



Substance Use Disorder (SUD) Programs  
**Safe Medication Practices: Narcotic Treatment Programs**

Program Name:	Client #:
Program Address:	Status:
Date of Review:	
County Reviewer:	
Counselor's Name:	Date of Program Admission:

### Medication Policy and Procedure

#### Ordering of Medications

Line #		M	NM	PM	N/A	Regulations	Comments
1	Each order form must be signed and dated by the person authorized to sign an application for registration/renewal application, and others designated by a power of attorney					<u>U.S. Dept. of Justice/Drug Enforcement Administration:</u> <u>Narcotic Treatment Programs Best Practice Guidelines,</u> <u>April 2000</u>	

**Ordering of Medications**

Line #		M	NM	PM	N/A	Regulations	Comments
						<u>Intergovernmental Agreement Exhibit A, Attachment I, III, CC, 9</u>	
2	Whenever a purchaser or supplier discovers that any used or unused order forms are stolen or lost, he/she must, immediately upon this discovery, report the theft or loss to the local DEA diversion field office, stating the serial number of each form.						
3	Any unused order form reported stolen or lost is subsequently recovered or found, the local DEA diversion field office must be immediately notified.						
4	One NTP staff member should be designated to monitor medication inventory, complete order forms, and ensure that adequate supplies of medication and order forms are available at the program						

**Receiving Medication**

Line #	Description	M	NM	PM	N/A	Regulations	Comments
1	Acceptance of delivery of narcotic substances must be made only by a licensed practitioner employed at the provider facility or by other authorized individuals designated in writing (excluding persons currently or previously dependent on narcotic drugs), who must sign for the narcotics					<u>U.S. Dept. of Justice/Drug Enforcement Administration: Narcotic Treatment Programs Best Practice Guidelines, April 2000</u>  <u>Intergovernmental Agreement Exhibit A, Attachment I, III, CC, 9</u>	
2	Provider must maintain a written list of all designated personnel who have been authorized to receive and store the medication.						
3	The NTP must retain Copy 3 of all completed order forms as part of the program's records of receipts						
4	Order forms must be maintained separately from all other records and must be retained at the registered location for two years after the date of execution						

**Receiving Medication**

Line #	Description	M	NM	PM	N/A	Regulations	Comments

**Dispensing/Administering**

1	Automated Dispensing Pumps for Liquid Medication: After beginning operation, follow the general care and usage instructions in the manufacturer's manual on a day-to-day basis.					<u>U.S. Dept. of Justice/Drug Enforcement Administration: Narcotic Treatment Programs Best Practice Guidelines, April 2000</u>  <u>Intergovernmental Agreement Exhibit A, Attachment I, III, CC, 9</u>	
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2	An automated dispensing system should be flushed with tepid, distilled water each day. (Tepid water is needed because excessively hot water can be corrosive to stainless steel equipment.)						
3	To minimize errors in the pumping of medication, automated dispensing pumps should be calibrated and serviced following the manufacturer's recommendations.						
4	The OTP should maintain a log documenting the history of pump recalibration.						
5	Pump output should be verified periodically, using either volumetric or gravimetric measures, as recommended by the pump's manufacturer.						
6	Tubing should be flushed and cleaned daily with tepid water.						
7	Even when tubing appears to be in good condition, it should be replaced quarterly or at the time interval recommended by the manufacturer.						
8	The OTP should validate the pump's calibration after the tubing has been replaced.						
9	Each OTP should develop operating instructions for manual dispensing to be implemented in the event that the automated system goes down.						

10	The OTP should conduct periodic drills to prepare personnel for system emergencies.						
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Disposal of Medication Spillage of Individual Patient Dose							
Line #	Description	M	NM	PM	N/A	Regulations	Comments
1	The employee who spilled the medication or who witnessed a patient spilling the medication should immediately report the incident to a supervisor.					<u>U.S. Dept. of Justice/Drug Enforcement Administration: Narcotic Treatment Programs Best Practice Guidelines, April 2000</u>  <u>Intergovernmental Agreement Exhibit A, Attachment I, III, CC, 9</u>	
2	After the spilling of medication has been reported to a supervisor, the medication should be properly disposed of.						
3	Documentation of spillage should be completed, indicating the drug, its strength and amount, and the date of spillage and signed by both the employee involved and a supervisor.						



2	<p>As an alternative to maintaining a dispensing log, an NTP may use an automated/computerized data processing system for the storage and retrieval of the program's dispensing records, if the following conditions are met:</p> <ul style="list-style-type: none"> <li>• The automated system maintains the information required in 21 CFR 1304.24(a),</li> <li>• The automated system has the capability of producing a hard copy printout of the program's dispensing records,</li> <li>• That an NTP print a hard copy of each day's dispensing log, which is then initialed appropriately by each person who dispensed medication to the program's patients, and</li> <li>• That the automated system is approved by DEA</li> </ul>				<p><u>Title 21 CFR 1304.24(a)</u></p>	
3	<p>Immediately upon discovery of a theft or significant loss of a controlled substance medication, the NTP must contact the local DEA diversion field office by telephone, facsimile, or with a brief written message explaining the circumstances. Further, a DEA Form -106, "Report of Theft or Loss of Controlled Substances", must be filed. [21 CFR 1201.74(c)]. The NTP should also notify the local police, as this may be required by state law.</p>				<p><u>Title 21 CFR 1201.74(c)</u></p>	



### Security of Controlled Substance Stocks

Line #	Description	M	NM	PM	N/A	Regulations	Comments
1	<p>Safes, steel cabinets, or vaults must be constructed to withstand the following:</p> <ul style="list-style-type: none"> <li>• 30 man-minutes against surreptitious entry,</li> <li>• 10 man-minutes against forced entry,</li> <li>• 20 man-hours against lock manipulation, and</li> <li>• 20 man-hours against radiological techniques.</li> </ul>						
2	<p>Components of the alarm system must include [21 CFR 1301.72(a)]:</p> <ul style="list-style-type: none"> <li>• Contact switches on the door of the vault;</li> <li>• A device designed to detect illegal entry into the vault (i.e., electrical lacing of walls, floors, and ceilings; sensitive ultra-sonic equipment within the vault; or sound accumulator system); and</li> <li>• Safes and steel cabinets, if necessary, depending on the quantities and type of controlled substance medications stored, must be equipped with an alarm system, which upon unauthorized entry will transmit a signal directly to a central station protection company, a police department, or a 24-hour control</li> </ul>					<p><u>Title 21 CFR 1301.72(a)</u></p>	

### Security of Controlled Substance Stocks

	<p>station operated by the NTP. It is recommended that each NTP contact their local DEA Diversion Field Office (see Appendix D) to determine if their program's safe/steel cabinet requires an alarm system.</p> <ul style="list-style-type: none"> <li>• Vaults must be equipped with an alarm system, which upon unauthorized entry will transmit a signal directly to a central station protection company, a police department, or a 24-hour control station operated by the NTP.</li> </ul>						
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**UNSUPERVISED APPROVED USE (TAKE-HOME) OF MEDICATION**

Line #	Description	M	NM	PM	N/A	Regulations	Comments
	<p>42 CFR § 8.12 (h) (4) (i) <i>Unsupervised or “take-home” use.</i> To limit the potential for diversion of opioid agonist treatment medications to the illicit market, opioid agonist treatment medications dispensed to patients for unsupervised use shall be subject to the following requirements:</p> <ul style="list-style-type: none"> <li>Any patient in comprehensive maintenance treatment may receive a single take-home dose for a day that the clinic is closed for business, including Sundays and State and Federal holidays.</li> <li>Treatment program decisions on dispensing opioid treatment medications to patients for unsupervised use beyond that set forth in paragraph (i) (1) of this section, shall be determined by the medical director.</li> </ul>					<p><u>42 CFR § 8.12 (h) (4) (i)</u></p>	
1	<p>In determining which patients may be permitted unsupervised use, the medical director shall consider the following take-home criteria in determining whether a patient is responsible in handling opioid drugs for unsupervised use:</p>						

**UNSUPERVISED APPROVED USE (TAKE-HOME) OF MEDICATION**

	<ul style="list-style-type: none"> <li>(i) Absence of recent abuse of drugs (opioid or nonnarcotic), including alcohol;</li> <li>(ii) Regularity of clinic attendance;</li> <li>(iii) Absence of serious behavioral problems at the clinic;</li> <li>(iv) Absence of known recent criminal activity, e.g., drug dealing;</li> <li>(v) Stability of the patient’s home environment and social relationships;</li> <li>(vi) Length of time in comprehensive maintenance treatment;</li> <li>(vii) Assurance that take-home medication can be safely stored within the patient’s home; and</li> <li>(viii) Whether the rehabilitative benefit the patient derived from decreasing the frequency of clinic attendance outweighs the potential risks of diversion.</li> </ul>						
2	<p>Such determinations and the basis for such determinations, consistent with the criteria outlined in paragraph (i) (2) of this section, shall be documented in the patient’s medical record. If it is determined that a patient is responsible in handling opioid drugs, the following restrictions apply:</p> <ul style="list-style-type: none"> <li>(i) During the first 90 days of treatment,</li> </ul>						

**UNSUPERVISED APPROVED USE (TAKE-HOME) OF MEDICATION**

	<p>the take-home supply (beyond that of paragraph (i) (1) of this section) is limited to a single dose each week and the patient shall ingest all other doses under appropriate supervision as provided for under the regulations in this subpart.</p> <p>(ii) In the second 90 days of treatment, the take-home supply (beyond that of paragraph (i) (1) of this section) is two doses per week.</p>					
3	<p>No medications shall be dispensed to patients in short-term detoxification treatment or interim maintenance treatment for unsupervised or take-home use.</p>					
4	<p>OTPs must maintain current procedures adequate to identify the theft or diversion of take-home medications, including labeling containers with the OTP's name, address, and telephone number. Programs also must ensure that take-home supplies are packaged in a manner that is designed to reduce the risk of accidental ingestion, including child-proof containers (see Poison Prevention Packaging Act, Public Law 91-601 (15 U.S.C. 1471 et seq.)).</p>				<p><u>15 U.S.C. 1471 et seq.)</u></p>	

## Summary of Strengths:

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## Corrective Action Plan

Please refer to each section on items that have been marked as NM (Not Met) or PM (Partially Met) to be addressed in the plan of correction (POC). The POC must be submitted by \_\_\_\_\_ to Monterey County Behavioral Health (MCBH) Quality Improvement at [415QI@co.monterey.ca.us](mailto:415QI@co.monterey.ca.us) and to the MCBH Substance Use Disorder Administrator at [AmeraultRE@countyofmonterey.gov](mailto:AmeraultRE@countyofmonterey.gov). The POC will be reviewed. At minimum, the POC must have the following elements:

- Description of how you will correct each deficiency
- Who will be responsible for quality assurance
- How often the program will monitor participant records in order to ensure compliance
- Proposed Implementation Date
- If applicable, submit proof of any corrections made

Your program may be contacted if further information is required.