

## 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

\_\_\_\_\_  
Witness 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 Name	Signature	Date/Time
_____	_____	_____
Provider Name	Signature	Date/Time
_____	_____	_____
Witness Name	Signature	Date/Time