Pharmacology Services

19 CSR 30-20.100
COP §485.635(a)(3)(iv)
COP §485.635(a)(3)(v)

Critical Access Hospital

Self-Assessment Question	Compliance: Yes	Partially	No	NA	Date/Initials	Comments
Note: Pharmaceutical services at a CAH can be provided either as direct services or through an agreement. The direction of pharmaceutical services may not require continuous on-premise supervision at the pharmacy but may be accomplished through regularly scheduled visits, and/or telemedicine in accordance with Federal and State law and regulation and accepted professional principles.						
Is a single pharmacist: a. responsible for the overall administration of the pharmacy service? b. responsible for developing, supervision, and coordinating all the activities of the CAH-wide pharmacy service? c. thoroughly knowledgeable about the pharmacy practice and management?						
If the pharmacy is not open 24/7, is a pharmacist available on-call at all times that pharmacy services are not available?						
If the pharmacy is not open 24/7, does your hospital have a process for providing medications to meet patient needs when the pharmacy is closed?						
Is the pharmacy integrated into the hospital-wide organization and QA/PI program?						
Is there a multidisciplinary pharmacy committee that regularly meets?						
Does the pharmacy committee approve all pharmacy's policies and procedures?						
Does the pharmacy have a therapeutic committee that regularly meets?						
Does the medical staff review and approve the hospital formulary on a continual basis?						
Do you have policies and procedures to address: a. processes to identify potential and actual adverse drug events? b. reporting serious drug reactions to the FDA in accordance with the MedWatch program?						

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Do you have policies and procedures to address: (continued) c. dosing limits, administration guidelines, packaging, labeling and storage for high-alert medications? d. limiting the variety of medication-related devices and equipment? e. availability of up-to-date medication information? f. availability of pharmacy expertise? g. avoidance of dangerous abbreviations? h. alert systems for look-like and sound-alike drug names? i. the use of facility approved pre-printed order sheets? j. prohibiting orders to "resume previous orders"? k. a voluntary, non-punitive, reporting system to monitor and report adverse drug events? l. ensuring that patient-specific information is readily accessible to all individuals involved in provision of pharmaceutical care? m. identifying when weight-based dosing for pediatric populations is required? n. requirements for review and revision of adverse drug events and QA/PI activities? o. evaluation, selection, supply and acquisition of medications in the hospital formulary, those needed on an emergency basis, and those not included in the formulary? p. drug recalls and reporting manufacturer drug problems?						

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Do you have policies and procedures to address: (continued) q. removal of outdated, mislabeled or otherwise unusable drugs? r. use of aseptic technique and sterilization by pharmacy personnel? s. compounding, repackaging, re-labeling by non-pharmacy personnel? t. preparation, timing and administration of medications in conjunction with nursing and administration? u. personal medications brought into the hospital? v. self-administered medications? w. dispensing medications to patients leaving the hospital when retail services are not reasonably available and include who, when, what and how many may be dispensed? x. labeling requirements for dispensing medication to patients who are discharged or outpatient? y. prescribing and writing medication orders and standing orders? z. removal of drugs and biologicals from the pharmacy or storage areas in the absence of a pharmacist including the amount permitted and documentation required?						
Do you have policies and procedures to address: a. reviewing and discontinuing medications and compliance with stop-order policies? b. authorization and access to controlled substance storage areas outside of the pharmacy that are written in conjunction with administration and nursing?						

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c. distribution and accountability of keys, magnetic cards, electronic codes or other security devises? d. provision for pharmacy services in the event of a disaster? e. utilization and monitoring of emergency and non-emergency floor stock medications? f. reconciling controlled substances discrepancies? g. reconciling medications not administered?						
Do you have policies and procedures that address the acquiring, storing, handling, preparation, compounding, packaging, labeling, dispensing, administration, disposal, inventory control, authorized and unauthorized usage and distribution of: a. sterile medications and biologicals? b. investigational drugs? c. cytotoxic/hazardous drugs? d. radiopharmaceutical and/or investigational drugs? e. sample medications?						
Is pharmacy staff educated on new and revised medication-related policies and procedures?						
Is nursing staff educated on new and revised medication related policies and procedures?						
Are pharmaceutical policies and procedures reviewed and evaluated on a regular basis?						
Is the director of pharmacy services: a. licensed as a pharmacist in Missouri and qualified by education and experience?						

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b. a member of the pharmacy and therapeutics committee(s) or its equivalent? c. a participant in all decisions made by pharmacy services or committee(s) regarding the use of medications? d. responsible for the authorization of access to the pharmacy by supervisory nursing personnel to obtain doses for administration when pharmacy services are not available? e. responsible for the authorization of access to controlled substance storage areas outside of the pharmacy? f. responsible for the authorization of emergency and non-emergency medications that can be stocked as floor stock? g. responsible in conjunction with nursing and administration for approving how and when medications for administration are prepared outside of the pharmacy? h. responsible for review and investigation of variances involving controlled substances? i. responsible for periodically monitoring adherence to policies and procedures?						
Do all full-time, part-time and/or consulting pharmacists: a. have a current license in Missouri? b. have a job description or a written agreement with responsibilities clearly defined including the development, supervision and coordination of all the activities of pharmacy services?						

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Are pharmacists responsible for: a. the development, supervision and coordination of all activities of pharmacy services? b. developing standards for the selection, distribution and safe and effective use of medications throughout the hospital? c. reconciling on a regular basis and maintaining a written account of all scheduled drugs for a minimum period of two years? d. the clinical interpretations of medication orders? e. reviewing the prescriber's order or a direct copy prior to the administration of the initial dose (or within 72 hours if an emergency or when the pharmacist is unavailable)? f. reviewing the medication profile for each patient prior to dispensing the medications for: - therapeutic appropriateness of a patient's medication regimen? - therapeutic duplication in the patient's medication regimen? - appropriateness of the drug, dose, frequency, route and method of administration? - real or potential medication, food, laboratory test and/or disease interactions? - real or potential allergies or sensitivities? - variation from organizational criteria for use? - other contraindications? g. being readily available to discuss drug therapy, interactions, side effects, dosage, etc., for individual patients with practitioners and nursing personnel?						

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Are pharmacists responsible for: (continued) h. personally, or by designee, offering to provide medication counseling when discharge or outpatient prescriptions are filled? i. supervising the work of all the support pharmacy personnel, including interpretation of medication orders and all compounding, labeling, repackaging and dispensing of all medications? j. acquisition, inventory control, dispensing, distribution and related documentation requirements of investigational medications? k. identifying and reporting drug administration errors, problems with controlled substances, adverse drug reactions and incompatibilities to the attending physician and, if appropriate, to the hospital-wide quality assurance program, then taking corrective action?						
Are all non-pharmacist support personnel: a. educated and trained for their assigned responsibilities? b. working under the supervision of a pharmacist? c. not allowed to perform duties that by law must be performed by a pharmacist including clinical interpretation of medication orders?						
Are there an adequate number of licensed pharmacist/pharmacy techs to meet the needs of staff and patients?						
Does the pharmacy have: a. adequate space, equipment and supplies? b. office space for administrative and clerical services?						

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Are storage areas inside the pharmacy: a. properly sanitized and maintain temperature, moisture, ventilation, segregation control? b. only accessed by authorized personnel? c. locked when appropriate?						
Does a pharmacist or designee inspect medication storage areas at least monthly?						
Are refrigerated medications inside and outside of the pharmacy separated from food and laboratory materials?						
Are floor stock medications limited to emergency and non-emergency medications that are authorized by the director of pharmacy in conjunction with nursing and administration?						
Are emergency medications available in designated areas?						
Has a medication use evaluation program been established which evaluates the use of selected medications to ensure that they are used appropriately, safely and effectively and is follow-up educational information provided in response to evaluation findings?						
Does the pharmacy department maintain current, accurate, traceable and readily retrievable records pertaining to: a. the flow of pharmaceuticals from their entry into the hospital through dispensation/administration? b. acquisition, inventory control, dispensing, distribution and identity of all recipients of investigational medications? c. controlled substances acquisition, compounding, repackaging, dispensing, distribution, administration, disposal for at least two years?						

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d. dispensing and extemporaneous compounding including sterile medications for a minimum of six months? e. the proper preparation, receipt, labeling, usage, transportation, storage and disposal of radiopharmaceuticals in accordance with accepted standards of practice?						
Are all schedule II controlled substance inventories inside and outside the pharmacy routinely reconciled?						
Are all schedule III – V controlled substance inventories outside the pharmacy routinely reconciled according to hospital policy?						
Is access to concentrated solutions (i.e., potassium chloride, sodium chloride solutions greater than 0.9 percent) restricted?						
Are all mobile storage units accessible only to authorized personnel and locked when appropriate?						
Is the supply and provision of emergency medications consistent with standards of practice and appropriate for specified age groups or disease treatments?						
Is current drug information readily available in nursing areas and/or drug storage areas?						
If applicable, is an investigational protocol available to prescribing health care providers?						
Does each patient's individual drug container bear his/her full name, prescriber's name, drug name, strength and quantity dispensed, expiration date, appropriate accessory and cautionary statements and, when applicable, the lot number and other pertinent information?						
Does each floor stock container, each single unit dose package and all compounded and repackaged medications bear the name and strength of the drug, lot and control number or equivalent and expiration date?						

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When mobile storage units are unlocked is someone with legal access to the drugs directly monitoring the cart?						
When locked mobile storage units are not in use, are they stored in a locked room, monitored area or secure location?						
Are controlled substance storage areas outside the pharmacy accessible only to persons authorized to administer them and to authorized pharmacy personnel and locked when appropriate?						
Are all controlled substances variances including, inventory, security, recordkeeping, administration and disposal reported to the pharmacy director for review and investigation?						
Are all losses, diversions, abuses or misuses of medications recorded and reported to the pharmacy director, administration, and local, state and federal authorities as appropriate?						
Is there a system that minimizes the time frame between the actual losses or diversion to the time of detection and determination of the extent of loss or diversion?						
Is there a system to prevent outdated, mislabeled, or otherwise unusable drugs and biologicals from being available for patient use?						
Have automatic stop orders for all medications been established, by the medical staff, with a procedure to notify the prescriber?						
Are compounded sterile medications routinely prepared by pharmacy personnel in a suitably segregated area in a class 100 environment?						
Are compounded sterile medications prepared by non-pharmacy personnel only when immediate preparation is necessary and pharmacy personnel are not available?						

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Are compounded sterile medications immediately administered by the person who prepared them except in cases approved by the director of pharmacy, nursing and administration?						
Are all compounded cytotoxic/hazardous medications prepared in a suitable segregated area in a class II biological safety cabinet or vertical airflow hood?						
Are radiopharmaceuticals only prepared by or under the supervision of personnel who are certified by the Nuclear Regulatory Commission?						
Are medication orders initiated or modified only by practitioners who have independent statutory authority to prescribe or who are legally given authority to order medications?						
Are all medication orders, written by persons without independent statutory authority to prescribe, completed according to the hospital's policies and procedures and included in the QA program?						
Except for influenza and pneumococcal vaccines, when standing orders or protocols are used, is a signed copy placed in the medical record?						
For influenza and pneumococcal vaccine, if approved medical protocols are used, is there an R.N. assessment in every medical record when these vaccines are administered?						
Are telephone or verbal orders only accepted by authorized staff, immediately written and the discussions with prescriber noted in the medical record and promptly signed by the ordering practitioner or other practitioner responsible for the patient's care in accordance with hospital policies and medical staff bylaws?						

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Are medications only administered by persons who have statutory authority to administer or who have been trained in each pharmacological category of medication they administer, according to your hospital's policies and procedures?						
When retail pharmacy services are not readily available and medications are provided to patients leaving the hospital, are hospital policies related to ordering limitations, labeling, patient counseling and record keeping followed by the prescriber or R.N.?						
Are medication incidents, including medication errors immediately reported to the presciber, the appropriate manager and the appropriate committee?						
Are adverse medication reactions recorded in the patient's chart and immediately reported to the prescriber and pharmacy director?						
Are adverse medication reactions reviewed by the pharmacy and therapeutics committee and other medical or administrative committees when appropriate?						
Are potential corrective actions identified and implemented, if appropriate, in the case of an adverse drug reaction?						
Are policies and procedures reviewed and amended based on: a. reports of adverse drug events? b. QA/PI activities pertaining to pharmaceutical care? c. evaluations of external alerts and/or recommendations from national associations and government agencies? d. evaluation of literature for new technologies or successful practices that have demonstrated enhanced medication safety?						

Notes: