PHARMACEUTICAL SERVICES

Self-Assessment Questions	YES	NO	N/A	Date / Initials	Comments
If your pharmacy is not open 24/7, is a pharmacist available on-call at all times that pharmacy services are not available? A-0493 COP §482.25(a)(2) 19 CSR 30-20.100	❑	❑	❑		
If your pharmacy is not open 24/7, does your hospital have a process for providing medications to meet patient needs when the pharmacy is closed? A-0493 COP §482.25(a)(2) 19 CSR 30-20.100	❑	❑	❑		
Can you demonstrate that your pharmaceutical services has the scope and complexity to meet the needs of the patients you serve? A-0489 COP §482.25	❑	❑	❑		
Is your pharmacy integrated into the hospital-wide organization and QA/PI program? A- COP §482.25	❑	❑	❑		
Has the medical staff delegated responsibility to the hospital's organized pharmacy for developing policies and procedures that minimize drug errors? A-0491 COP §482.25(a)	❑	❑	❑		
Do you have a multidisciplinary pharmacy committee (pharmacy and therapeutics – P&T) that regularly meets and approves all pharmacy's policies and procedures? A- COP §482.25	❑	❑	❑		
Does the medical staff review and approve the hospital formulary on a continual basis? A-0511 COP §482.25(b)(9)	❑	❑	❑		
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 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?	❑ ❑ ❑ ❑ ❑ ❑	❑ ❑ ❑ ❑ ❑ ❑	❑ ❑ ❑ ❑ ❑ ❑		

PHARMACEUTICAL SERVICES

Self-Assessment Questions	YES	NO	N/A	Date / Initials	Comments
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?	❑	❑	❑		
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?	❑	❑	❑		
aa. high alert medications?	❑	❑	❑		
bb. investigational medications to ensure there is	❑	❑	❑		

PHARMACEUTICAL SERVICES

Self-Assessment Questions	YES	NO	N/A	Date / Initials	Comments
a written process for reviewing, approving, supervising and monitoring, specifically when the pharmacy is providing the service? cc. does the hospital have a policy for determining Beyond Use Date (BUD) for medications that are CSP's and consistent with USP standards? dd. can the hospital demonstrate the pharmacy personnel assigned to determine the BUD when not readily available from one manufacturer have the expertise and technical support needed and they are consistent with policy? ee. does the hospital's policy for unit dose systems include labeling the single dose unit with name and strength of dose, lot and control number equivalent, expiration date, and/or if applicable the BUD? 19 CSR 30-20.100 A-0490 COP §482.25 A-0500 COP §482.25(b) A-0501 COP §482.25(b)(1) A-0502 COP §482.25(b)(2)(i) A-0504 COP 4§82.25(b)(4) A-0505 COP §482.25(b)(3) A-0511 COP §482.25(b)(9)	❑ ❑ ❑	❑ ❑ ❑	❑ ❑ ❑		
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 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? A-0500 COP §482.25(b) A-0507 COP §482.25(b)(5) A-0509 COP §482.25(b)(7)	❑ ❑ ❑ ❑ ❑ ❑ ❑	❑ ❑ ❑ ❑ ❑ ❑ ❑	❑ ❑ ❑ ❑ ❑ ❑ ❑		

PHARMACEUTICAL SERVICES

Self-Assessment Questions	YES	NO	N/A	Date / Initials	Comments
NOTE: This information taken from "Nursing Services" A-0405 COP §482.23 Nursing Services and Pharmacology Services overlap. Do you have policies and procedures that:					
a. require confirmation of the following before administering each medication (often referred to as the "five rights of medication administration practice): - right patient – required* - right medication – required* - right dose – required* - right route – required* - right time – required* - right documentation – suggested - right action – suggested - right form – suggested - right response – suggested	❑	❑	❑		
b. identify, either in general or specific clinical application, medications not eligible for scheduled dosing times?	❑	❑	❑		
c. address for medications not eligible for scheduled dosing times:					
- how to ensure timely administration that is consistent with accepted standards of practice?	❑	❑	❑		
- if policy applies hospital-wide or only for specific diagnosis types, units or clinical situations?	❑	❑	❑		
d. identify medications eligible for scheduled dosing times?	❑	❑	❑		
e. address for medications eligible for dosing times:	❑	❑	❑		
- handling first dose medications, including parameters for which nursing staff are allowed to use their own judgment on the timing of the first and subsequent doses which may fall between scheduled dosing times?	❑	❑	❑		
- retiming of missed or omitted doses?	❑	❑	❑		
- those patient units that are not subject to following the scheduled dosing times?	❑	❑	❑		
f. identify time-critical scheduled medications — those for which an early or late administration of more than 30 minutes may harm or have a significant, negative impact on the intended therapeutic or pharmacological effect?	❑	❑	❑		
g. reconciling medications not administered? - medications prescribed for daily, weekly	❑	❑	❑		

PHARMACEUTICAL SERVICES

Self-Assessment Questions	YES	NO	N/A	Date / Initials	Comments
or monthly—may be administered within two hours before or after the scheduled dosing time, for a total window that does not exceed four hours? - medications prescribed more frequently than daily but no more frequently than every four hours—may be administered within one hour before or after the scheduled dosing time, for a total window that does not exceed two hours? f. address the actions to be taken when medications with scheduled dosing times are not administered within their permitted window of time, such as: - the patient is temporarily away from the nursing unit - patient refusal - the patient is unable to take the medication - unavailable medications, etc. g. outline guidelines for the administration and timing of new medications that are initiated between standardized dosing times? h. identify parameters when nursing personnel can use their own judgment on the rescheduling of missed or late doses, when notification of the physician or other practitioner responsible for the care of the patient is required before doing so? i. require the reporting of medication errors to the attending physician that are the result of missed or late dose administration in accordance with requirements of A-0508 COP §482.25(b)(6)? A-0405 COP §482.23(c)(1), (c)(1)(i) and (c)(2)	❑ ❑ ❑ ❑ ❑ ❑ ❑	❑ ❑ ❑ ❑ ❑ ❑ ❑	❑ ❑ ❑ ❑ ❑ ❑ ❑		
Do you have medical staff approved policies and procedures that address the categories of licensed personnel including nursing and other personnel who may administer drugs and the types of medications they are permitted to prepare and administer? A-0405 COP §482.23(c)(1), (c)(1)(i) and (c)(2)	❑	❑	❑		
Does the training given during hospital orientation provide sufficient education or is ongoing in-service or continuing education required to demonstrate competency? A-0405 COP §482.23(c)(1), (c)(1)(i) and (c)(2)	❑	❑	❑		

PHARMACEUTICAL SERVICES

Self-Assessment Questions	YES	NO	N/A	Date / Initials	Comments
Are all personnel preparing and administering drugs and biologicals trained on: a. safe handling and preparation of authorized medications? b. knowledge of the indications, side effects, drug interactions, compatibility and dose limits of administered medications? c. equipment, devices, special procedures and techniques required for medication administration? A-0405 COP §482.23(c)(1), (c)(1)(i) and (c)(2)	❑ ❑ ❑	❑ ❑ ❑	❑ ❑ ❑		
Does your hospital educate and train all personnel preparing and administering drugs and biological on: a. all new policies and procedures? b. safe handling and preparation of authorized medications? c. knowledge of the indications, side effects, drug interactions, compatibility and the dose limits of administered medications? d. equipment, devices, special procedures and/or techniques required for medication administration? e. what scheduled medications are considered time-critical and non time-critical? f. what medications are not eligible for scheduled dosing times? g. requirements for the timing of administration of time critical (within 30 minutes before or after scheduled dosing time) and nontime critical medications (within one to two hours before or after scheduled dosing time) in accordance with the hospital's policies? h. actions to be taken when medications with scheduled dosing times are not administered within their permitted window of time? i. administration and timing of new medications that are initiated between standardized dosing times? j. parameters for when nursing personnel can use their own judgment on the rescheduling of missed or late doses and when notification of the physician or other practitioner responsible for the care of the patient is required before doing so? k. reporting medication errors to the attending physician that are the result of missed or late dose administration, in accordance with requirements?	❑ ❑ ❑ ❑ ❑ ❑ ❑ ❑ ❑ ❑ ❑	❑ ❑ ❑ ❑ ❑ ❑ ❑ ❑ ❑ ❑ ❑	❑ ❑ ❑ ❑ ❑ ❑ ❑ ❑ ❑ ❑ ❑		

PHARMACEUTICAL SERVICES

Self-Assessment Questions	YES	NO	N/A	Date / Initials	Comments
A-0405 COP §482.23(c)(1), (c)(1)(i) and (c)(2)					
Is the content of the training and documentation of competence in accordance with A-0405 COP §482.23(c)(1), (c)(1)(i) and (c)(2)	❑	❑	❑		
Are pharmaceutical policies and procedures including administration timing policies periodically reviewed, evaluated and revised? A-0405 COP §482.23(c)(1), (c)(1)(i) and (c)(2)	❑	❑	❑		
Is the director of pharmacy services: a. licensed as a pharmacist in Missouri and qualified by education and experience? b. has the Director of Pharmacy been granted privileges by the medical staff according to their qualifications? c. a member of the pharmacy and therapeutics committee(s) or its equivalent? d. a participant in all decisions made by pharmacy services or committee(s) regarding the use of medications? e. responsible for the authorization of access to the pharmacy by supervisory nursing personnel to obtain doses for administration when pharmacy services are not available? f. responsible for the authorization of access to controlled substance storage areas outside of the pharmacy? g. responsible for the authorization of emergency and non-emergency medications that can be stocked as floor stock? h. responsible in conjunction with nursing and administration for approving how and when medications for administration are prepared outside of the pharmacy? i. responsible for review and investigation of variances involving controlled substances? j. responsible for periodically monitoring adherence to policies and procedures? 19 CSR 30-20.100 A-0491 COP §482.25(a) A-0492 COP §482.25(a)(1) A-0509 COP §482.25(b)(7)	❑ ❑ ❑ ❑ ❑ ❑ ❑ ❑ ❑ ❑	❑ ❑ ❑ ❑ ❑ ❑ ❑ ❑ ❑ ❑	❑ ❑ ❑ ❑ ❑ ❑ ❑ ❑ ❑ ❑		

PHARMACEUTICAL SERVICES

Self-Assessment Questions	YES	NO	N/A	Date / Initials	Comments
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?	❑	❑	❑		
d. the clinical interpretations of medication orders?	❑	❑	❑		
e. reviewing the prescriber's order or a direct copy prior to the administration of the first 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?	❑	❑	❑		
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,	❑	❑	❑		

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Self-Assessment Questions	YES	NO	N/A	Date/Initials	Comments
to the hospital-wide quality assurance program, then taking corrective action? A-0492 COP §482.25(a)(1) A-0494 COP §482.25(a)(3) A-0500 COP §482.25(b) A-0508 COP §482.25(b)(6) A-0510 COP §482.25(b)(8)					
Are there an adequate number of licensed pharmacist/pharmacy techs to meet the needs of staff and patients? A-0493 COP §482.25(a)(2)	❑	❑	❑		
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? 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? A-0491 COP §482.25(a) A-0500 COP §482.25(b)	❑ ❑ ❑ ❑ ❑	❑ ❑ ❑ ❑ ❑	❑ ❑ ❑ ❑ ❑		
Is access to concentrated solutions (i.e., potassium chloride, sodium chloride solutions greater than 0.9 percent) restricted? A-0500 COP §482.25(b)	❑	❑	❑		
Is the supply and provision of emergency medications consistent with standards of practice and appropriate for specified age groups or disease treatments? A-0500 COP §482.25(b)	❑	❑	❑		
Is current drug information readily available in nursing areas and/or drug storage areas? A-0510 COP §482.25(b)(8)	❑	❑	❑		
If the hospital obtains compounded medications from a compounding pharmacy rather than a	❑	❑	❑		

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Self-Assessment Questions	YES	NO	N/A	Date / Initials	Comments
manufacturer or registered outsourcing facility, how does it assure the compounded medication it receives has been prepared according to accepted professional principles, state and federal laws? (USP Principles) A-0501 COP §482.25(b)(1)					
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? A-0505 COP §482.25(b)(3)	❑	❑	❑		
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? A-0505 COP §482.25(b)(3)	❑	❑	❑		
Are all drugs and biologicals kept in a secure area and locked when appropriate? A-0502 COP §482.25(b)(2)(i)	❑	❑	❑		
Are all Schedule II-V drugs kept locked within a secure area? A-0503 COP §482.25(b)(2)(ii)	❑	❑	❑		
Are mobile storage units kept locked in a secure area when not in use? A-0502 COP §482.25(b)(2)(i)	❑	❑	❑		
Does your hospital have a policy addressing the security and monitoring of mobile storage units? A-0502 COP §482.25(b)(2)(i)	❑	❑	❑		
Are automated medication distribution units: a. actively maintain security features? b. kept in a secure area? A-0502 COP §482.25(b)(2)(i)	❑ ❑	❑ ❑	❑ ❑		
Does the hospital have a policy and procedure allowing patient self-administration of drugs and biologicals that: a. is limited to non-controlled substances? b. addresses staff and patient education? c. addresses security of medication? d. documentation of self-administration? e. specifies the need for an order for the medication to be self-administered?	❑ ❑ ❑ ❑ ❑				

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Self-Assessment Questions	YES	NO	N/A	Date / Initials	Comments
f. requires identification and visual inspection of self-administered medications brought from home? A-0502 COP §482.25(b)(2)(i)	❑				
Does the hospital have a policy: a. detailing who is authorized to access locked storage areas for drugs and biologicals? b. Limiting access to locked storage areas to authorized personnel only? A-0504 COP §482.25(b)(2)(iii)	❑ ❑	❑ ❑	❑ ❑		
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? A-0503 COP §482.25(b)(2)(ii)	❑	❑	❑		
Are all controlled substances variances including, inventory, security, recordkeeping, administration and disposal reported to the pharmacy director for review and investigation? A-0509 COP §482.25(b)(7)	❑	❑	❑		
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? A-0509 COP §482.25(b)(7)	❑	❑	❑		
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? A-0494 COP §482.25(a)(3)	❑	❑	❑		
Is there a system to prevent outdated, mislabeled, or otherwise unusable drugs and biologicals from being available for patient use? Does each floor stock container contain the name and strength of the drug, lot and control number and expiration date? A-0505 COP §482.25(b)(3)	❑ ❑	❑ ❑	❑ ❑		
Have automatic stop orders for all medications been established, by the medical staff, with a procedure to notify the prescriber? A-0507 COP §482.25(b)(5)	❑	❑	❑		

PHARMACEUTICAL SERVICES

Self-Assessment Questions	YES	NO	N/A	Date / Initials	Comments
If the organization prepares compounded sterile and nonsterile medications, are they able to demonstrate they meet all of the following requirements:					
a. compounded medications used and/or dispensed by the hospital are consistent with standard operating procedures and quality practices equivalent to or more stringent than nationally accepted principles (USP 795 and 797) standards?	❑	❑	❑		
b. if the organization uses an external compounding source, is the external source registered with the FDA as an outsourcing facility, or if not registered, can the organization demonstrate that it systematically evaluates and monitors whether the outside compounding pharmacy adheres to accepted standards for safe compounding?	❑	❑	❑		
c. can the pharmacy director explain the risk levels of the CSPs (compounded sterile preparations) being produced in-house and/or obtained from external sources?	❑	❑	❑		
d. if the CSPs are produced in the hospital, can the hospital demonstrate how it determined the BUD based on policy?	❑	❑	❑		
e. can staff who engage in sterile and non-sterile compounding demonstrate knowledge of the applicable levels of aseptic practices?	❑	❑	❑		
f. can the director of pharmacy demonstrate how the hospital is meeting or exceeding nationally accepted principles (USP 795 and 797) when compounding preparations with regards to:					
- verification of compounding accuracy and sterility?	❑	❑	❑		
- environmental quality and controls, including environmental sampling; testing and monitoring; and cleaning and disinfection?	❑	❑	❑		
- personal training and competency (accuracy/precision with measure ingredients, cleansing and garbing, aseptic manipulation skills, environmental quality and disinfection, appropriate work practices within and adjacent to the direct compounding area, verification and calibration of equipment, sterilization, and post-production quality checks)?	❑	❑	❑		
g. can the hospital demonstrate how it ensures	❑	❑	❑		

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Self-Assessment Questions	YES	NO	N/A	Date/Initials	Comments
the quality of CSPs during storage, transporting or dispensing? (Note: temperature, light exposure, movement) h. can the hospital demonstrate that it is documenting, monitoring and tracking adherence to the above requirements? A-0501 COP § 482.25(b)(1)	❑	❑	❑		
Do you have policies and procedures that address: a. the process by which a standing order is developed, approved, monitored, initiated by authorized staff and subsequently authenticated by physicians or practitioners responsible for the care of the patient? b. the education of the medical, nursing and other applicable professional staff on the conditions and criteria for using standing orders and the individual staff responsibilities associated with their initiation and execution? c. the process whereby the physician or other practitioner responsible for the care of the patient acknowledges and authenticates the initiation of all standing orders (except influenza and pneumococcal polysaccharide vaccines) after the fact? d. a process for monitoring and evaluating the use of standing orders, including proper adherence to the order's protocol? e. A process for the identification and timely completion of any requisite updates, corrections, modifications or revisions? A-0457 COP §482.24(c)(3)	❑ ❑ ❑ ❑ ❑	❑ ❑ ❑ ❑ ❑	❑ ❑ ❑ ❑ ❑		
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? A-0407 COP §482.24(c)(3)(i)	❑	❑	❑		
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.? 19 CSR 30-20.100	❑	❑	❑		
Are drug administration errors, including adverse drug reactions and incompatibilities immediately	❑	❑	❑		

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Self-Assessment Questions	YES	NO	N/A	Date/Initials	Comments
reported to the prescriber, the appropriate manager and the appropriate committee (QAPI)? A-0508 COP 482.25(b)(6)					
Are drug administration errors, including adverse drug reactions and incompatibilities recorded in the patient's chart and immediately reported to the prescriber and pharmacy director? A-0508 COP §482.25(b)(6)	❑	❑	❑		
Are potential corrective actions identified and implemented, if appropriate, in the case of an adverse drug reaction? A-0508 COP §482.25(b)(5)	❑	❑	❑		
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? A-0490 COP §482.25	❑ ❑ ❑ ❑	❑ ❑ ❑ ❑	❑ ❑ ❑ ❑		

Helpful Hints

- See also Nursing Services checklist regarding medication administration.
- The medication process is generally recognized as five stages. Hospitals are also expected to comply with requirements in Pharmaceutical Services COP §482.25 and the patient safety requirement under Quality Assessment and Performance Improvement COP §482.21, using a comprehensive systems approach to all components of the medication process.

Key Resources and Links

- 19 CSR 30-20.100
- Appendix A-Pharmaceutical Services COP §482.25