

CRITICAL ACCESS HOSPITALS

PHARMACOLOGY SERVICES					
Self-Assessment Questions	YES	NO	N/A	Date/Initials	Comments
<p>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.</p>					
<p>Has the CAH identified the qualifications of and designated a pharmacist responsible for developing and implementing the rules of the CAH's pharmacy services? C-0276 COP§485.635(a)(3)(iv)</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<p>Is this pharmacist:</p> <p>a. responsible for the overall administration of the pharmacy service?</p> <p>b. responsible for developing, supervision, and coordinating all the activities of the CAH-wide pharmacy service?</p> <p>c. thoroughly knowledgeable about the pharmacy practice and management?</p> <p>d. knowledgeable about compounding policies, practices and quality assurance, selecting and overseeing any external sources of compounded medications?</p> <p>e. capable of conducting effective quality oversight consistent with USP 795 and 797 standards?</p> <p>f. capable of assigning risk levels of compounded sterile products consistent with USP 797? C-0276 COP§485.635(a)(3)(iv)</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<p>Is a pharmacist available during appropriate hours to provide necessary contact with medical and nursing staff? 19 CSR 30-20.100(4)</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<p>If the pharmacy is not open 24/7, is a pharmacist available on-call at all times that pharmacy services are not available? 19 CSR 30-20.100(4)</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<p>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? 19 CSR 30-20.100(14) C-0276 COP§485.635(a)(3)(iv)</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<p>Is the pharmacy integrated into the hospital-wide organization and QA/PI program? 19 CSR 30-20.100(1)</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

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Is there a multidisciplinary pharmacy committee that regularly meets? C-0276 COP§485.635(a)(3)(iv)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are pharmacy rules developed in consultation with the advice of the CAH's professional staff? C-0276 §485.635(a)(3)(iv)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is the formulary established, reviewed and revised on a continual basis based upon objective evaluation of the therapeutic merits, safety and cost of medications? 19 CSR 30-20.100(31)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Do you have policies and procedures to address:					
a. processes to identify potential and actual adverse drug events?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
b. a voluntary, non-punitive, reporting system to monitor and report adverse drug events?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
c. requirements for review and revision of adverse drug events and QA/PI activities?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
d. evaluation, selection, supply and acquisition of medications in the hospital formulary, those needed on an emergency basis, and those not included in the formulary?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
e. drug recalls and reporting manufacturer drug problems?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
f. removal of outdated, mislabeled or otherwise unusable drugs?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
g. use of aseptic technique and sterilization by pharmacy personnel?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
h. record keeping, quality control and end product testing, when appropriate, of medications compounded in the pharmacy?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
i. compounding, repackaging, re-labeling by non-pharmacy personnel?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
j. preparation, timing and administration of medications in conjunction with nursing and administration?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
k. personal medications brought into the hospital?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
l. self-administered medications?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
m. 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?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
n. labeling requirements for dispensing medication to patients who are discharged or outpatient?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

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o. prescribing and writing medication orders and standing orders? p. removal of drugs and biologicals from the pharmacy or storage areas in the absence of a pharmacist including the amount permitted and documentation required? 19 CSR 30-20.100(8)(14)(15)(16)(23)(24)(29)(38) C-0276 COP§485.635(a)(3)(iv) C-0277 COP§485.635(a)(3)(v)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
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? c. distribution and accountability of keys, magnetic cards, electronic codes or other security devices? d. provision for pharmacy services in the event of a disaster? e. criteria, utilization and monitoring of emergency and non-emergency floor stock medications? f. reconciling controlled substances discrepancies? g. reconciling medications not administered? h. Inspecting medication storage areas at least monthly by a pharmacist or designee? i. determining beyond use dates based on accepted professional standards equivalent to, or more stringent than USP formulary? 19 CSR 30-20.100 (12)(14)(24)(25)(36) C-0276 COP§485.635(a)(3)(iv)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
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? 19 CSR 30-20.100(17)(18)(26)(27) C-0276 COP§485.635(a)(3)(iv)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

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Do your policies and procedures for cytotoxic/hazardous drugs include personnel training, aseptic technique, and equipment operating requirements, access to emergency spill supplies, sterilization and quality control? 19 CSR 30-20.100(17)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is pharmacy staff educated on new and revised medication-related policies and procedures? C-0276 COP§485.635(a)(3)(iv)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is nursing staff educated on new and revised medication related policies and procedures? C-0276 COP§485.635(a)(3)(iv)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are pharmaceutical policies and procedures reviewed and evaluated on a regular basis? C-0276 COP§485.635(a)(3)(iv)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is the director of pharmacy services:					
a. licensed as a pharmacist in Missouri and qualified by education and experience?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
b. a member of the pharmacy and therapeutics committee(s) or its equivalent?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
c. advising the medical staff on medication matters?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
d. responsible with the assistance of medical, nursing and administration for the development of standards for the selection, distribution and safe and effective use of medications in the hospital?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
e. a participant in all decisions made by pharmacy services or committee(s) regarding the use of medications?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
f. responsible for the authorization of access to the pharmacy by supervisory nursing personnel to obtain doses for administration when pharmacy services are not available?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
g. responsible for the authorization of access to controlled substance storage areas outside of the pharmacy?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
h. responsible in conjunction with nursing administration for the authorization of emergency and non-emergency medications that can be stocked as floor stock?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
i. responsible in conjunction with nursing and administration for approving how and when medications for administration are prepared outside of the pharmacy?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
j. responsible for review and investigation of variances, inventory, security, record keeping,	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

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administration and disposal of controlled substances? k. responsible for periodically monitoring adherence to policies and procedures? 19 CSR 30-20.100(1)(6)(12)(24)(31) C-0276 COP§485.635(a)(3)(iv)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
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? 19 CSR 30-20.100(2) C-0276 COP §485.635(a)(3)(iv)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
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. the clinical interpretations of medication orders? d. 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)? e. 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? f. being readily available to provide counseling on drug therapy, interactions, side effects,	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

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dosage, etc., for individual patients with practitioners and nursing personnel? g. personally, or by designee, offering to provide medication counseling when discharge or outpatient prescriptions are filled? h. supervising the work of all the support pharmacy personnel, including interpretation of medication orders and all compounding, labeling, repackaging and dispensing of all medications? i. acquisition, inventory control, dispensing, distribution and related documentation requirements of investigational medications? j. 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? 19 CSR 30-20.100(15)(19)(26)(30)(32) C-0276 COP §485.635(a)(3)(iv) C-0277 COP §485.635(a)(3)(v)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are all non-pharmacist support personnel: a. educated and trained for their assigned responsibilities? b. working under the supervision of a pharmacist when processing, selecting, compounding, packaging, labeling and dispensing medications? c. not allowed to perform duties that by law must be performed by a pharmacist including clinical interpretation of medication orders? 19 CSR 30-20.100(2) (3)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are there an adequate number of licensed pharmacist/pharmacy techs to meet the needs of staff and patients? C-0276 COP §485.635(a)(3)(iv)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
For the scope of services provided, does the pharmacy have: a. adequate space, equipment and supplies? b. office space for administrative and clerical services? c. adequate area to meet standards that provide for the safety or personnel and the security and stability of medications stored, handled and dispensed? 19 CSR 30-20.100(5)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

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Are storage areas inside the pharmacy: a. properly sanitized and maintain temperature, light, moisture, ventilation and segregation control? b. locked and only accessible by pharmacy and authorized nursing supervisory personnel? c. for controlled substances separately locked and accessible only by authorized pharmacy staff? 19 CSR 30-20.100(6)(11)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are medication storage areas outside of the pharmacy: a. accessible only to authorized personnel? b. locked when appropriate? c. designed to ensure proper conditions of sanitation, temperature, light, moisture, ventilation and segregation? 19 CSR 30-20.100(7)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does a pharmacist or designee inspect medication storage areas at least monthly? 19 CSR 30-20.100(25)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are refrigerated medications inside and outside of the pharmacy separated from food and laboratory materials? 19 CSR 30-20.100(6)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
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? 19 CSR 30-20.100(24)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are emergency medications available in designated areas? 19 CSR 30-20.100(24)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
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? 19 CSR 30-20.100(31)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

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<p>Does the pharmacy department maintain current, accurate, traceable and readily retrievable records pertaining to:</p> <p>a. the flow of pharmaceuticals from their entry into the hospital through dispensation, administration, destruction or return to manufacturer?</p> <p>b. acquisition, inventory control, dispensing, distribution and identity of all recipients of investigational medications?</p> <p>c. controlled substances acquisition, compounding, repackaging, dispensing, distribution, administration, disposal for at least two years?</p> <p>d. dispensing and extemporaneous compounding including sterile medications for a minimum of six months?</p> <p>e. the proper preparation, receipt, labeling, usage, transportation, storage and disposal of radiopharmaceuticals in accordance with accepted standards of practice?</p> <p>19 CSR 30-20.100(9)(26) C-0276 COP §485.635(a)(3)(iv)</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<p>Are all schedule II controlled substance inventories inside and outside the pharmacy routinely reconciled?</p> <p>19 CSR 30-20.100(10)</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<p>Are all schedule III – V controlled substance inventories outside the pharmacy routinely reconciled according to hospital policy?</p> <p>19 CSR 30-20.100(10)</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<p>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?</p> <p>19 CSR 30-20.100(11)</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<p>Are all controlled substances variances including, inventory, security, recordkeeping, administration and disposal reported to the pharmacy director for review and investigation?</p> <p>19 CSR 30-20.100(13)</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<p>Are all mobile storage units accessible only to authorized personnel and locked when appropriate?</p> <p>C-0276 COP §485.635(a)(3)(iv)</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

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Is current medication information readily available in patient care areas and/or drug storage areas? 19 CSR 30-20.100(30)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
If applicable, is an investigational protocol available to prescribing health care providers? 19 CSR 30-20.100(26)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is the identity of all recipients of investigational medication readily retrievable? 19 CSR 30-20.100(26)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
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? 19 CSR 30-20.100(20)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
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? C-0276 COP §485.635(a)(3)(iv)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
When mobile storage units are unlocked, is someone with legal access to the drugs directly monitoring the cart? C-0276 COP §485.635(a)(3)(iv)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
When locked mobile storage units are not in use, are they stored in a locked room, monitored area or secure location? C-0276 §485.635(a)(3)(iv)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
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? 19 CSR 30-20.100(13)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
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? C-0276 COP §485.635(a)(3)(iv)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is there a system to prevent outdated, mislabeled, manufacturer's recall or otherwise unusable drugs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

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and biologicals from being available for patient use? C-0276 COP §485.635(a)(3)(iv)					
Have automatic stop orders for all medications been established, by the medical staff, with a procedure to notify the prescriber? 19 CSR 30-20.100(36)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is there a maximum stop order for all medications which do not have a shorter stop order? 19 CSR 30-20.100(36) Note: Medication stop orders are not required if a pharmacist continually monitors medication orders.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are compounded sterile medications routinely prepared by pharmacy personnel in a suitably segregated area in a class 100 environment? 19 CSR 30-20.100(17)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are compounded sterile medications prepared by non-pharmacy personnel only in specific areas or situations when immediate preparation is necessary and pharmacy personnel are not available? 19 CSR 30-20.100(17)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are sterile compounded medications: a. labeled with patient name, medication name, strength, beyond use date, identity of person compounding and other pertinent information? b. administered with 24 hours of preparation? c. compounded outside of the pharmacy immediately administered by the person who prepared them except in cases approved by the director of pharmacy, nursing and administration? 19 CSR 30-20.100(16)	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>		
Are all compounding personnel trained and assessed for competency on; a. accuracy/precision in identifying and measuring ingredients? b. cleansing and garbing? c. aseptic manipulation skills? d. environmental quality and disinfection? e. appropriate work practices within and adjacent to the direct compounding area? f. verification/calibration of equipment?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>		

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g. sterilization and post-production quality checks? C-0276 COP §485.635(a)(3)(iv)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are compounded sterile products packaged to protect package integrity and sterility? C-0276 COP §485.635(a)(3)(iv)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<p>Note: If the hospital compounds sterile and non-sterile preparations, the hospital must be able to demonstrate how it assures that compounded preparations are prepared, dispensed and administered according to the applicable standards for safe compounding in USP Chapters 795 and 797. Be sure to review standards related to compounding these USP chapters and under C-0276.</p>					
<p>Note: If the hospital obtains compounded medications from a compounding pharmacy “503A pharmacy” rather than a manufacturer or registered outsourcing facility, then the CAH must demonstrate how it assures that the compounded medications it receives under the arrangement are prepared in accordance with accepted standards and applicable state pharmacy board and federal regulations. The CAH must ensure that it has access to the quality assurance data verifying that the vendor is adhering to USP 795 and 797 and Section 503A of the FDCA concerning pharmacy compounding of human drug products.</p>					
Are all compounded cytotoxic/hazardous medications prepared in a suitable segregated area in a class II biological safety cabinet or vertical airflow hood? 19 CSR 30-20.100(17)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are radiopharmaceuticals only prepared by or under the supervision of personnel who are certified by the Nuclear Regulatory Commission? 19 CSR 30-20.100(18)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Do the personnel assigned to determining beyond use dates when manufacturer’s instructions are not available, have the expertise to make such determinations? C-0276 COP §485.635(a)(3)(iv)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does each patient’s individual drug container bears his/her full name, strength and quantity of drug dispensed, appropriate cautionary statements including expiration date and, when appropriate, beyond use date? C-0276 COP §485.635(a)(3)(iv)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
If unit dose system is utilized, does each single unit dose package bear the name and strength of the drug, lot and control number equivalent, expiration date, and, when applicable, beyond use date? C-0276 COP §485.635(a)(3)(iv)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

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Does each floor stock container bear the name and strength of the drug, lot and control number equivalent, expiration date, and, when applicable, beyond use date? C-0276 COP §485.635(a)(3)(iv)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are all medication orders, written by persons without independent statutory authority to prescribe, completed according to the hospital's credentialing process, policies and procedures and included in the QA program? 19 CSR 30-20.100(35)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the hospital pharmacy and therapeutics committee or equivalent approve all hospital-based medication agreements, protocols and standing orders? 19 CSR 30-20.100(33)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Except for influenza and pneumococcal vaccines, when a standing order or protocol is used, is a copy of each medication order signed by the ordering practitioner placed in the medical record? 19 CSR 30-20.100(34)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
When medication therapy is based upon a protocol or standing order, is a signed copy of the protocol or abbreviated protocol placed in the chart? 19 CSR 30-20.100(34)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
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? 19 CSR 30-20.100(34)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
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? 19 CSR 30-20.100(34)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are medications only administered by persons who have statutory authority to administer or by persons without statutory authority who have been trained in each pharmacological category of	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

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medication they administer, according to your hospital's policies and procedures? 19 CSR 30-20.100(37)					
Are persons without statutory authority to administer medications included in quality improvement program? 19 CSR 30-20.100(37)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are persons without statutory authority prohibited from administering parenteral medications, controlled substances or other medications requiring professional judgement? 19 CSR 30-20.100(37)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are medications brought in the hospital only administered by a responsible party upon order of a prescriber and after being identified by the pharmacist or prescriber? 19 CSR 30-20.100(38)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are medications allowed to be self-administered only upon an order of practitioner and according to hospital policies and procedures? 19 CSR 30-20.100(39)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are medications dispensed to patients discharged from the hospital or outpatients in compliance with 4 CSR 220? 19 CSR 30-20.100(28)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
If the hospital permits medications to be dispensed to patients leaving the hospital when retail pharmacy services are not readily available, does the hospital have policies and procedures related to: a. circumstances when medications may be provided? b. practitioners authorized to order? c. limits on medications and quantities? d. requirements for prepackaging and labeling by the pharmacist and final labeling to facilitate correct administration? e. patient counseling and record keeping followed by the prescriber or R.N.? 19 CSR 30-20.100(29)	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>		
Are medication incidents, including medication errors, recorded in the patient's chart and immediately reported to the prescriber, the	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

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appropriate manager and the appropriate committee? 19 CSR 30-20.100(40) C-0277 COP §485.635(a)(3)(v)					
Are adverse medication reactions recorded in the patient's chart and immediately reported to the prescriber and pharmacy director? 19 CSR 30-20.100(40) C-0277 COP §485.635(a)(3)(v)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are adverse medication reactions reviewed by the pharmacy and therapeutics committee and other medical or administrative committees when appropriate? 19 CSR 30-20.100(40)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are potential corrective actions identified and implemented, if appropriate, in the case of an adverse drug reactions and events? C-0277 COP §485.635(a)(3)(v)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the CAH take proactive steps to identify medication errors and adverse drug reactions in addition to self-reported incidents? C-0277 COP §485.635(a)(3)(v)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Can the CAH demonstrate that staff are educated on medication administration errors and adverse drug reactions, the criteria for reporting for QI purposes, and how, to whom and when they should be reported? C-0277 COP §485.635(a)(3)(v)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are policies and procedures reviewed and amended based on: a. reports of adverse drug events? b. QA/PI activities pertaining to pharmaceutical care? C-0277 COP §485.635(a)(3)(v)	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>		

Helpful Hints

CAH's must review and also ensure that it complies with state professional licensure board regulations regarding administration of drugs and biologicals. Also review C-0297 §485.635(d)(3) concerning medication administration by CAH nursing staff.

Key Resources and Links

- [19 CSR 30-20.100](#)
- [COP §485.635\(a\)\(3\)\(iv\)](#)
- [COP §485.635\(a\)\(3\)\(v\)](#)