

STOCKBRIDGE-MUNSEE HEALTH & WELLNESS CENTER POLICY

Department: Medical

Department Head: Medical Director

Review Date: New

Policy Title and #: #202MED0016 Controlled Substances Prescribing

Effective: _____

Supersedes: Pain Management by Use of Opioid Therapy #202MED0015

REVIEW/APPROVAL PROCESS		
LEGAL: 10-19-13	HEALTH BOARD: 10-28-13	TRIBAL COUNCIL: 11-19-13

Title: Controlled Substances Prescribing

Reasoning

Controlled substances (CS) can be useful adjuvants in the treatment of certain medical conditions. Examples include, but are not limited to, the treatment of moderate to severe pain (opioids and tramadol), anxiety (benzodiazepines), and attention deficit disorder (stimulants).

The Federal Drug Enforcement Agency regulates the prescribing of CS. These powerful drugs have the potential for abuse or diversion and they are associated with a number of serious side effects, including death. Problems associated with the misuse and diversion of these drugs has reached epidemic proportion around the country and in Tribal Communities.

Purpose

It is the purpose of this policy to establish procedures regarding the management of CS that will be safe and effective for the Patient. To comply with State^{1,2} and Federal³ laws, to minimize the risk for abuse and diversion of these drugs, as well as to reduce other adverse consequences associated with the use of these medications.

Policy

Stockbridge-Munsee Health and Wellness Center (SMHWC) providers and patients will follow the procedures herein.

Procedures

1. Evaluation of patient (follows current best practice guidelines^{4,5,6})
 - A. Complete history and physical
 - B. Document chief complaint(s): severity, intensity, duration, frequency
 - C. Current and past treatments used
 - D. Diagnosis of underlying or coexisting physical or mental diseases or conditions
 - E. Effect of symptoms on patient's physical, psychological, and social function
 - F. History of substance use/abuse
 - G. Current risk for diversion or abuse of controlled medication to be prescribed (with a validated screening tool)

- H. If long term prescribing of CS is anticipated, the patient will be given a baseline urine drug screen.
 - I. Review the Wisconsin Prescription Drug Monitoring Program (PDMP)
2. Treatment Plan
- A. An initial trial medication, NOT TO EXCEED 28 days, with treatment goals and monitoring of medication side effects.
 - B. State objectives used for treatment success to include but not limited to
 - i. Improved quality of life
 - ii. Improvement of symptoms
 - iii. Improved physical function (patient-driven functional goals)
 - iv. Improved psychosocial function
 - C. Further physical and psychological diagnostic evaluations
 - D. Should the baseline drug screen come back positive, then patient is referred to behavioral health
 - E. Adjust drug therapy to the individual medical needs with documentation of the reason for each dose or medication change
 - F. NOTE: Goal of therapy is not to stop the use of controlled substances. Goals are to reduce symptoms and to improve function and quality of life. Appropriate dosage of drug is the dosage that alleviates symptoms and does not cause undesirable side effects.
3. Informed Consent and Agreement for Treatment
- A. Prior to prescribing a controlled substance, the provider will discuss the risks and benefits of the use of the controlled medication and have patient sign the Informed Consent document (“Consent”; Attachment A).
 - B. If long term therapy (more than 30 days) is anticipated an Agreement for Long Term Therapy with Controlled Substances (“Agreement” Attachment B) must be signed by the provider and patient. If the agreement is not signed, then no prescription will be written.
 - C. A copy of the “Agreement” will be provided for the patient’s chart, patient’s personal records, pharmacy, and SMHWC Controlled Substance Oversight Committee (see item 7)
 - D. The provider and patient must sign an amended “Agreement” before any change in dosage, instructions, or CS medication
4. Periodic Review
- A. At reasonable intervals (not to exceed 90 days) treatment goals of long term therapy should be assessed.
 - B. If goals are not being met, the appropriateness of continued treatment should be assessed.
 - C. Necessity for outside referrals will be determined
 - D. Provider must always be vigilant for evidence of abuse or diversion. Monitoring may include pill counts, periodic urine drug screens, communication with other providers and pharmacies, and query the Wisconsin Prescription Drug Monitoring Program.
 - E. Medical providers will order a minimum of 2 (two) randomized urine drug screen test annually to test for the presence of expected levels of prescribed medication(s) as well as to identify the presence of illegal substances and/or medications that are not legally prescribed to the patient, according to the controlled substance agreement
 - 1. Patients receiving a prescription for tramadol must follow the same urine drug screen protocol and a special lab must be ordered to test for this agent.

2. The presence of an illicit substance or prescription medications that are not prescribed to the patient may disqualify the patient from obtaining controlled substances from the primary care provider. In addition the absence of prescribed medications that are expected to be present in the patient's urine may also disqualify the patient from obtaining controlled substances from the primary care provider. At the discretion of the provider, an alcohol screen may be performed.
 3. If a patient refuses or leaves the clinic before providing a urine sample, then the CS will be discontinued.
5. Consultation (prescribing CS long term)
 - A. Provider will refer patient as deemed necessary for additional evaluation and treatment in order to achieve treatment objectives.
 - B. Failure of patient to keep appointments or follow through with alternative treatment strategies constitutes sufficient reason to begin procedures to cease prescribing CS medications.
 - C. Special attention should be given to those patients who are at higher risk for misusing their CS medication or whose living arrangement poses a risk for medication misuse or diversion as defined in "Agreement".
 - D. Management of patients with a history of substance abuse or drug seeking behavior will require extra care, monitoring, documentation, and referral to experts in management of such patients.
6. Medical Records⁶

The provider should keep accurate and complete records to include:

 - A. Medical history
 - B. Physical exam
 - C. Diagnostic, therapeutic and laboratory results
 - D. Evaluations and consultations
 - E. Treatment objectives
 - F. Discussion of risks and benefits
 - G. Signed "Consents" and "Agreements"
 - H. Treatments rendered
 - I. Medications—dates, types, dosages, quantities and instructions
 - J. Periodic reviews
7. Quality Control
 - A. Controlled Substance Oversight Committee to meet monthly and review five records, randomly selected, of patients receiving long term CSs for completeness
 - B. Committee will submit results and suggestions to prescribing provider, who will sign off on suggestions
 - C. Review forms to be kept in administrative peer review files
 - D. Provider may discuss recommendations with the Chair of the CS Oversight Committee.
8. Prescribing and Dispensing
 - A. Patients must present a valid ID (driver's license, tribal ID, passport, or active duty card) every time when picking up a controlled substance or written prescription from the pharmacy and must sign their name on the electronic signature pad. If the patient is unable to pick up their own CS medication or written prescription, then the provider may allow them to designate a proxy who must present to the pharmacy with a signed authorization document or in an emergent case may speak directly with a pharmacist (not just pharmacy staff) and inform of EXACTLY who will be picking up the medication.

- The proxy must present a valid ID upon pick up of a controlled substance for another patient. No person(s) under 18 may pick up a controlled substance from the pharmacy.
- B. Prescriptions reported as lost or stolen will not be refilled before the scheduled refill date.
 - C. Early request for refills will not be filled without adequate justification documented in medical record.
9. Specific procedures associated with this policy shall be periodically reviewed and updated consistent with the requirements and standards established by the Tribal Council, Health Center management, federal drug enforcement laws, and applicable accrediting and review organizations.

References:

1. Wisconsin Chapter 961, Uniform Controlled Substances Act. <https://docs.legis.wisconsin.gov/statutes/statutes/961.pdf> accessed May 15, 2013.
2. Wis. Adm. Code § Med 21.03 Minimum standards for patient health care records. https://docs.legis.wisconsin.gov/code/admin_code/med/21.pdf accessed May 15, 2013.
3. Title 21 CFR, Part 1300-1399. As of January 2, 2013. <http://www.deadiversion.usdoj.gov/21cfr/cfr/> accessed May 15, 2013.
4. Chou R, Fanciullo GJ, Fine PG, et al. Opioid Treatment Guidelines: Clinical Guidelines for the Use of Opioid Therapy in Chronic Noncancer Pain. *The Journal of Pain*. 2009;10(2):113-130.
5. VA/DoD Clinical Practice Guideline: Management of Opioid Therapy for Chronic Pain (2010). VA/DoD Evidence Based Practice. http://www.healthquality.va.gov/COT_312_Full-er.pdf accessed May 15, 2013.
6. Rhyne J, chair. Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain (July 2013). http://www.fsmb.org/pdf/pain_policy_july2013.pdf accessed August 28, 2013.

**STOCKBRIDGE-MUNSEE HEALTH AND WELLNESS CENTER
CONSENT FOR TREATMENT WITH A CONTROLLED MEDICINE**

_____ is prescribing
(name of doctor)

a medicine called _____ for
(name of medicine)

_____, _____, _____
(name of patient) (date of birth) (chart #)

for the treatment of _____.
(name of condition)

This medicine is called a “controlled” medicine because there are laws controlling how it can be used. The type of medicine that I am being given is called a _____.
(opioid, benzodiazepine, or stimulant)

When this type of medicine is used for a long time, there are often side effects and risks.

The following things might happen when I take this type of medicine for a long time:

With opioids or benzodiazepines:

- being sleepy, tired
- not reacting to things as fast
- not thinking as clearly

With opioids:

- being depressed
- becoming constipated
- becoming more sensitive to pain
- may not help with long-term pain control
- low testosterone levels that may cause sexual problems for men
- becoming sick to my stomach
- weakening my immune system

With stimulants:

- my blood pressure may go up
- becoming jittery or nervous
- chest pain
- becoming sick to my stomach

With any of these medicines there is also a risk of:

1. Needing more and more medicine to get the same result. This is called **“tolerance”**.
2. Becoming physically **“dependent”** on the medicine (meaning you could have withdrawal symptoms if you suddenly stop or extremely reduce the medicine).
3. Becoming **“addicted”** to the medicine which means losing control over how you take the medicine, always trying to get more of the medicine even when it has a bad effect on important parts of your life.
4. Taking more medication than your provider ordered may cause an overdose, resulting in harm or death.

People who have been addicted to drugs or alcohol in the past might start using drugs or alcohol again when they are treated with any of these medicines.

When you take opioids or benzodiazepines, it can be dangerous to do certain things like use heavy equipment, work in high places where you might fall, or drive. If the medicine you are taking is an opioid or a benzodiazepine, it can make you groggy and make you react to things more slowly. You might not even notice that the medicine is affecting you.

This medication has been diverted (shared, sold, and stolen). People you know may ask you to divert it or may try to divert it themselves. **DIVERSION IS DANGEROUS AND ILLEGAL. You are responsible to protect this medication from diversion.**

- ✓ I have read this form or someone has read it to me.
- ✓ I have had a chance to ask questions about using this medicine, and my questions have been answered.
- ✓ I give permission to my medial provider to treat me with the controlled medicine that is listed above.
- ✓ I understand the risks of taking this type of medicine and I understand the side effects that I might have with this medicine.

Patient’s signature _____ date _____

Medical Provider’s signature _____ date _____

Stockbridge-Munsee Health and Wellness Center Medication Safety Agreement

My Stockbridge-Munsee Health and Wellness Center (SMHWC) provider, _____, has prescribed _____ to treat my _____. This medicine is one that is dangerous if not used in the right way. I understand that:

1. This medicine will not cure my problem, it only treats symptoms.
 - a. I will do other tests and treatments for my problem as recommended by my provider. This may include things like counseling, physical therapy, exercise, injections, surgery, other medications, referrals, etc.
 - b. I will work with my provider to improve my other health conditions such as diabetes, depression, high blood pressure, etc. Improving my health will often improve pain, sleep, and behavior problems.
 - c. I will keep my appointments with my provider. If I go longer than _____ without seeing my provider, then my medicine will be stopped.
 - d. If this medicine does not work to improve my symptoms or help me do the things I need to do, then it will be stopped and we will try other treatments.
2. This medicine has powerful effects on the brain that can lead to addiction, illness, injury, or death if not used exactly as my provider tells me.
 - a. I will take my medication exactly as prescribed. I will not take extra medication or stop medication without talking to my primary care team first.
 - b. I will not mix this medication with beer, wine, hard liquor, or illegal drugs.
 - c. I will not take anyone else's prescription medications.
 - d. I will give blood or urine samples to test for drugs whenever requested by my provider. If I refuse to give a sample, give a sample that is not really my urine, leave before giving a sample or if illegal drugs show up in my system, then my medication will be stopped.

- e. I will bring in my unused medication to every visit for a pill count and other times as requested by provider.
 - f. I will not drive or operate machinery if my medicine makes me sleepy.
 - g. I will not take medicines prescribed by other providers or filled at other pharmacies without telling my provider.
 - i. If I have an emergency and am given a prescription for a medicine on the list, then I will tell my provider the following business day.
 - ii. If I have surgery and my surgeon gives me pain medication, then I will tell my provider within one business day.
3. If a report from the State of Wisconsin shows I am getting medications that I did not tell my provider about, then my medicine will be stopped. This medicine is one that is often illegally bought and sold in our community (diverted). Medicines that are diverted lead to addiction, crime, suffering, and death especially among our youth. When you are caught diverting these medicines you could be prosecuted and/or incarcerated.
- a. I will not sell, trade, or share this medication with anyone else. I understand I can be arrested for doing this.
 - b. I will keep my medicine in a safe place to keep anyone from stealing it. If my medicine is lost or stolen it will not be replaced until the next scheduled refill. If you are experiencing withdrawal symptoms, then seek medical attention.
 - c. If random blood or urine samples do not show the medicine in my system in the expected amount for my prescription, then my medicine will be stopped.
 - d. I will always get my medicine at the same pharmacy.
I will always get my medicine at _____
(Name of Pharmacy)
 - e. I agree to let my provider give a copy of this agreement to any and all providers and pharmacists who may be involved in my care, including the emergency room staff. I agree to sign a release of information for all providers regarding my medicine.
 - f. The SMHWC does not release any information about your medicine, your condition, or your drug testing results to legal authorities without your permission.

- g. If you attempt to steal, pick up someone else's medicine without permission, lie about who you are to obtain, buy, or sell medicine on SMHWC property, then we will call the police.
- h. If you threaten, assault, or verbally abuse SMHWC personnel, then your medicine will be stopped and your access to the facility may be restricted.

We promise to give you the best health care possible:

- 1. We will treat you with courtesy and respect. This includes making sure we discuss all medication concerns in private.
- 2. We have a Medication Safety Committee made up of clinic administration and staff. This committee reviews treatment plans and use of these medications.
- 3. We will take the time to make sure you understand how to safely take your medication, rules to follow with these medications, and what will happen if you do not follow the rules.
- 4. We will generally provide these medications in 7-28 day supplies, always due on the same day of week.
- 5. If you have followed your agreement, then you may request an early pickup of medication up to twice a year at your provider's discretion. The refill after that date is counted from the day you were due, not the early pick up date.
- 6. You will get clear instructions about how to contact your primary care team to discuss side effects, dosage change, or to report other prescriptions.
- 7. If you have not followed your agreement, then we will stop these medications and will:
 - a. Explain to you why your medications are being stopped.
 - b. Continue to treat you and help you with your problem using other treatment methods.
 - c. Continue to treat your other medical problems.

Provider

Date

Patient

Date

Agreement for how to take medicines:

Patient Name: _____ DOB: _____ Chart # _____

Date _____

I _____ am prescribing _____
(name of provider) (name of drug and dose)

The maximum number of pills to be taken each day are _____

Patient's signature _____ Provider's signature _____

Updated _____

I _____ am prescribing _____
(name of provider) (name of drug and dose)

The maximum number of pills to be taken each day are _____

Patient's signature _____ Provider's signature _____

Updated _____

I _____ am prescribing _____
(name of provider) (name of drug and dose)

The maximum number of pills to be taken each day are _____

Patient's signature _____ Provider's signature _____