CONTROLLED SUBSTANCE PAIN MANAGEMENT AGREEMENT

Patient-Practice Agreement for Opioid/Controlled Substance Therapy

This Agreement is entered into between the patient named above ("Patient") and the prescribing MARIETTA PSYCHIATRY ASSOCIATES ("Provider"). It governs the prescription and use of controlled substances for chronic or acute pain management. This Agreement is required by federal regulation and is consistent with guidance from the U.S. Food and Drug Administration (FDA), the Drug Enforcement Administration (DEA), and the Centers for Disease Control and Prevention (CDC) guidelines for prescribing opioids.

1. PURPOSE OF THIS AGREEMENT

The purpose of this Agreement is to: (a) ensure the safe and effective use of controlled substance medications; (b) reduce risks of misuse, abuse, and diversion; (c) comply with FDA REMS (Risk Evaluation and Mitigation Strategy) requirements and DEA Controlled Substances Act (21 U.S.C. SS 801 et seq.) obligations; and (d) set forth the mutual responsibilities of the Provider and Patient.

2. PRESCRIBED MEDICATION(S)

The record of the prescribed medications will be maintained in the practice maintained EHR electronically to the pharmacy on records in the EHR.

3. PATIENT RESPONSIBILITIES

By signing this Agreement, the Patient agrees to the following terms and conditions:

3.1 Prescription and Medication Use

- I will take medication only as prescribed. I will not increase doses or frequency without my Provider's authorization.
- I will obtain controlled substance prescriptions only from this Provider/practice unless expressly authorized in writing.
- I will not share, sell, or otherwise transfer my medications to any other person. Diversion of controlled substances is a federal crime under 21 U.S.C. § 841.
- I will keep medications in a secure location to prevent theft, loss, or unauthorized access by others, including children.
- Lost or stolen medications may not be replaced early. I will report theft to local law enforcement and provide a copy of the police report.

3.2 Single Pharmacy Requirement

- I will use only one designated pharmacy for all controlled substance prescriptions. I have this pharmacy on record in the EHR system
- I authorize my Provider to communicate with this pharmacy regarding my controlled substance prescriptions.

3.3 Drug Testing (Urine Drug Screens – UDS)

- I consent to random and scheduled urine drug screens (UDS) at any time as determined by my Provider.
- Testing may include screening for prescribed medications (to confirm adherence) and illicit/non-prescribed substances.
- A positive screen for non-prescribed substances or a negative result for prescribed medications may result in modification or termination of this Agreement.
- Refusal to submit to drug testing will be treated as a violation of this Agreement.

3.4 Pill / Medication Counts

- I agree to bring my medications to any appointment upon request for a pill count verification.
- Significant discrepancies between expected and actual pill counts may constitute a violation of this Agreement.

3.5 Prescription Drug Monitoring Program (PDMP)

- I consent to my Provider querying the state Prescription Drug Monitoring Program (PDMP) database at any visit or as required by state law.
- I understand that prescribing providers are required to check the PDMP under state and federal guidelines before issuing controlled substance prescriptions.

3.6 Substance Use and Prohibited Activities

- I will not use illicit drugs (e.g., heroin, cocaine, methamphetamine, non-prescribed fentanyl) while under this Agreement.
- I understand that combining opioids with alcohol, benzodiazepines, or other CNS depressants significantly increases the risk of overdose and death (FDA Black Box Warning).
- I will disclose all other medications, supplements, and substances (including alcohol and cannabis) to my Provider.

3.7 Appointments and Follow-Up

- I will keep all scheduled appointments. Missing appointments without advance notice may delay or prevent early prescription refills.
- I understand that prescriptions for Schedule II controlled substances cannot be refilled; a new written or electronic prescription is required each time.
- Early refill requests more than 2 days before the scheduled refill date will generally not be honored without documented clinical justification.

4. PROVIDER RESPONSIBILITIES

- The Provider will evaluate and treat the Patient's pain condition using evidence-based practices consistent with FDA and CDC guidelines.
- The Provider will prescribe the lowest effective dose for the shortest appropriate duration, consistent with 21 CFR Part 1306 and applicable DEA regulations.
- The Provider will monitor the Patient for signs of misuse, abuse, dependency, or diversion and adjust treatment accordingly.
- The Provider will maintain Patient records in accordance with HIPAA (45 CFR Parts 160 and 164) and applicable state law.
- The Provider will review PDMP data before prescribing controlled substances as required by applicable law.
- The Provider will prescribe naloxone (Narcan) or educate the Patient about its availability when opioid risk factors are identified, consistent with FDA opioid REMS requirements.

5. FDA & DEA REGULATORY NOTICE

> **⚠ FDA BLACK BOX WARNING: Opioid medications carry a risk of addiction, abuse, and misuse, which can lead to overdose and death. Concomitant use with benzodiazepines or other CNS depressants may result in profound sedation, respiratory depression, coma, and death. REMS programs may apply to extended-release and long-acting opioids.**

The medications prescribed under this Agreement are classified as controlled substances under the Controlled Substances Act (CSA), 21 U.S.C. § 801 et seq., and their prescribing, dispensing, and use are governed by DEA regulations at 21 CFR Parts 1300–1321. Prescriptions for Schedule II substances must comply with 21 CFR § 1306.11 and may not be issued for more than a 90-day supply in most circumstances.

Where applicable, this practice participates in the FDA's Opioid Analgesic REMS program, which requires prescriber education on safe prescribing practices, patient counseling, and use of patient-prescriber agreements such as this one.

6. RISKS, SIDE EFFECTS, AND ALTERNATIVES

The Patient acknowledges being informed of the following:

- Common side effects of opioid medications include constipation, nausea, sedation, dizziness, and hormonal changes.
- Serious risks include respiratory depression, physical dependence, addiction, opioid use disorder (OUD), and overdose death.
- Non-opioid pain management alternatives exist and have been discussed, including NSAIDs, physical therapy, interventional procedures, cognitive behavioral therapy, and others.
- The Patient has had the opportunity to ask questions and has them answered to their satisfaction.

7. GROUNDS FOR TERMINATION OF AGREEMENT

This Agreement may be modified or terminated by the Provider if any of the following occur:

- Violation of any term of this Agreement
- Unauthorized use, sharing, selling, or diversion of controlled substances
- Obtaining controlled substance prescriptions from other providers without authorization ("doctor shopping")
- Failure to appear for scheduled appointments or drug testing
- Positive UDS for illicit substances or non-prescribed controlled substances
- Negative UDS for prescribed medications (indicating non-adherence or diversion)
- Threatening or abusive behavior toward Provider or staff
- Any criminal activity related to controlled substances

If this Agreement is terminated, the Provider may taper the patient off medication to minimize withdrawal risks and may refer the patient to appropriate addiction or pain management services. Emergency care will not be withheld regardless of Agreement status.

8. NALOXONE (NARCAN) EDUCATION

The Patient has been informed about naloxone (Narcan), an opioid overdose reversal medication, and its availability without a prescription at many pharmacies. The Patient is encouraged to keep naloxone accessible and to ensure that household members or close contacts know how to use it in the event of an overdose emergency. Call 911 immediately in any suspected overdose situation.

9. CONSENT AND AUTHORIZATION

By signing below, the Patient acknowledges that they have:

- Read and understood this Agreement (or had it explained to them);
- Had the opportunity to ask questions and had those questions answered;
- Voluntarily agreed to comply with all terms and conditions herein;
- Received a copy of this Agreement for their records.

_____ _____

Patient Signature *Date*

Patient Printed Name	*Date*
Legal Guardian / Authorized Representative (if applicable)	*Date*
Prescribing Provider Signature	*Date*
Provider Printed Name & Credentials	*Date*

This document is for informational and clinical use only and does not constitute legal advice. Providers should consult with legal counsel to ensure compliance with applicable federal and state laws, including 21 U.S.C. § 801 et seq., 21 CFR Parts 1300–1321, applicable FDA REMS requirements, and state prescription monitoring laws. Form should be reviewed and updated periodically.