INDIAN HEALTH MANUAL CHAPTER 7

Pharmacy Program Review 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
PHARMACY AND THERAPEUTICS COMMITTEE 3-7.3 **review 3 mandatory**					
P&T membership has at least one physician and one pharmacist.					
Local formulary reviewed at least annually.					
Emergency medications and other medications stocked in patient care areas are reviewed at least annually.					
Formulary – review 2 mandatory plus choose 1 additional element					
Evidence of adherence to the IHS NCF.					
Formulary restrictions identified on formulary with objective criteria for use.					
All providers have access to current formulary when prescribing.					
Utilization of non-formulary drug requests.					
Sample medications are prohibited.					
Records Maintenance – all mandatory					
All records pertaining to the acquisition, receipt, and distribution of non- controlled medications will be maintained on file or stored electronically according to IHS records management policy and DSCSA requirements.					
1. All medication stock invoices are maintained for no less than 3 years.					
2. Records of all medication inventories are kept for a minimum of 3 years.					
3. Records of all disposals are kept for a minimum of 3 years.					
4. Records involving losses of non-controlled substances are maintained on-site for 3 years.					
INVENTORY MANAGEMENT ***3-7.6 all mandatory elements***					
Required Inventories					
Annual inventory completed for all pharmaceuticals. May use the "halves" method and open containers may be counted as ½ bottle.					
Monthly Enhanced Surveillance Inventory (ESI) includes at a minimum 5 medications (1 strength of each medication).					
List of ESI medications is reviewed at least annually when updated by the NPC Inventory Management Subcommittee.					

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

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Medication Storage – review 8 mandatory plus 1 additional element					
Hazardous medications and Look Alike / Sound Alike (LASA) medications are stored as required by local policy in all locations.					
Appropriate manual, electromechanical or electronic temperature recording equipment devices and/or logs are utilized to document proper storage of prescription drugs.					
All medication storage locations are inspected monthly for proper storage and expiration dates by pharmacy staff.					
Medications at each nursing location will be stored in a separate secure medication storage cabinet.					
Cabinets outside of pharmacy department are kept secured at all times except when authorized personnel are preparing medications or are in constant attendance.					
Expired medications are segregated and labeled "Expired Drugs: Do not use."					
Expired medications are returned with the Reverse Distributor.					
A secured medication storage cabinet or ADC is used to store medications that are approved by the local P&T for after-hours use.					
Medications for external use are stored separately from internal and injectable medications.					
Disinfectants are stored separately from internal and injectable medications.					
All flammable products are stored in a safety cabinet in compliance with Occupational Safety and Health Administration (OSHA) guidelines.					
ADC transaction reports are stored electronically or printed and kept on file for at least 3 years.					
Loss or Theft of Non-Controlled Medications – all mandatory					
Written reports are completed within 1 day and provided to officials as required in IHM Chapter 7					
PHARMACY SECURITY ***3-7.7 – all mandatory***					
Access to medications within the facility is controlled and limited.					
Access to the pharmacy after hours is limited to pharmacists.					
Closed circuit television cameras are installed inside the pharmacy and at remote medication storage areas.					
Recorded footage is securely stored with restricted access. Cameras provide footage in all medication filling/handling locations including:	[redacted]				
1. Counseling rooms					
2. Controlled substance safe					
3. Pharmacy patient reception					
4. Automated dispensing unit(s)/robot(s)					
5. Prescription shelving/storage					
6. Pharmacy entrance(s)/exit(s)					
Cameras are protected against tampering/disabling.					
Electronic Access Control	[redacted]				
1. Any door leading into the pharmacy has a security-enhanced access (Personal					
2. Locks provide a centralized, readily retrievable history of entrance into the pharmacy.					
3. Only pharmacists may have physical keys that can override security-enhanced locks.					
4. Local policy restricts the use of physical keys to times when PIV card access is not functioning (e.g. during a power outage)					
5. Combination on the cipher lock is changed every 90 days and as soon as possible after an employee leaves IHS employment.					

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All visitors and non-pharmacy personnel entering the pharmacy are escorted by the pharmacy					
Alarm system contains the following:					
1. Motion detectors and auto-dialer is installed					
2. Is routinely tested					
3. At least a 24-hour battery or other power source					
Automated Dispensing Robots and Cabinets contain biometric authentication when available (if not available, user passwords are changed every 90 days).					
Pharmacy windows located on the exterior of the facility have bars that are sufficient to deter/prevent forcible entry into pharmacy.					
Exterior pharmacy windows in interior of facility have barriers sufficient to prevent unauthorized access to facility (bars, bullet-proof glass or security shutters-pharmacy staff must be physically present when shutters are open).					
PHARMACY SERVICES ***3-7.8 – all mandatory***					
Patient Care Activities					
Counseling is provided to each patient receiving new medication and/or medication therapy changes.					
If patient refuses counseling, pharmacy staff documents refusal per local procedure.					
Medication/Drug Recalls					
Drug recall reports, notices, and actions taken are maintained in the pharmacy. Recalls are acted upon in accordance with FDA regulations and are documented in the file.					
MEDICATION ORDERING/PRESCRIBING ***3-7.9***					
Medications are only dispensed if an allergy assessment is completed (unless emergency situation when overridden by provider).					
Clinical Protocols					
All pharmacy clinical protocols will be maintained in the pharmacy department in a readily retrievable manner and have been reviewed and approved by the Clinical Director.					
Non-IHS Providers					
When prescriptions are received by a non-IHS provider that is not on the formulary, the pharmacist consults with the IHS prescriber to recommend alternative therapy.					
Appropriateness of Medication Therapy					
Pharmacists are documenting appropriate interventions, including Type A and B errors.					
The provider visit note is completed prior to or along with current prescriptions in EHR.					

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PREPARING AND DISPENSING MEDICATIONS *3-7.10*					
Prepackaging					
Pre-labeled prepackaged drugs may be utilized for field clinics that do not have pharmacies when meeting the following:					
1. Pre-pack log is digitally archived, printed at least monthly or maintained manually on a pharmacy chronological control log.					
2. A uniform system for designating the control number is used (7 digits – first two numbers are the month, second two numbers are the year, and the last three numbers are the order the drugs are on the form).					
Prepack items used in the outpatient pharmacy contain the following on a preprinted label:					
1. Required cautionary labels, generic name and strength, lot number, pre-packaging control number, expiration date, quantity					
2. Expiration date (one year from date of repackaging unless expiration date on stock bottle is less than 1 year					
Returning Medications to Stock					
All prescriptions not picked up by patient within 10 days are returned to stock in RPMS and other automation.					
Returned medications are not returned to the original stock bottles.					
CLINICAL PHARMACY SERVICES *3-7.11*					
As appropriate with licensure, pharmacists that serve as primary care or intermittent providers with prescriptive authority have either an approved CPA or are credentialed and privileged through the local medical staff.					
INPATIENT PHARMACY *3-7.12*					
Unit dose system utilized and allows identification of drugs up to the point of administration (Bar Coded Medication Administration)					
Intravenous Admixtures					
Intravenous admixture program meets current USP standards.					
1. Pharmacists and pharmacy technicians are certified annually in the preparation of IV admixtures.					
2. Pharmacy department ensures training provided to all nursing and medical personnel who may prepare IV admixtures in the absence of a pharmacist.					
Cytotoxic and Other Hazardous Drugs					
Comply with IHM Part 3, Chapter 27 – Controlling Occupational Exposure to Hazardous Drugs					
QUALITY ASSURANCE AND IMPROVEMENT *3-7.14*					
QAPI plan is approved by the SU CD and the CEO.					
QAPI plan includes (but not limited to) the following:					
1. Ensure medications are safely stored, dispensed, and/or administered (safety measures for look-alike sound-alike; high alert; and hazardous medications).					
2. Monitoring and evaluating the QAPI plan.					
3. Written annual evaluation of the pharmacy QAPI.					
4. Reporting and monitoring of pharmacy services to other departments (facility QAPI committee, Governing Body).					

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Reporting Adverse Events and Medication Errors					
All adverse events are reported to and reviewed by the SU P&T, quality assurance and/or medication safety committee.					
1. All allergic responses to drugs, side effects, and any other unexpected response to a drug.					
2. All serious, unusual or previously unreported adverse effects are reported directly to the FDA MedWatch program.					
3. Adverse reactions to vaccines are reported online to the Vaccine Adverse Event Reporting System (VAERS).					
Pharmacy interventions are reviewed and analyzed by the SU P&T, quality assurance and/or medication safety committee.					
Medication errors are entered into IHS approved reporting database and reviewed by SU P&T Committee, quality assurance and/or medication safety committee.					
OTHER					
Pharmacy mailing CIII – CV medications.					
RRM reviewed within the last year					
Staffing levels in accordance with RRM					
Annual review of pharmacy access					
Mobile nursing carts, anesthesia carts, epidural carts and other medication carts containing Schedule II-V medications must be locked within a secure area					

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REVIEWER COMMENTS/FOLLOW-UP ITEMS/ACTION PLAN