



PIONEER MEDICAL CENTER

P.O. Box 1228, Big Timber, MT
406-932-4603 Fax: 406-932-5468

POLICY and PROCEDURE	
Title	Controlled Substances Distribution and Accountability
Manuals	ADC-PCMM
	CAH-PCMM
	LTC-PCMM
Approved By	Date: <u>01/21/2015</u> By: <u>Erik Wood</u> Title <u>CEO</u>

Highlights	Policy Statement
Intent	<p>All controlled substances will be distributed, stored and accounted for in a safe manner following all state and federal requirements.</p> <p>This policy describes how controlled substances will be dispensed, stored and accounted for in Pioneer Medical Center.</p>
General Considerations	<ol style="list-style-type: none"> 1. Controlled substances as defined by the Federal Controlled Substances Act are those that have a potential for abuse and/or physical or psychological dependence. Controlled substances are placed into one of five schedules depending upon their potential for abuse and dependence. Schedule II-V is subject to the rule of this policy. Schedule I substances have no current accepted medical use in the United States and lack accepted safety for use under medical supervision. 2. Any discrepancy in narcotic counting, tampering or administration shall be reported via the Medication Variance Form.
Storage	Procedure
Access	<ol style="list-style-type: none"> 1. All controlled substances shall be kept in designated locked storage within a secure area of the PMC. 2. Access shall be limited to authorized individuals. Whenever persons without legal access to the drugs have access or could gain access to the drugs, the facility is not in compliance with the requirements of secure and locked storage. 3. Only authorized staff should have access to keys. (Nurses on duty, DON). 4. Scheduled II controlled substance regulations require their transfer be initiated through completion of a Federal Form 222 submitted to ordering company. Schedule C-III, C-IV and C-V requests are made on the drug requisition form and submitted to Heartland or McKesson or ordering agent. <ol style="list-style-type: none"> a. Complete DEA Form 222. b. Only DEA registrant and those with Power of Attorney may complete and sign the Form 222.
Ordering	<ol style="list-style-type: none"> 5. A perpetual inventory system is utilized to assist with accountability of controlled substances stored at Pioneer Medical Center. 6. All controlled substances need a "Pharmacy/Resident/Patient Controlled Medication Record/Count". This form must be utilized to document the disposition of stock and includes space to document patient name, dosages administered, dosages wasted, signature of person administering and signature of person witnessing any waste. 7. Record all required information, subtract doses removed and verify the actual count matches the expected count. 8. If the licensed nurse needs to waste part or all of the dosage a second signature of a licensed practitioner is required. 9. Completed "Pharmacy/Resident/Patient Controlled Medication Record/Count" sheets shall be returned to DON for review and storage. 10. All controlled substances and narcotic keys will be accounted for each shift change. Counting of pharmacy and patient/resident narcotics in medication carts will be done at shift change by the nurse leaving shift and oncoming nurse. They will verify that the quantity on hand matches the
Perpetual Inventory	
Controlled Substance Counts	



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Misplaced Key	<p>quantity documented on the “Pharmacy/Resident/Patient Controlled Medication Record/Count” sheet.</p>
Controlled Substance Discrepancy	<p>11. If there is a discrepancy between the documented number and actual number on-hand, follow discrepancy resolution procedures outlined.</p> <p>12. If an RN/LPN leaves the premises with narcotic keys, he/she must return them immediately.</p> <p>13. If a set of keys is unaccounted for, nursing management will determine when and if, locks and keys must be changed. A Performance Improvement Event (PIE) form must be completed when a missing key cannot be found.</p> <p>14. If a discrepancy occurs between the “Pharmacy/Resident/Patient Controlled Medication Record/Count” and actual controlled substances all licensed nurses involved in controlled substances administration will remain on shift and a search for the missing controlled substances will take place.</p> <ul style="list-style-type: none">a. If the discrepancy cannot be found, the DON or designee will be notified and will conduct an investigation. A Medication Variance Report will be completed.b. All the nurses administering controlled substances on that shift shall sign the occurrence report. If it is a patient/resident missing narcotic nurses using that medication cart will sign the report. If it is the pharmacy discrepancy nurses during that shift will sign the report. <p>15. If there is a noticeable behavior change in a staff member then DON or designee must be consulted.</p> <p>16. In case of suspected tampering, the DON or designee/pharmacy will be notified. The substance along with sign out sheets will be removed. A Medication Variance report will also be completed.</p> <ul style="list-style-type: none">a. Documented thefts will also be reported to appropriate regulatory agencies (State Board of Pharmacy, DEA, State Board of Nursing, etc.).
Administration of Controlled Substances	<p>17. When controlled substances are signed out on the wrong line, a single line will be drawn through the incorrect date on the sheet and the reason will be written for the error and signed. Correct documentation will be then be done on the next line.</p>
Biennial Controlled Substances Inventory (every 2 years)	<p>18. Controlled substances may only be administered pursuant to a provider order Controlled substances must be documented on the Medication Administration Record (MAR) or appropriate part of the patient record.</p> <p>19. Every DEA registrant that orders and maintains controlled substances on site must complete a biennial inventory of controlled substances. Pharmacy will review inventory requirements with the DON or designee and set a date for the biennial inventory to meet these requirements.</p> <ul style="list-style-type: none">a. The controlled substances inventory requirements are located at the following Drug Enforcement Administration link: http://www.deadiversion.usdoj.gov/21cfr/cfr/1304/1304_11.htmb. An actual physical count must be made of all Schedule II substances. For the inventory of Schedules III, IV and V controlled substances, an estimated count may be made. An actual physical count must be made if the container holds more than 1000 dosage units and has been opened. Registrant must also be inventory that is no longer saleable. Each controlled substance that is (1) damaged, defective, or impure and is awaiting disposal, (2) held for quality control purposes, or (3) maintained for extemporaneous compounding, must be inventoried.c. The Code of Federal Regulations (CFR) requires that the inventory include:<ul style="list-style-type: none">i. The inventory date.ii. The time of the inventory is takeniii. The drug nameiv. The drug strengthv. The drug form (e.g. tablet, capsule, etc.).vi. The total quantity or total number of units/volume.d. If there are no stocks of controlled substances on hand, the registrant should make a record showing a zero inventory.



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Regulatory Reference Sources	
OBRA Regulatory Reference Numbers	
Survey Tag Numbers (optional)	