

Informed Consent for Controlled Substances Policy

SCOPE AND APPLICATION:

Purpose: The objective of this policy is to outline the expectations in place to maintain a therapeutic relationship between the patient and the prescriber when “controlled substances” are prescribed.

Definition: Controlled substances are defined by Federal Law and include classes of drugs such as opiates, benzodiazepines, stimulants that may be prescribed for such conditions as pain, anxiety, insomnia, muscle spasticity, convulsive disorders, and/or detoxification from alcohol or other substances. These drugs are regulated by state and federal laws with the intent to control the risk of addiction, abuse, physical and mental harm, illegal trafficking, and the potential for dangerous actions by those who have used the substances. Such drugs may be declared illegal for sale or use, but may be dispensed with a prescription from a licensed prescriber.

Policy: Any time a provider is prescribing a controlled substance for a condition, an informed consent for controlled substance may be initiated. The purpose of an informed consent is to outline the risks, benefits, alternatives and expectations for a patient using these medications, as they may be addictive in nature and/or have significant consequences if not taken as prescribed.

Procedure: Informed Consent for Controlled Substance may be initiated by any provider for any patient that is being treated for a non-acute problem at any time. Informed consent is not required, but if initiated, informed consent for controlled substances must be documented using the Informed Consent for Controlled Substances Agreement Form. It is recommended that the Agreement Form be reviewed and updated annually.

The prescriber must review the form with the patient. This review cannot be delegated. Once the form has been reviewed by the provider, both the prescriber and the patient must sign.

A copy of the signed form must be given to the patient. The original will be scanned into the patient’s electronic medical record under consents > controlled substance agreement.

Controlled Substance Agreement

The purpose of this Agreement is to establish a clear understanding between the patient and prescriber in regards to the use of Controlled Substances (e.g. opiates, benzodiazepines, stimulants). This class of medications are commonly prescribed for very specific conditions, and present a higher risk for misuse, abuse, or addiction **if not taken exactly as prescribed**. Because these drugs have the potential for abuse, strict accountability is necessary when use is prolonged.

I understand the importance of complying with the rules outlined in this agreement to protect my health and wellbeing, my access to controlled substances, and to protect my provider's ability to prescribe them to me.

I understand that my provider is treating me based on this Agreement.

The medication(s) I will be taking include: _____

This medication(s) is being used to treat a diagnosis of: _____

The pharmacy I will be using for this medication(s) is: _____

Potential side effects of this medication(s) may include the following:

- Nausea, vomiting, constipation
- Blurred vision
- Impaired coordination, sleepiness, and confusion
- Memory loss
- Breathing problems
- Fatigue
- Dizziness
- Muscle weakness
- Impaired ability to drive or operate machinery
- Personality Changes
- Allergic reactions, overdose and fatal complications
- Addiction
- Serious effects if used in conjunction with alcohol or other medications

I will not participate in any activities that may be dangerous to me or someone else while taking this medication. I am aware that certain types of these medications may slow reflexes and reaction time, increasing the risk of motor vehicle accidents. Activities that could be dangerous include, but are not limited to, operating heavy equipment or motor vehicles, working in dangerous environments, or being responsible for another individual who is unable to care for themselves.

I am aware that tolerance can occur with the use of these medications. Tolerance is defined as a need for a higher dose to maintain the same effect. If my treating physician determines that continued escalation of the dose is not in my best interest, the medication may need to be tapered or discontinued and may necessitate another form of treatment. I understand that physical dependence is possible. I am aware that physical dependence means that if my medication is decreased or stopped, I could experience a withdrawal syndrome (including but not limited to: sweating, increased heart rate and high blood pressure, insomnia, abdominal cramps, tremors, diarrhea, muscle or bone aching, seizures). Withdrawal symptoms in rare cases, may be life threatening and may require hospitalization.

I understand that addiction is a possible risk to the use of this medication. Addiction is recognized as when an individual abuses a drug to obtain mental numbness or euphoria; when an individual shows a drug craving behavior, visits multiple doctors and pharmacies in pursuit of a medication or demonstrates manipulative attitude towards the provider in order to obtain the drug. The medication will be tapered and discontinued if addictive behavior is observed by the prescriber.

Females only: I understand that while on benzodiazepine therapy I should maintain safe and effective birth control. If I plan to become pregnant or believe that I am pregnant while taking this medication, I will immediately notify my provider. I am aware that benzodiazepines cross the placenta, can cause birth defects and are therefore classified as class D teratogens. They may lead to the development of dependence and consequent withdrawal symptoms in the fetus. Benzodiazepines are excreted in breast milk and are usually contraindicated in breastfeeding mothers.

I understand that my privacy or confidentiality may be waived if an investigation is initiated with a federal law enforcement agency of any possible misuse, sale, or other diversion/inappropriate use of my medications.

Rules of the Controlled Substance Agreement

1. This medication will be filled only by my provider and his/her partner(s). I will not get this medication from another provider (including emergency room doctors, dentists, etc.) I will tell my provider about all other medications and treatments that I am receiving. I will keep my provider informed of new medications or medical conditions that arise (pregnancy, ER treatment, etc.) I understand that other providers should not change the dose of my medication, and I will notify my provider of any changes to my medications made by another provider and the reason for the change.
2. I will take this medication as prescribed by my provider. If I use too much, I will not have my medication until the next refill is due. I will not increase or change how I take my medication without consultation with my provider during scheduled appointments (not via phone, evenings, weekends, or

holidays.)

3. I will notify my provider **at least 3 working days** before I will need a refill on my medication. **No refills will be given outside of business hours.** Prescriptions will be ordered electronically (e-scribed), and will not be mailed. Prescriptions will only be filled once every 30 days (or as directed by my provider). There will be no early refills. I will not be given extra medication for travel.
4. I will attend scheduled appointments with my provider at least every 90 days (or as directed by my provider) to continue receiving my medication.
5. I will keep my medicine in a secure, safe place. **Lost or stolen medicine will not be replaced.**
6. I will not share, sell or trade my medication. I will not use any illegal drugs or alcohol while taking this medication. I will inform my provider of any past/present drug or alcohol use, addiction, withdrawal symptoms or legal problems related to substance abuse.
7. Upon my provider's recommendation, I will participate in any medical, psychological, psychiatric assessments, or treatment programs designed to improve the safety and benefit of the medication treatment plan.
8. If deemed necessary, I agree to random blood or urine screenings to ensure that I am only taking the prescribed medication. I understand that any out-of-pocket expenses for these screenings will be my responsibility.
9. I will not place calls to the office staff with demands for variations, or exceptions to the contract. I will not be disrespectful, use profanity, or harass clinic staff or clinicians. I understand that doing so could be grounds for discharge from the Company.
10. I understand that my provider may **STOP** prescribing my medication if:
 - a. I do not show any symptom improvement.
 - b. I develop rapid tolerance to the medication or if there is loss of effectiveness from the treatment.
 - c. I develop significant side effects from the medication.
 - d. I refuse to consent to a drug screening or I am found to be using illegal substances (e.g. Cocaine) or controlled medications prescribed by another provider.
 - e. I fail to comply with all aspects of my treatment program as recommended by my provider, including but not limited to medical evaluation or counseling.
 - f. I do not fulfill any of the responsibilities outlined above, which may also result in being discharged from care by my provider.
 - g. I miss two consecutively scheduled appointments with my provider.
 - h. If my provider determines, for any other reason, that the medication is not advisable.

I have read the above consent and Agreement, and it has been explained to me. I understand and accept the risks, conditions and terms of the Agreement as presented. I have discussed the risks, benefits and alternatives for treatment with my provider, and my questions and concerns have been adequately addressed.

Patient (or Guardian) Name (print) Patient (or Guardian) Signature Date

Provider Name (print) Provider Signature Date

Copy of Agreement given to patient

Annual Controlled Substance Therapy Agreement Review and Renewal: By signing on the appropriate year row below, we attest that we have re-read the above agreement and continue to agree to abide by the content.

Date Signed	Patient Signature	Provider Signature