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Patient Information and Consent to Treatment with Buprenorphine/Naloxone

Name:

Date:

Suboxone® (a tablet or strip with buprenorphine and naloxone in it) is an FDA approved medication for treatment of people with heroin or other opioid (prescription pain medication) addiction. Buprenorphine can be used for detoxification or for maintenance therapy. Maintenance therapy can continue as long as medically necessary. There are other treatments for opiate addiction, including methadone, naltrexone, and some treatments without medications that include counseling, groups, and meetings.

If you are dependent on opiates - any opiates - **you should be in as much withdrawal as possible 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 2-3 hours. You should not drive or operate machinery until you know how buprenorphine/naloxone affects you. Therefore, you must arrange not to drive after your first dose, because some patients get drowsy until the correct dose is determined for them. You must either take public transportation to the office visits for induction or you must have someone drive you to the induction appointment(s).

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. You should not take any other medication without discussing it with the physician first.

Combining buprenorphine with alcohol or other sedating or tranquilizer medications is dangerous. The combination of buprenorphine with benzodiazepines (such as Valium®, Librium®, Ativan®, Xanax®, Klonopin®, etc.) has resulted in deaths. You must agree not to take such medications without discussing this with your doctor. If you think you need to take these medications, you may be referred to other treatment for your opioid addiction and you agree to this before starting buprenorphine/naloxone.

Although buprenorphine given under the tongue has not been shown to be liver-damaging (except when people take very large amounts of buprenorphine or sometimes, if Hepatitis C is present), your doctor will monitor your liver tests while you are taking buprenorphine. (This is a blood test.)

The form of buprenorphine (Suboxone®) you will be taking is a combination of buprenorphine with a short-acting opiate blocker (naloxone) in a 4 to 1 ratio (4 mg of buprenorphine to 1 mg naloxone). **It will maintain physical dependence**, and if you discontinue it suddenly, you will likely experience withdrawal symptoms. If you are not already dependent, you should not take buprenorphine, it could eventually cause physical dependence. Buprenorphine/naloxone tablets or the buprenorphine/naloxone strip must be held under the tongue until it is dissolved completely. You will be given your first dose at the clinic, and you will have to wait as it dissolves, and for two hours after it dissolves, to see how you react. **It is important not to talk and to swallow as little as possible until the medication dissolves.** This takes up to ten minutes.

Buprenorphine is then absorbed over the next 30 to 120 minutes from the tissue under the tongue. Buprenorphine is poorly absorbed from the stomach. **If you swallow the tablet, you will not have the important benefits of the medication, and it may not relieve your withdrawal.**

Most patients end up at a daily dose of 12/3-16/4 mg of buprenorphine. Beyond that dose, the effects of buprenorphine plateau, so there may not be any more benefit to increase in dose. It may take several weeks to determine just the right dose for you. The first dose is usually 2/0.5-4/1 mg.

If you are transferring to Suboxone® from methadone maintenance, your dose must be tapered until you have been at or **below 30mg for at least a week**. There must be **at least 24 hours** (preferably longer) between the time you take your last methadone dose and the time you are given your first dose of buprenorphine. Your doctor will examine you for clear signs of withdrawal, and you will not be given buprenorphine until you are in withdrawal.

I have read and understand these details about buprenorphine treatment. I have had my questions about buprenorphine/naloxone and treatments for opioid addiction answered. I wish to be treated with buprenorphine.

Patient Signature

Date

Print Name

Consent for Treatment with Buprenorphine/Naloxone

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

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

I understand that I am dependent on opiates (heroin or prescription opioids such as Lortab or Lorcet, Percodan or Percocet, Oxycontin, Dilaudid, Methadone, Morphine, MS Contin), and I should be in as much withdrawal as possible when I take the first dose of buprenorphine. If I am not in withdrawal, buprenorphine may cause significant opioid withdrawal and physical discomfort. For that reason, I agree to take the first dose in the doctor's office and remain in the office for observation for up to 3 hours. Within a few days, I will have a prescription for buprenorphine that will be filled in a pharmacy.

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

Combining buprenorphine with alcohol or some other medications may also be hazardous. The combination of buprenorphine with medication such as Xanax, Valium, Librium, Ativan or other sedatives or tranquilizers has resulted in deaths. I agree not to take such medications with buprenorphine.

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

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

Buprenorphine can cost \$10+/day just for the medication. If I have medical insurance, will need to find out whether or not buprenorphine is a benefit. In any case, **office fees must be kept current, or I understand that I will not be able to continue receiving this treatment from this program.**

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 opioid maintenance therapy include methadone maintenance. Some opioid treatment programs use naltrexone, a medication that blocks the effects of opioids, but has no opioid effects of its own.

Patient Signature

Date

Print Name

Agreement for Treatment with Buprenorphine/Naloxone

<input type="checkbox"/> Yes	<input type="checkbox"/> No	I understand that buprenorphine/naloxone is a medication to treat opiate addiction (for example: heroin, prescription opiates such as oxycodone, hydrocodone, methadone). Buprenorphine/naloxone contains the opiate narcotic analgesic medication, buprenorphine, and the opiate antagonist drug, naloxone, in a 4 to1 (buprenorphine to naloxone) ratio. The naloxone is present in the tablet to prevent diversion to injected abuse of this medication. Injection of buprenorphine/naloxone by a person who is addicted to opiates will produce severe opiate withdrawal.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	1. I agree to keep appointments and let staff know if I will be unable to show up as scheduled
<input type="checkbox"/> Yes	<input type="checkbox"/> No	2. I agree to report my history and my symptoms honestly to my physician, nurses, and counselors involved in my care. I also agree to inform staff of all other physicians and dentists who I am seeing; of all prescription and nonprescription drugs I am taking; of any alcohol or street drugs I have recently been using; and whether I have become pregnant or have developed hepatitis.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	3. I agree to cooperate with witnessed urine drug testing whenever requested by medical staff, to confirm if I have been using any alcohol, prescription drugs, or street drugs. I agree that if any urine drug screen is positive and disputed by self, I will cooperate with a serum blood drug screen.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	4. I have been informed that buprenorphine is a narcotic analgesic, and thus it can produce a "high"; I know that taking buprenorphine/naloxone regularly can lead to physical dependence and addiction, and that if I were to abruptly stop taking buprenorphine/naloxone after a period of regular use, I could experience symptoms of opiate withdrawal. I also understand that combining buprenorphine/naloxone with benzodiazepine (sedative or tranquilizer) medications (including but not limited to Valium, Klonopin, Ativan, Xanax, Librium, Serax) has been associated with severe adverse events and even death. I also understand that I should not drink alcohol with buprenorphine/naloxone since it could possibly interact with buprenorphine/naloxone to produce medical adverse events such as reduced breathing or impaired thinking. I agree not to use benzodiazepine medications or to drink alcohol while taking buprenorphine/naloxone and I understand that my doctor may end my treatment with buprenorphine if I violate this term of the treatment agreement.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	5. I have been informed that buprenorphine/naloxone is to be placed under the tongue for it to dissolve and be absorbed, and that it should never be injected. I have been informed that injecting buprenorphine/naloxone after taking buprenorphine/naloxone or any other opiate regularly could lead to sudden and severe opiate withdrawal.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	6. I have been informed that buprenorphine/naloxone is a powerful drug and that supplies of it must be protected from theft or unauthorized use, since persons who want to get high by using it or who want to sell it for profit, may be motivated to steal my take-home prescription supplies of buprenorphine/naloxone.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	7. I have a means to store take-home prescription supplies of buprenorphine/naloxone safely, where it cannot be taken accidentally by children or pets or stolen by unauthorized users. I agree that if my buprenorphine/naloxone pills are swallowed by anyone besides me, I will call 911 or Poison Control at 1-800-222-1222 immediately and I will take the person to the doctor or hospital for treatment.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	8. I agree that if my doctor recommends that my home supplies of buprenorphine/naloxone should be kept in the care of a responsible member of my family or another third party, I will abide by such recommendations.

<input type="checkbox"/> Yes	<input type="checkbox"/> No	9. I will be careful with my take-home prescription supplies of buprenorphine/naloxone, and agree that I have been informed that if I report that my supplies have been lost or stolen, that my doctors will not be requested or expected to provide me with make-up supplies. This means that if I run out of my medication supplies it could result in my experiencing symptoms of opiate withdrawal. Also, I agree that if there has been a theft of my medications, I will report this to the police and will bring a copy of the police report to my next visit.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	10. I agree to bring my bottle of Buprenorphine/naloxone in with me for every appointment with my doctor so that remaining supplies can be counted.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	11. I agree to take my Buprenorphine/naloxone as prescribed, to not skip doses, and that I will not adjust the dose without talking with my doctor about this so that changes in orders can be properly communicated by to my pharmacy.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	12. I agree that I will not drive a motor vehicle or use power tools or other dangerous machinery during my first days of taking Buprenorphine/naloxone, to make sure that I can tolerate taking it without becoming sleepy or clumsy as a side-effect of taking it.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	13. I agree that I will arrange transportation to and from the treatment facility during my first days of taking Buprenorphine/naloxone so that I do not have to drive myself to and from the clinic or hospital
<input type="checkbox"/> Yes	<input type="checkbox"/> No	14. I want to be in recovery from addiction to all drugs, and I have been informed that any active addiction to other drugs besides heroin and other opiates must be treated by counseling and other methods. I have been informed that buprenorphine, as found in Buprenorphine/naloxone, is a treatment designed to treat opiate dependence, not addiction to other classes of drugs.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	15. I agree that medication management of addiction with buprenorphine, as found in Buprenorphine/naloxone, is only one part of the treatment of my addiction, and I agree to participate in a regular program of professional counseling while being treated with Buprenorphine/naloxone.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	16. I agree that professional counseling for addiction has the best results when patients also are open to support from peers who are also pursuing recovery.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	17. I agree to participate in a regular program of peer/self-help while being treated with Buprenorphine/naloxone. -
<input type="checkbox"/> Yes	<input type="checkbox"/> No	18. I agree that the support of loved ones is an important part of recovery, and I agree to invite significant persons in my life to participate in my treatment
<input type="checkbox"/> Yes	<input type="checkbox"/> No	19. I agree that a network of support, and communication among persons in that network, is an important part of my recovery. I will be asked for my authorization, to allow telephone, email, or face-to-face contact, as appropriate, between my treatment team, and outside parties, including physicians, therapists, probation and parole officers, and other parties, when the staff has decided that open communication about my case, on my behalf, is necessary.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	20. I agree that I will be open and honest with my counselors and inform staff about cravings, potential for relapse to the extent that I am aware of such, and specifically about any relapse which has occurred -before a drug test result shows it.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	21. I have been given a copy of clinic procedures, including hours of operation, the clinic phone number, and responsibilities to me as a recipient of addiction treatment services, including buprenorphine treatment with Buprenorphine/naloxone.

Patient Signature

Date

Staff Signature/Title

Date

**Buprenorphine/Naloxone Maintenance Treatment
Intake Questionnaire for Patient Treatment-Planning Questions**

Name:

Date:

Please answer the following questions which will help us design your plan of treatment:

What is the best time of day and day of week for you for clinic visits? _____

Are there any months of the year when you may have difficulty making it in for appointments?

Is there any problem that makes it hard for you to give routine urine specimens?

Do you have any disabilities that make it hard for you to read labels or count pills?

What are your reasons for being interested in Buprenorphine/Naloxone treatment?

What "triggers" do you know which have put you in danger or relapse in the past or which might in the future?

What coping methods have you developed to deal with these triggers to relapse?

What plans do you have for the coming year?

Work?

Home?

Other?

What kinds of help would you like from your counselor? _____

What are your strengths and skills to handle take-home Buprenorphine/Naloxone (Suboxone)?

What worries do you have about extended take homes? _____

Is anyone in your home actively addicted to drugs or alcohol? _____

What are the major sources of stress in your life? _____

What family or significant others will be supportive to you during your treatment? _____

Would you be willing to sign a release so that the person(s) identified above can be spoken to regarding your treatment? _____

What medical care will you have in the coming year? _____

How will you comply with the annual physical examination and laboratory and urine testing requirements?

Have you ever been treated for a psychiatric problem or mental illness or prescribed psychiatric medications?



Notice of Privacy Practices (HIPAA)

****This notice describes how medical information about you may be used and disclosed, and how you can get access to this information. Please read it carefully.****

The Health Insurance Portability & Accountability Act of 1996 (HIPAA) is a federal program that requires that all medical records and other individually identifiable health information used or disclosed by Ballen Medical and Wellness in any form, whether electronically, on paper, or orally are kept properly confidential. HIPAA gives you, the patient, the right to understand and control how your personal health information (PHI) is used. HIPAA provides penalties for covered entities that misuse personal health information.

As required by HIPAA, we prepared this explanation of how we are to maintain the privacy of your health information and how we may disclose your personal information.

We may use and disclose your medical records only for the following purposes: treatment, payment, and health care operation.

- Treatment means providing, coordinating, or managing healthcare and related services by one or more healthcare providers. An example of this is if you are referred to a primary care doctor or another specialist.
- Payment means such activities as obtaining reimbursement for services, confirming coverage, billing or collections activities, and utilization review. An example of this would include sending your insurance company a bill for your visit. (Please note that Ballen Medical and Wellness does not submit to insurance.)
- Health Care Operations include the business aspects of running our practice, such as conducting quality assessments and improving activities, auditing functions, cost management analysis, and customer service. An example of this would be patient survey cards.
- The practice may also be required or permitted to disclose your PHI for law enforcement or other legitimate reasons. In all situations, we shall do our best to assure its continued confidentiality to the extent possible.

We may also create and distribute de-identified health information by removing all reference to individually identifiable information.

We may contact you, by phone or in writing, to provide appointment reminders or information about treatment alternatives or other health-related services, in addition to other fundraising communications, that may be of interest to you. You do have the right to "opt out" with respect to receiving fundraising communications from us.

The following use and disclosures of your PHI will only be made pursuant to us receiving a written authorization from you:

- Most uses and disclosure of psychotherapy notes (these are not part of your medical record under HIPAA).
- Uses and disclosure of your PHI for marketing purposes, including subsidized treatment and health care operations.
- Disclosures that constitute a sale of PHI under HIPAA.
- Other uses and disclosures not described in this notice.

You may revoke such authorization in writing, and we are required to honor and abide by that written request, except to the extent that we have already taken actions relying on your prior authorization.

You may have the following rights with respect to your PHI

- The right to request restrictions in certain uses and disclosures of PHI, including those related to disclosures of family members, other relatives, close personal friends, or any other person identified by you. We are, however not required to honor a request restriction except in limited circumstances which we shall explain if you ask. If we do agree to the restriction, we must abide by it unless you agree in writing to remove it.
- The right to reasonable requests to receive confidential communications of Protected Health Information by alternative means or at alternative locations.
- The right to inspect and copy your PHI.
- The right to amend your PHI.
- The right to receive an accounting of disclosures of your PHI.
- The right to obtain a paper copy of this notice from us upon request.
- The right to be advised if your unprotected PHI is intentionally or unintentionally disclosed.

If you have paid for services “out of pocket”, in full and in advance, and you request that we not disclose PHI related solely to those services to a health plan, we will accommodate your request, except where we are required by law to make a disclosure.

We are required by law to maintain the privacy of your Protected Health Information and to provide you the notice of our legal duties and our privacy practice with respect to PHI.

This notice is effective as of the initial date of service and it is our intention to abide by the terms of the Notice of Privacy Practices and HIPAA Regulations currently in effect. We reserve the right to change the terms of our Notice of Privacy Practice and to make the new notice provision effective for all PHI that we maintain. We will post and you may request a written copy of the revised Notice of Privacy Practice from our office.

You have recourse if you feel that your protections have been violated by our office. You have the right to file a formal, written complaint with office and with the Department of Health and Human Services, Office of Civil Rights. We will not retaliate against you for filing a complaint.

Feel free to contact the Practice Director, Elizabeth Reece, RN BSN, for more information, in person or in writing.

Receipt of Notice of Privacy Practices and Written Acknowledgement Form

Patient Name: _____ **Date of Birth:** _____

I am a patient of Ballen Medical and Wellness. I, _____ hereby
acknowledge receipt of Ballen Medical & Wellness' Notice of Privacy Practices.

Patient Signature: _____ **Date:** _____