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25.00.00 Condition of Participation: Pharmaceutical Services. The hospital must have pharmaceutical services that meet the needs of the patients. The institution must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision.	A hospital must provide pharmaceutical services that meet the needs of its patients. The services must include either a pharmacy that is directed by a pharmacist, or, when appropriate, a drug storage area that is competently supervised. The hospital's medical staff is responsible for developing pharmaceutical policies and procedures that minimize the potential for medication errors, but may delegate this function to the pharmaceutical service.	INTERVIEW, OBSERVATION, DOCUMENT REVIEW, & CHART REVIEW 1. Interview the Chief Pharmacist or the individual delegated to fulfill the functions. • Determine that either the medical staff has developed policies and procedures regarding the management of pharmaceuticals or that this function is fulfilled by the pharmacy service.	iant ot
The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service. §482.25	The manner or degree of noncompliance with the requirements of this Condition and its component standards must be evaluated to determine whether there is substantial noncompliance with the Condition, warranting a Condition-level citation. Provision of pharmaceutical services must meet the needs of the patients' therapeutic goal by promoting a	 Verify that the purpose of pharmaceutical policies and procedures is to minimize drug errors. Review the pharmaceutical policies and procedures, the hospital's formulary and, if there is a pharmacy and therapeutic committee, the minutes of the committee meetings. 	
	safe medication use process that ensures optimal selection of medications, dose, dosage form, frequency, route, duration of therapy and that substantially reduces or eliminates adverse drug events and duplication of treatment.	 3. Does a multidisciplinary committee composed of representatives from nursing, pharmacy, administration and medicine develop policies and procedures? 4. Are there policies and procedures to 	
	The hospital's pharmacy must be directed by a registered pharmacist. If a drug storage area is used	minimize drug errors?	
	instead of a pharmacy at any location providing pharmacy services that storage area must be under competent supervision in accordance with State and Federal law.	 5. Are policies and procedures reviewed and amended based on: Facility-generated reports of adverse drug events; 	
	Pharmaceutical Services would include:	Facility QAPI activities pertaining to	

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	 The procuring, manufacturing, compounding, packaging, dispensing, ordering, distributing, disposition, use, and administering of all medications, biologicals, chemicals and the use of medication related devices. 		 pharmaceutical care; Evaluation of external alerts and/or recommendations from national associations; and 	
	 Provision of medication-related information to hospital health care professionals and patients necessary to optimize therapeutic outcomes. 		 Evaluation of literature for new technologies or successful practices that have demonstrated enhanced medication safety in other organizations. 	
	 Provision of pharmaceutical care. Pharmaceutical care is defined as the direct, responsible provision of medication-related care for the purpose of achieving definite outcomes that improve a 	6.	Is the staff familiar with the medication- related policies and procedures?	
	patient's quality of life while minimizing patient risk. Functions of Pharmaceutical Care are the: Collection and organization of patient-specific information;	7.	Is there a method to periodically review and evaluate the actual implementation of pharmaceutical policies and procedures by staff?	
	 Determination of the presence of medication-therapy problems both potential and actual; Summary of the patient's medication related 	8.	Upon review of patient clinical record are issues with regard to provision of pharmaceutical services identified? Is the facility aware of the issues? Was there a failure to implement a policy and procedure?	
	• Identification and specification of pharmacotherapeutic goals;		Are pharmacists an integral component of pharmaceutical care? Verify that the hospital's pharmacy service is	
	Development of a pharmacotherapeutic regimen;		integrated into its hospital-wide QAPI program.	
	 Implementation of a monitoring plan in collaboration with the patient, if applicable, and 			

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other health care professionals;

- Monitoring the effects of the pharmacotherapeutic regimen; and
- Redesigning the regimen and monitoring plan as indicated.

POLICIES AND PROCEDURES

Medication errors are a substantial source of morbidity and mortality in the hospitalized setting. Therefore, the development of policies and procedures to minimize medication errors should be based on accepted professional principles; external alerts and proactive review of facility reported and reviewed adverse drug events. It is important to flag new types of mistakes and continually improve and refine things, based on what went wrong.

The hospital's medical staff must develop policies and procedures to minimize drug errors, but may delegate this function to the hospital's organized pharmaceutical service.

Policies and procedures to minimize drug errors should include:

- 1. High-alert medications: dosing limits, administration guidelines, packaging, labeling and storage;
- 2. Limiting the variety of medication-related devices and equipment. For example limit the types of general-purpose infusion pumps to one or two;

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- 3. Availability of up-to-date medication information;
- 4. Availability of pharmacy expertise. Pharmacist available on-call when pharmacy does not operate 24 hours a day;
- 5. Standardization of prescribing and communication practices to include:
 - Avoidance of dangerous abbreviations;
 - All elements of the order dose, strength, units (metric), route, frequency, and rate;
 - Alert systems for look-like and sound-alike drug names;
 - Use of facility approved pre-printed order sheets whenever possible.
- 6. That orders to "resume previous orders" are prohibited;
- A voluntary, non-punitive, reporting system to monitor and report adverse drug events (including medication errors and adverse drug reactions);
- 8. The preparation, distribution, administration and proper disposal of hazardous medications;
- 9. Drug recalls;
- 10. That patient-specific information is readily

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accessible to all individuals involved in provision of pharmaceutical care. The patient information must be sufficient to properly order, prepare, dispense, administer and monitor medications as appropriate;

- 11. Identification of when weight-based dosing for pediatric populations is required; and
- 12. Requirements for review and revision based on facility-generated reports of adverse drug events and QAPI activities.

The hospital should have policies and procedures to actively identify potential and actual adverse drug events. Proactive identification could include; direct observation of medication administration, review of patient's clinical records, identification of patient signals that would warrant immediate review of patient's medication therapy and implementation of medication use evaluation studies.

The hospital should have a means to incorporate external alerts and/or recommendations from national associations and governmental agencies for review and facility policy and procedure revision consideration. National associations could include:

- Institute for Safe Medications Practice,
- National Coordination Council for Medication Error Reporting and Prevention and
- Joint Commission for Accreditation of Health

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Care Facilities, Sentinel Event Reports.

Governmental agencies may include:

- Food and Drug Administration,
- Med Watch Program, and
- Agency for Health Care Research and Quality.

The hospital's pharmacy services must be integrated into its hospital-wide QAPI program.