>

- Patient education materials: http://www.naabt.org/documents/NAABT_PrecipWD_HiRes.pdf;
http://www.naabt.org/collateral/How_Bupe_Works.pdf ;
<http://www.addictionsurvivors.org/documents/AddSurvBrochure.pdf>

Opioid Converter Tool (for MED Calculation): <http://www.globalrph.com/opioidconverter2.htm>

Opioid Dose Calculators

[Centers for Disease Control and Prevention \(CDC\) Opioid Dose Calculator](#)

[Washington State Opioid Dose Calculator](#)

Partnership Healthplan of California: Managing Pain Safely:

<http://www.partnershiphp.org/Providers/HealthServices/Pages/Managing-Pain-Safely.aspx>

Providers' Clinical Support System for Medication Assisted Treatment: <http://pcssmat.org>

Mentoring

U.C.S.F.: <http://nccc.ucsf.edu/clinician-consultation/substance-use-management>

National Providers' Clinical Support System for MAT: <http://pcssmat.org>

- <http://pcssmat.org/mentoring>

Project ECHO: <http://echo.unm.edu>

- <http://echo.unm.edu/wp-content/uploads/2014/10/Opioid-Abuse-and-Addiction-Management-Protocol.pdf>

HealthKnowledge course: 3-hour self-paced course for office staff; free online learning and low-cost CEU

<http://healthknowledge.org/course/index.php?categoryid=49>

Appendix A: DSM-V Criteria

Patient's Name:		Date of Birth:	
Worksheet for DSM-V criteria for diagnosis of opiate use disorder			
Diagnostic Criteria* (Opioid Use Disorder requires at least 2 within 12 month period)	Meets criteria		Notes/supporting information
	Yes	No	
1. Opioids are often taken in larger amounts or over a longer period of time than intended.			
2. There is a persistent desire or unsuccessful efforts to cut down or control opioid use.			
3. A great deal of time is spent in activities necessary to obtain the opioid, use the opioid, or recover from its effects.			
4. Craving, or a strong desire to use opioids.			
5. Recurrent opioid use resulting in failure to fulfill major role obligations at work, school or home.			
6. Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids.			
7. Important social, occupational or recreational activities are given up or reduced because of opioid use.			
8. Recurrent opioid use in situations in which it is physically hazardous			
9. Continued use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by opioids.			
10. *Tolerance, as defined by either of the following: (a) a need for markedly increased amounts of opioids to achieve intoxication or desired effect (b) markedly diminished effect with continued use of the same amount of an opioid			
11. *Withdrawal, as manifested by either of the following: (a) the characteristic opioid withdrawal syndrome (b) the same (or a closely related) substance are taken to relieve or avoid withdrawal symptoms			

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

Severity: **Mild:** 2-3 symptoms, **Moderate:** 4-5 symptoms. **Severe:** 6 or more symptoms.

Signed _____ Date _____

Criteria from American Psychiatric Association (2013). Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition. Washington, DC, American Psychiatric Association page 541.

Source: American Psychiatric Association (2013). Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Washington, DC, American Psychiatric Association, page 541.



Appendix B: Buprenorphine treatment checklist (SAMHSA)

Check-list and Considerations before beginning MAT program:

1. Does the patient have a diagnosis of opioid dependence?
2. Are there current signs of intoxication or withdrawal? Is there a risk for severe withdrawal?
3. Is the patient interested in buprenorphine treatment?
4. Does the patient understand the risks and benefits of buprenorphine treatment?
5. Can the patient be expected to adhere to the treatment plan?
6. Is the patient willing and able to follow safety procedures?
7. Does the patient agree to treatment after a review of the options?
8. Can the needed resources for the patient be provided (either on- or offsite)?
9. Is the patient psychiatrically stable? Is the patient actively suicidal or homicidal; has he or she recently attempted suicide or homicide? Does the patient exhibit emotional, behavioral, or cognitive conditions that complicate treatment?
10. Is the patient pregnant?
11. Is the patient currently dependent on or abusing alcohol?
12. Is the patient currently dependent on benzodiazepines, barbiturates, or other sedative-hypnotics?
13. What is the patient's risk for continued use or continued problems? Does the patient have a history of multiple previous treatments or relapses, or is the patient at high risk for relapse to opioid use? Is the patient using other drugs?
14. Has the patient had prior adverse reactions to buprenorphine?
15. Is the patient taking other medications that may interact with buprenorphine?
16. Does the patient have medical problems that are contraindications to buprenorphine treatment? Are there physical illnesses that complicate treatment?
17. What kind of recovery environment does the patient have? Are the patient's psychosocial circumstances sufficiently stable and supportive?
18. What is the patient's level of motivation? What stage of change characterizes this patient?

Source: SAMSHA, TIP 40 https://www.ncbi.nlm.nih.gov/books/NBK64245/pdf/Bookshelf_NBK64245.pdf page 44



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

<https://www.drugabuse.gov/sites/default/files/files/ClinicalOpiateWithdrawalScale.pdf>

Clinical Opiate Withdrawal Scale (COWS)

<p>This flow sheet measures symptoms over a period of time during buprenorphine induction. Patient's Name: _____ Date: _____ Buprenorphine induction: Enter scores at time zero, 30 min after first dose, 2h after first dose, etc. Times: _____</p>				
<p>Resting Pulse Rate: (record beats per minute) <i>Measured after patient is sitting or lying for one minute</i> 0 pulse rate 80 or below 1 pulse rate 81-100 2 pulse rate 101-120 4 pulse rate greater than 120</p>				
<p>Sweating: <i>over past ½ hour not accounted for by room temperature or patient activity.</i> 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</p>				
<p>Restlessness: <i>Observation during assessment</i> 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</p>				
<p>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</p>				
<p>Bone or Joint aches: <i>If patient was having pain previously, only the additional component attributed to opiates withdrawal is scored.</i> 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</p>				

<p>Runny nose or tearing: <i>Not accounted for by cold symptoms or allergies</i></p> <p>0 not present 1 nasal stuffiness or unusually moist eyes 2 nose running or tearing 4 nose constantly running or tears streaming down cheeks</p>				
<p>GI Upset: <i>over last ½ hour</i></p> <p>0 no GI symptoms 1 stomach cramps 2 nausea or loose stool 3 vomiting or diarrhea 5 multiple episodes of diarrhea or vomiting</p>				
<p>Tremor: <i>observation of outstretched hands</i></p> <p>0 No tremor 1 tremor can be felt, but not observed 2 slight tremor observable 4 gross tremor or muscle twitching</p>				
<p>Yawning: <i>Observation during assessment</i></p> <p>0 no yawning 1 yawning once or twice during assessment 2 yawning three or more times during assessment 4 yawning several times/minute</p>				
<p>Anxiety or Irritability</p> <p>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</p>				
<p>Gooseflesh skin</p> <p>0 skin is smooth 3 piloerection of skin can be felt or hairs standing up on arms 5 prominent piloerection</p>				
<p>Total scores with observer's initials</p>				
Score				
5-12	Mild			
13-24	Moderate			
25-36	Moderately Severe			
>36	Severe Withdrawal			



Appendix D: Pre-visit Counseling and Consents; Source: Mendocino Community Health Centers

I. Buprenorphine Program: Expectations and Requirements

Please initial each of the following to indicate your acceptance of the individual requirements:

- _____ Admission into this program **requires** that you make it a top priority in your life. We wish you success in your recovery.
- _____ It is **your responsibility** to arrive on time for your appointments.
- _____ You are **required** to attend addiction treatment education group sessions in conjunction with your scheduled medication appointments.
- _____ You are also **required** to attend an annual one-on-one counseling session to evaluate your progress in the program and in your recovery.
- _____ You **may be** required to attend an NA or AA meeting group per agreement with your counselor.
- _____ Children are not allowed into the group sessions, counseling sessions, or medication appointments. You are responsible for setting up childcare before you come into the clinic.
- _____ A Urine Toxicology test **will be** done during your scheduled appointments. We check to make sure the urine hasn't been tampered with. **We may also do random urine checks.**
- _____ Pregnancy testing will be done along with regular urine toxicology screenings for all women of childbearing age (18-55 years).
- _____ A **"slip up"** is defined as an illicit drug use, positive urine toxicology test, missed appointments with a physician or psychologist, or a missed group meeting in accordance with your treatment plan. At the discretion of the treating provider, excessive cancellation will result in dismissal from the program. We would prefer you be honest with us about a "slip up" or drug use, rather than finding out through a urine test.
- _____ We do **not** demand perfection, however after three "slip-ups", we will discuss dismissing you from the program.
- _____ You are **required** to keep all clinic fees current, to include medical visit fees, lab and drug costs and primary care counseling fees. Failure to meet financial obligations will result in tapering off the medication in consultation with your medical provider.

You may contact _____ with any further questions or concerns; call _____ and leave a detailed message with a current phone number.

Patient signature _____ Print name _____ Date _____

Parent/Guardian signature _____ Print name _____ Date _____

Witness signature _____ Print Name/relationship _____ Date _____

Provider signature _____ Print name _____ Time/Date _____



II. Buprenorphine Care Agreement

The following information represents a voluntary agreement between me and my treating providers with whom I have a relationship at _____, for treatment of my substance use disorder while in the buprenorphine program:

1. I agree to keep and be on time to all of my scheduled appointments with the doctor and other providers at the clinic. I will be responsible for scheduling my appointments.
2. I understand that medication alone is not a sufficient treatment for addiction. I agree to attend the groups and other counseling services required of me. I acknowledge that I want to be clean and sober.
3. I agree that I will not “just drop by” the clinic for medication: I must obtain my medication during my scheduled visits.
4. I agree to conduct myself in a courteous manner in the clinic at all times.
5. I agree that I will not share, sell, or give any of my medication to another person. Not taking my medication as prescribed is a violation of this agreement and will result in immediate dismissal from this program.
6. I agree that I am responsible for my medication and I agree to keep it in a safe, secure place. I understand that lost medication will not be replaced.
7. I understand that this medication is an opiate and can be dangerous/deadly if used improperly. I agree to store my medication in a safe place, away from children and pets. If anyone other than me takes the medication, I will call 911.
8. I agree not to obtain medications from any physicians, pharmacies, emergency rooms, hospitals, or other people or institutions without informing my doctor.
9. I agree to not mix other medications with my buprenorphine, especially alcohol, benzodiazepines (Valium, Klonopin, Xanax, and Ativan) or other drugs of abuse (including opiates) because it is dangerous. I understand that a number of deaths have been reported among persons who mixed buprenorphine with the above substances.
10. I agree to take my medication as prescribed and to talk with the treatment team before making any adjustments to my dose of medication.



11. I have been informed of the risks, benefits, and side effects of treatment with buprenorphine.
12. I agree to cooperate with requests for urine and blood samples.
13. I agree to talk with a provider or other sober person if I have the urge to relapse. If I do relapse, I will notify the clinic. Relapse to opiates can be life threatening.
14. It is my responsibility to inform any and all medical personnel involved in my care, that I am taking buprenorphine.
15. I agree to allow my treating provider to contact any health care professional, pharmacy, legal authority or regulatory agency to obtain or provide information about my care or actions if the treating provider feels it is necessary.
16. I agree that members of my treatment team can speak with other providers, CPS, probation/parole, and/or County AODP Programs in order to provide the best comprehensive treatment. I understand they will disclose only the minimum necessary information for treatment under this program
17. I understand that I may request in writing a list of individuals and entities to whom their information has been disclosed. I may also request to withhold disclosure of some of the information contained in my record and will notify the treating provider of that information if any before it is released. Otherwise, all minimum information necessary to coordinate my care will be released to the treating provider at the programs and services noted below.

Indicate here other programs/services in which you are involved:

18. I agree that I cannot be involved with secondary syringe exchange programs while receiving buprenorphine.

Your signature below indicates that you have read, understood, and agree to abide by the rules of this program. If you are confused or you have questions, please ask for clarification, as you will be expected to follow all of these rules without exception. Not following through with rules can result in dismissal from the program.

Patient signature _____ Print name _____ Date _____



Parent/Guardian signature _____ Print name _____ Date _____

Witness signature _____ Print Name/relationship _____ Date _____

Provider signature _____ Print name _____ Time/Date _____

III. Consent to Treatment with Buprenorphine

- Buprenorphine is an FDA-approved medication for treatment of people with opiate dependence. Qualified physicians may treat as many as 100 patients for opiate dependence. Buprenorphine can be used for detoxification or for maintenance therapy. Maintenance therapy can continue as long as medically necessary.
- Buprenorphine itself is an opiate but it is longer acting than most other opioids. Buprenorphine treatment can result in physical dependence of the opiate type. Buprenorphine withdrawal is generally less intense than with heroin or methadone. If buprenorphine is suddenly discontinued, some patients have no withdrawal symptoms; others have symptoms such as muscle aches, stomach cramps, or diarrhea lasting for several days. To minimize the possibility of opiate withdrawal, buprenorphine should be discontinued gradually, usually over several weeks or more.
- If you are dependent on opiates, you should be in withdrawal when you take the first dose of buprenorphine. If you are not in withdrawal, buprenorphine can cause severe opiate withdrawal. For that reason, you should take the first dose in the office and remain in the office for at least two hours. After that, you will be given some tablets to take at home. Within in a few days, you will have a prescription for buprenorphine that will be filled in a pharmacy.
- Some patients find that it takes several days to get used to the transition from the opiate they had been using to buprenorphine. During that time, any use of other opiates may cause an increase in symptoms. After you become stabilized on buprenorphine, it is expected that other opiates will have less effect.
- Attempts to override the buprenorphine by taking more opiates could result in an opiate overdose.
- **When taking Buprenorphine, you should not take any other medication without discussing it with your doctor first.** Combining buprenorphine with alcohol or some other medication may also be hazardous. The combination of buprenorphine with medications such as Valium, Librium, and Ativan, has resulted in deaths.
- The form of buprenorphine (Suboxone) you will be taking is a combination of buprenorphine with a short-acting opiate blocker (Naloxone). If the Suboxone tablet were dissolved and injected by someone taking heroin or another strong opiate, it would cause severe opiate withdrawal.
- Buprenorphine tablets must be held under the tongue until they dissolve completely. Buprenorphine is then absorbed over the next 30 to 120 minutes from the tissue under the tongue. Buprenorphine will be absorbed from the stomach if it is swallowed.

Alternatives to Buprenorphine

- Some hospitals that have specialized drug abuse treatment units can provide detoxification and intensive counseling for drug abuse. Some outpatient drug abuse treatment services also provide individual and group therapy, which may emphasize treatment that does not include maintenance on buprenorphine or other opiate-like medications. Other forms of opiate maintenance therapy include



methadone maintenance. Some opiate treatment programs use naltrexone, a medication that blocks the effects of opiates but has no opiate effects of its own.

Patient Signature _____ Print Name _____ Date _____
Parent/Guardian Signature _____ Print Name _____ Date _____
Witness Signature _____ Print Name/relationship _____ Date _____
Provider Signature _____ Print Name _____ Time/Date _____

IV. Buprenorphine Participation Agreement and Consent to Treatment

As a participant in _____ Buprenorphine Program, I am expected to abstain from non-prescribed medications and mood altering substances. I will provide _____ with copies of all prescriptions from all of my health care provider(s) and abide by the Buprenorphine Medication Policy. My signature below indicates my understanding of and willingness to abide by the following:

1. I agree to tell my health care provider(s) that I am in treatment for a substance use disorder.
2. I agree to participate in my treatment by:
 - Attending all scheduled appointments, groups and meetings on time as shown in my treatment plan
 - Being actively involved in those groups and meetings
 - Regularly checking my mail for notices from _____ and informing _____ staff right away of any changes in my address and/or phone number.
 - Making payments for my program fees as agreed upon in my financial agreement.
3. I agree to dress modestly, and to wear clothing that is free of alcohol, tobacco or drug logos, references to substance use, gang-related and/or racially or sexually demeaning.
4. I will not bring weapons of any kind to _____.
5. I understand that social misconduct of any kind, including, but not limited to, negative involvement with law enforcement, could result in discharge or temporary suspension.
6. I agree to treat MCHC staff, visitors and clients with respect, and engage in no acts or threats of violence to people or property.
- 7. I agree to maintain the confidentiality of other clients, including their names.**
8. I understand that if I drive to the health center and appear to be intoxicated or under the influence of substances, I will be asked to turn over my car keys and find a sober driver. If I then attempt to drive, I understand that the police will be contacted in order to ensure my safety and that of others.
9. I understand that I am responsible for keeping all agreements I make, including those in my signed treatment plan.
10. I understand that violation of this agreement is cause for dismissal. I understand that if I am unable to maintain my sobriety in an outpatient program, _____ may recommend other treatment resources including referral to alcohol and other drug programs or residential treatment. I understand and hereby agree to comply with this Participation Agreement, and authorize and give my consent for treatment at _____.



11. Alcohol and/or drug treatment records are protected under Federal and State confidentiality regulations governing *Confidentiality of Alcohol and Drug Abuse Patient Records, 42 Code of Federal Regulations (CFR) Part 2, and the Health Insurance Portability and Accountability Act of 1996 (HIPPA), 45 CFR Parts 160 and 164*, and cannot be disclosed without my written consent except for those individuals or entities with whom I have a current and future treating relationship. I understand that the Redwood Community Health Coalition may share data with the _____ health information exchange and _____ entities.

Patient signature _____ Date _____

Counselor/nurse/witness signature _____ Date _____

Appendix E: Sample Induction Workflow

- a. Patients must come in already experiencing some degree of opioid withdrawal syndrome. This means abstaining from opioids for a period of time dependent on the half-life of the opioid that is being used.
- b. Patients will be given a prescription on the day of the consult visit to take to pharmacy. Depending on the reliability of the patient, they will either pick up the medication on their own, or clinic staff will pick up the medication from pharmacy on the day of induction.
- c. On induction day, patient will come in and have the following:
 - i. Vital signs done
 - ii. COWS score done by clinician along w/ brief exam
 - iii. Urine toxicology to evaluate for presence of other drugs or opioids
- d. Depending on the COWS score, will give 1 dose of Suboxone (buprenorphine 2mg to patient under supervision (COWS score greater than 7 indicates appropriate for Suboxone, as anything less means patient is not in active withdrawal and Suboxone may actually induce worse withdrawal symptoms)
- e. Patient waits 30 min
- f. Re-evaluated, possibly measure COWS score again, and depending on patient's symptoms may administer another 2mg dose.
- g. Step c-f repeated the following day – on day 2, may increase dose of Suboxone administered to 4mg at a time (or 2x2mg tabs), or 8mg total.
- h. Patient is then sent home with meds or RX for 1 week, and will follow up next week.
- i. The next week dosage may be titrated based on patient's symptoms, cravings, side effects. Once patient is on a stable daily dose, patient can enter *Maintenance* phase and be seen monthly.