MONTANA CHEMICAL DEPENDENCY CENTER POLICY AND PROCEDURE MANUAL

Policy Subject: Buprenorphine Administration	**Related Policies: Letter of July 8, 2005 (Encl-1) H. Wesley Clark, MD. JD. MPH. Director Center for Substance Abuse Treatment, DHHS**
Policy Number: MNP-13 (a)	**Standards/Statutes: ARM 37.27.130**
Effective Date: 8/30/05	**Page 1 of 9**

PURPOSE: To insure appropriate standards of care for management and administration of agonist therapy for treatment of opiate dependent individuals.

POLICY: This policy clarifies Buprenorphine Administration procedures for Nursing and Medical personnel, that instructs for compliance with MNP 13, and with Title 21 of Federal Regulations, Parts 1301 and 1306, as modified by DEA Regulations Final Rule of 6/23/05, effective on 7/25/05, for these regulations which concern standards or care in dispensing Buprenorphine as Subutex and Suboxone for selected opiate-dependent individuals.

PROCEDURE:

1. Use of buprenorphine is allowed under DATA 2000, for expansion of treatment by certified physicians for detoxification and maintenance of individuals who are diagnosed as having Opiate Dependence by DSM-IV ® criteria. The two marketed forms of buprenorphine, which are allowed, and which are specific to that purpose are Suboxone and Subutex, which are Schedule III controlled substances. Other forms of buprenorphine and other opiates are not allowed.

2. No other medications are allowed under Federal statute, and no others will be used or substituted, including other available forms of buprenorphine, a Schedule II controlled substance.

3. Section 1306.05 (a) requires certified practitioners to include their unique identification number on all orders for medications and all prescriptions when issuing Subutex and Suboxone for addiction treatment. Any practitioner must be individually certified, and cannot use the unique identification DEA number of any other provider.

4. Certified physicians are required to keep records of all prescriptions written for controlled substances listed in any schedule for maintenance of detoxification treatment of an individual [21 CFR §1304.03 (c)].

5. Records shall be maintained include inventories, records of receipt, reports of theft or loss, destruction of controlled substances, and records of dispensing. These records will be maintained for two years.

6. Certified physicians are to keep separate records for their Subutex and Suboxone addiction treatment patients. If kept in a computer system, there must be a "hard copy" backup.

7. Schedule III, IV, V controlled drugs are subject to the storage and security requirements under [21 CFR § 1301.75 (b)] which states that: *"controlled drugs must be stored in a securely locked, substantially constructed cabinet"*.
8. Schedule III (benzodiazepines) are currently stored in compliance by the Nursing Department.
9. Schedule III substances Suboxone & Subutex shall be stored in a manner to comply, as above.

10. There shall be a limit of less than 30 patients treated for detoxification or maintained at any time by any individual practitioner as well as by any group practice.

11. A limited "starter" stock of Suboxone and Subutex (used for women who may be pregnant) will be maintained to initiate therapy when regular pharmacy services are not immediately available and all records and logs will be maintained as required and as noted in item # 5.

12. Nursing Department will be responsible for assessment of any individual who may be Opiate Dependent and manifesting Opiate Withdrawal Syndrome, by use of Clinical Opiate Withdrawal Scale (COWS), a urine drug screen (UDS), noting time of last use, route, specific dose and substance used, and if any alcohol or other substances consumed, and will then notify the MCDC physician to report these findings (24/7).

13. Only a certified physician shall initiate treatment with Suboxone or Subutex and only after physical examination to determine the appropriateness for these medications, and only then by written order. Verbal orders or telephone responses for controlled substances are not valid.

14. Only a physician shall continue treatment if another certified practitioner prior to patient admission has prescribed these medications to MCDC, and only if a specific order is written. Patient-provided medication may be dispensed only if prescribed by a qualified Montana licensed practitioner, only if received by U.S. Postal Service (or) UPS in the original container, only if correctly labeled, only if mailed by the pharmacy, and only if the original seal is unbroken. Conditions listed in MCDC Policy MNP 13, of 1/1/02, sections 11 (a-g.) must be satisfied.

15. A Consent for Treatment with Buprenorphine **FORM** will be signed by each individual deemed appropriate for treatment, which will provide a full explanation about risks, benefits, and alternatives to buprenorphine treatment, and signature will indicate understanding and agreement.

16. A Daily Monitoring During Buprenorphine Detoxification **FORM** will be utilized for daily monitoring of treatment effectiveness and which will include "COWS" tests used sequentially.

17. A DO NOT USE **FORM** will be discussed and provided to each individual in order to detect any concurrent substances which may cause an adverse reaction when combined with buprenorphine, including metabolic drug interactions of drugs used to treat other medical conditions. Drugs

smuggled into MCDC for self-medication must be inquired about, and surrendered, for safety. Nursing staff suspicion of smuggled drugs will void the Consent for Treatment.

18. A Physician's Expectations & Patient Expectations **FORM** will be provided to each individual to clarify his or her contract for treatment. This may include specifics about the drug to avoid patient issues of doubt, fear and confusion, and allow for reasonable engagement and better outcomes.

CONSENT FOR TREATMENT WITH BUPRENORPHINE FORM (1)

Buprenorphine is an FDA approved medication for treatment of persons with opiate dependence. Qualified physicians can treat up to 30 patients for opiate dependence. Buprenorphine can be used for detoxification and for maintenance therapy. Maintenance therapy can continue as long as necessary.

Buprenorphine itself is an opiate, but is not as strong an opiate 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 a week or so. The rate of discontinuation is a variable, or individual function, and therefore, use for detoxification is individualized in a gradual manner.

If you are dependent on 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 will be given the first dose at the nurse's station, and should be under observation for the next 2 hours. After that, you will be evaluated several times in the next few days, and then the physician, which will allow gradual dose reduction without the discomfort of usual opiate withdrawal, will formulate a schedule for withdrawal. Without medical therapy, the withdrawal is sometimes called "kicking" the habit or "cold turkey" for the common "gooseflesh" reaction.

Some patients find that it takes several days to get used to the transition from the opiate they had been using prior 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, and cravings for other opiates will become minimal. If you attempt to override the buprenorphine by taking more opiates, that could result in a serious opiate overdose. You should not take any other medications without discussing it with the medical staff first.

Combining buprenorphine with alcohol or some other medication may be hazardous. The combination of buprenorphine with sedating medications, such as benzo's (*Xanax, Valium, Ativan, Klonopin*), barbiturates (*Seconal, Amytal*) or muscle relaxers (*Soma*) or sleeping meds (*Sonata, Ambien*) which can and have resulted in death from non-intentional overdose. Please review the attached list of "DO NOT" drugs and discuss these important details with the medical staff – before consenting to treatment!

The form of buprenorphine (Suboxone) you will be taking is a combination of buprenorphine combined with a short-acting opiate blocker (Naloxone). If the Suboxone tablet were dissolved and injected by someone taking heroin or some strong opiate, it would cause immediate and severe opiate withdrawal.

Buprenorphine tablets must be held under the tongue until they dissolve completely, usually within 15-20 minutes from the tissue under the tongue. Buprenorphine will not be absorbed from the stomach if it is swallowed. Eating, drinking, smoking and speaking are best avoided during the administration, and after a full 20 minutes, swallow your saliva, but continue to avoid the above activities for another 30 minutes.
You can't speed up the absorption, so find a quiet place and relax as the buprenorphine tablet dissolves.

Other medications for detoxification include Clonidine and Bentyl, but are generally not needed with buprenorphine therapy. Valium or other sedatives or tranquilizers may be hazardous, and are not given.

CONSENT FOR TREATMENT WITH BUPRENORPHINE FORM - (2)

Nearly every medication has been tried over the past century, including heroin (for morphine addiction) and cocaine (for heroin addiction). Methadone has been used for the past 40 years, but is illegal for the purpose of opiate detoxification and maintenance except at federally regulated Methadone Clinics, and no clinics exist in Montana, which uses that drug. Naltrexone (Revia) has usefulness but requires complete detoxification before it can be started, which limits usefulness for the purpose of detoxification.

Actually, buprenorphine has been evaluated extensively prior to availability in 2003, and has replaced most of the previous methods for moderate-severe symptoms of opiate withdrawal. It may not be the "best", but seems to help most addicts withdraw or maintain in a non-craving, non-using stabilization of their dependency.

Dr. Dirkers does not maintain an office for the purpose of continuation of buprenorphine therapy as long-term maintenance, and therefore limits use to in-patient detoxification only at MCDC. If you are unwilling to undergo complete detoxification from all drugs, and engage with the program of substance rehabilitation which MCDC provides, tell us now, and we can help you select an alternative program.
Better now, because if you leave after buprenorphine has started, and use any drug or alcohol, you will be placing yourself at high risk for a serious complication. We don't want that for you, or for us at MCDC.

Please review the **"DO NOT USE"** list attached, and if you have further questions, doubts, or just hesitancies, please discuss your concerns with the medical staff. If you desire to try buprenorphine for withdrawal from your opiate dependency, indicate that you understand and accept these conditions by signing your name.

Patient Name (Print) _____

Name (Signed) _____

Date / Time Signed _____

Staff Witness _____

Daily Monitoring During Buprenorphine Detoxification - FORM

Each morning: Name _____

Date / time: _____ Date Suboxone started: _____
Day of therapy: _____

Clinical Opiate Withdrawal Scale (COWS) = _____

Today's dose: _____
Time given _____

Physical Well-Being:

Any new physical complaints, problems?
_____

Appetite, and bowel actions?
_____

Complaints about side effects?
_____

Difficulties with dosing?
_____

Is dose holding?
_____

Drug seeking behaviors?
_____

New medications begun / stopped?
_____

Emotional Well-Being:

Affect normal?
_____

Engagement with counseling program?
_____

Self-report:
_____

_____
_____

_____
_____

Information: DO NOT USE with Buprenorphine! FORM

Benzodiazepines
Ativan (lorazepam)
Xanax (alprazolam)
Klonopin (clonazepam)
Valium (diazepam)
Librium (chlordiazepoxide)

Barbiturates
Luminal (phenobarbital)
Mebaral (mephobarbital)
Nembutal (pentobarbital)
Fiorinal (butalbital)
Donnatal+Pb (phenobarbital)

Tranxene	(chlorazepate)		
Serax	(oxazepam)	Muscle Relaxants	
Restoril	(temazepam)	Soma	(carisoprodol)
Halcion	(triazolam)		
Dalmane	(fluazepam)	Sleepers	
		Ambien	(zolpidem)
Alcohol –	Any & All	Sonata	(zaleplon)
		Lunesta	(eszopiclone)

CYP3A Liver Enzyme Interactions ----------

(These interfere with the liver metabolism of buprenorphine)

Moderate Inhibitors **(Raises level - avoid)**	Potent Inhibitors **(Raises level x5 -must avoid)**	Inducers **(Lowers levels of bup.)**
aprenavir	amiodarone	carbamazepine
antifungals (ketoconazole)	atazanavir	efavirenz (Sustiva)
ciprofloxin (Cipro)	cistapride (Propulsid)	nevirapine
(Viramune) diltiazem	clarithromycin (Biaxin)	phenytoin
(Dilantin)		
erythromycin	indinavir	phenobarbital
fluconazole (Diflucan)	itraconazole (Sporanox)	rifabutin (Mycobutin)
fluvoxamine	ketoconazole (Nizoral)	rifapentine (Prifadin)
grapefruit juice (low doses)	grapefruit juice (doses >1 qt)	rifampin (Rifadin)
norfloxin (Noroxin)	nefazodone (Serzone)	St. John's Wart
verapamil	nelfinavir	
	telithromycin	
	troleandromycin (TAO)	
	voriconazole (Vfend)	
	<u>HIV Protease Inhibitors, e.g.</u>	
	Indinavir, ritonavir, saquinavir	

References: **----------**

The Medical Letter: CYP3A and Drug Interactions; Volume 47, Issue 1212, July 4, 2005

Wesson, D.R. (2004): Buprenorphine in the Treatment of Opiate Dependence: Its Pharmacology and Social Context of Use in the U.S.; Journal of Psychoactive Drugs, SARC Supplement 2, May 2004.

Physician's Expectations & Agreements - FORM

Patient will:

Agree to treatment medical and nursing staff in a respectful and courteous manner
Agree to take medication dose daily in the manner described by the medication nurse.

Agree to refrain from smoking, drinking, eating, chewing, and talking for 20 minutes during dosing.
Agree to volunteer any observations about side effects or unusual sensations
Agree not to ingest any other medications, drugs, or alcohol while taking Buprenorphine
Agree to discuss any thoughts of leaving prematurely (AMA) with nursing staff or counselor
Agree, if already on Buprenorphine therapy, to return to care of original prescribing physician
Agree that Buprenorphine therapy is not a formula or ritual, but variable among individuals
Agree to submit to urine drug testing upon staff request, to detect any other drugs or alcohol Remember that the consent for treatment implies an agreement of mutual trust - You and Us - that if a problem occurs it is not of our intent, and that MCDC staff will attempt to remedy any shortcoming or problem - promptly, safely, and satisfactorily.

(Patient signs agreement) _____

Patient Expectations

Medical and Nursing Staff will:

Agree to treat each individual with courtesy, respect and understanding
Agree to maintain patient confidentiality and a professional manner of behavior
Agree to thoroughly answer questions you may have about medications administered
Agree will be open-minded to adjusting my dose depending on my status and dose effects
Agree to provide medications based on my medical need, and never change dose arbitrarily or as a disciplinary measure, or withheld to leverage compliance on some other issue
Agree to provide round-the-clock readiness to meet the needs for each person
Agree to attend to changes of status by daily, morning monitoring assessment
Agree to make provisions for the best continuing care for each individual in case of - emergency leave, transfer to another facility, leaving MCDC prematurely, leaving AMA.

Remember that the consent for treatment implies an agreement of mutual trust - You and Us -that if a problem occurs it is not of your intent, and that MCDC staff will respond to any problem you may have, and try to resolve it promptly, safely, and satisfactorily.

(Physician signs agreement) _____

MCDC OPIATE WITHDRAWAL PROTOCOL for BUPRENORPHINE

Subutex = buprenorphine only. **Suboxone =** buprenorphine + naloxone (4:1 ratio)
2mg and 8mg (oval-white SL's)2/. 5mg and 8/2mg SL's (hexagonal-orange SL's)

Warnings:

Do not administer if recent consumption of Alcohol, Benzodiazepines or other Opioids.
Do not administer with CYP3A potent inhibitors or with CYP3A4 inducers.

Administer tablet sub-lingual route over 20 minutes with no smoking, drinking, talking, and do not swallow saliva for 20 min. Administer in presence of nurse, and record dose given.

Initial Assessment

Date/Time of last use: _____ Dose: _____ @ Time _____
Hours since last use _____
COWS Score is: _____ Admin by ____ @ Time _____

Date: _____Time_____ Induction -- Day 1
Subutex /Suboxone Dose: _____mg. @ Time _____ Admin by _____

Date: _____Time_____ Induction – Day 2
Subutex Dose _____mg. @ Time_____ Admin by _____

Date: _____Time_____ Induction/Maintenance – Day 3
Subutex Dose _____mg. @ Time_____ Admin by _____

Date: _____Time_____ Maintenance – Day 4
Suboxone Dose _____mg. @ Time_____ Admin by _____

Date: _____Time_____ Reduction – Day 5
Suboxone Dose _____mg. @ Time_____ Admin by _____

Date: _____Time_____ Reduction – Day 6
Suboxone Dose _____mg. @ Time_____ Admin by _____

Date: _____Time_____ Reduction – Day 7
Suboxone Dose _____mg. @ Time_____ Admin by _____

Date: _____Time_____ Reduction – Day 8
Suboxone Dose _____mg. @ Time_____ Admin by _____

Date: _____Time_____ Reduction – Day 9
Suboxone Dose _____mg. @ Time_____ Admin by _____

Date: _____Time_____ Termination – Day 10
Suboxone Dose _____mg. @ Time_____ Admin by _____

Date Suboxone last dose: _____ Completed? Yes___ No___ AMA___

_____
Jerome D. Dirkers, MD.
Call if a question, problem, doubt, or concern.
Home Ph: 494-3707 Cell: 560-8335

Addendum: additional information about these requirements is available from:

H. Wesley Clark, M.D., J.D., M.P.H., C.A.S., FASAM.
Director, Center for Substance Abuse Treatment
Substance Abuse and Mental Health Services Administration
Department of Health and Human Services, Rockville, MD. 20857

Letter of July 8, 2005 as Attachment (1)

and Mr. Nicholas Reuter at: 240-276-2716 or Nicholas.Reuter@samhsa.hhs.gov

8/30/05 / jd