INDIAN HEALTH MANUAL CHAPTER 7

Pharmacy Controlled Substances Audit Tool

	Area:	**Facility Location:**
Date of Review:		**Completed By:**
Date of Last Review:		

PERFORMANCE ELEMENT	Methodology	Satisfactory	Unsatisfactory	NA	DATE OF COMPLETION EVIDENCE OF COMPLIANCE
Program Management					
All staff are trained on drug diversion prevention before working in the pharmacy.					
All staff are trained on drug diversion prevention annually.					
APC or designee (must be senior level pharmacist from outside SU) conducts annual physical audit of schedule II-V controlled substances.					
1. Count is verified against the inventory record.					
2. Exact count must be completed.					
3. Includes all stocks in pharmacy and all locations where controlled substances are stored.					
4. Visual inspection for quality control to determine integrity of the containers.					
5. Records of stocks received are verified for entry on the inventory record at each location Schedule II medications are stocked.					
6. DEA form 222 and electronic generated orders (CSOS) are randomly audited for accuracy.					
7. Procurement records for Schedule II medications are audited and verified with pharmacy records.					
MEDICATION PROCUREMENT *3-7.5*					
Ordering Controlled Substances					
Current DEA registration					
Ordering and receiving controlled substances will be performed by different					
Primary method for ordering Schedule II drugs is via the DEA Controlled Substance Ordering					
Unless otherwise registered with the DEA, personnel authorized to order Schedule II controlled substances must be designated in writing via completion of a DEA Power of Attorney form.					
Power of Attorney forms are kept on file in the pharmacy.					
When available, pharmacy stocks controlled substances in 100-count bottles or smaller.					

PERFORMANCE ELEMENT	Methodology	Satisfactory	Unsatisfactory	NA	DATE OF COMPLETION EVIDENCE OF COMPLIANCE
Receiving Controlled Substances					
All orders for controlled substances are delivered directly to the pharmacy in unopened shipping containers or boxes.					
Two facility employees (one being a pharmacist) acknowledge and sign for receipt of the order on appropriate forms.					
The receipt of the controlled substances are finalized in the pharmaceutical prime vendor ordering system.					
Controlled substances are logged correctly into the inventory.					
Order discrepancies are reconciled before controlled substances are accepted into the pharmacy inventory.					
Records Maintenance					
All records pertaining to the acquisition, receipt, and distribution of controlled medications will be maintained on file or stored electronically according to IHS records management policy and DSCSA requirements.					
1. All CS medication stock invoices are maintained for no less than 3 years.					
2. Records of all CS medication inventories are kept for a minimum of 3 years.					
3. Records of all CS disposals are kept for a minimum of 3 years.					
4. Records of CS balance adjustments are readily retrievable on paper or electronically for a minimum of 3 years.					
5. Records involving losses of CS are maintained on-site for 3 years.					
6. The RPMS CSM is printed daily, signed by all dispensing pharmacists, and maintained for 3 years.					
7. Hard-copy CS prescriptions are maintained in the pharmacy for 3 years. CII are filed separately than CIII-V.					
8. Electronic records are readily retrievable.					
INVENTORY MANAGEMENT *3-7.6*					
Required Inventories					
Perpetual inventory is maintained for all schedule II CS.					
Perpetual inventory is maintained for all schedule III-V CS.					
Monthly inventory is performed for all schedule II CS and report submitted to APC, CEO, and CD.					
Monthly inventory is performed for all schedule III-V CS and report submitted to APC, CEO, and CD.					
Monthly reconciliation is performed for all schedule II CS (accounting for all CS received + dispensed + returned to stock + wasted + expired).					
Monthly reconciliation is performed for all schedule III-V CS (accounting for all CS received + dispensed + returned to stock + wasted + expired).					
Biennial inventory of schedule II CS is produced and date is within the past 2 years.					

PERFORMANCE ELEMENT	Methodology	Satisfactory	Unsatisfactory	NA	DATE OF COMPLETION EVIDENCE OF COMPLIANCE
Medication Storage					
All controlled substances are securely locked at all times.					
Controlled substances awaiting pickup are locked at all times.					
Only pharmacists have the combination/keys to the pharmacy controlled substances safe/storage areas unless electronic access is recorded, then technicians may be permitted to access.					
Expired or damaged CS medications awaiting Reverse Distribution or destruction are stored in a securely locked area and inventory is maintained on these items.					
Loss or Theft of Controlled Medications					
Written reports of loss or theft are completed within 1 day and provided to officials as required in IHM Chapter 7					
Adjustments are completed on paper with 2 signatures by individuals authorized in local policy (Electronic signatures may be used in inventory management software).					
1. All balance adjustments are reviewed by the Chief Pharmacist, Clinical Director (or designee) and reported to the CEO and APC on the monthly inventory.					
2. Any accidental loss, breakage or destruction of insignificant quantities of Schedule II-V controlled substance are signed by person responsible and reported to the immediate supervisor.					
3. If explanation is not satisfactory by immediate supervisor, incident is reported to Chief Pharmacist, CEO and APC for investigation.					
MEDICATION ORDERING/PRESCRIBING *3-7.9*					
Controlled Substance Prescribing					
All providers employed by the facility that prescribe controlled substances are registered with the DEA.					
1. Providers can prescribe under the facility DEA followed by a unique identifier if provider has a pending application to the DEA or the contract prescriber is not licensed in the state where delivering services					
2. When using the facility DEA with provider-specific identifier:					
a. The provider-specific identifier is readily retrievable.					
b. The provider-specific identifier is only used within the confines of the Service Unit.					
Schedule II prescriptions provided to the patient are prescribed using tamper-evident process and in accordance with Federal law, including DEA regulations.					
Schedule III-V prescriptions are issued in accordance with Federal law including DEA regulations.					
Prescription paper (including pads) is securely stored, tracked and inventoried.					
Participation in State Prescription Drug Monitoring Programs - mandatory					
Report to State Prescription Drug Monitoring Programs DAILY.					
Documentation of Prescription Drug Monitoring checks required in Part 3 Chapter 35 of the Indian Health Manual.					

Methodologies: D = Demonstration/Observation Q = QA Findings V = Verbal

PERFORMANCE ELEMENT	Methodology	Satisfactory	Unsatisfactory	NA	DATE OF COMPLETION EVIDENCE OF COMPLIANCE
PREPARING AND DISPENSING MEDICATIONS *3-7.10*					
Dispensing					
If automated robots are used for controlled substances robot is locked with only pharmacist access.					
Each patient/proxy picking up controlled substance medications must have valid photo ID checked and documented.					
Mailing Prescriptions					
Schedule II prescriptions are not mailed.					
Returning Medications to Stock					
All controlled substances not picked up and are returned to stock must be processed in RPMS, checked into inventory and returned to stock all on the same day.					
The process of returning controlled substance prescriptions to physical stock must be completed by a pharmacist and witnessed by another pharmacist, pharmacy technician, or by another licensed healthcare professional.					
OTHER ELEMENTS TO CONSIDER					
Use of RRIP tool to identify high-risk opioid use patients					
Justification for MME > 90					
Co-prescribing naloxone for > 50 MME					

Methodologies: D = Demonstration/Observation Q = QA Findings V = Verbal

REVIEWER COMMENTS/FOLLOW-UP ITEMS/ACTION PLAN