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[§482.25 Condition of Participation: Pharmaceutical Services

…..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(a) Standard: Pharmacy Management and Administration

The pharmacy or drug storage area must be administered in accordance with accepted professional principles.

Interpretive Guidelines §482.25(a)

Pharmaceutical services must be administered in accordance with accepted professional principles. Accepted professional principles includes compliance with applicable Federal and State laws, regulations, and guidelines governing pharmaceutical services, as well as,

standards or recommendations promoted by nationally recognized professional organizations, such as those found in the U.S. Pharmacopeia/National Formulary (USP/NF).

The hospital's pharmacy service must ensure safe and appropriate procurement, storage, preparation, dispensing, use, tracking and control, and disposal of medications and medication-related devices throughout the hospital, for both inpatient and outpatient services.

Hospitals may choose how to set up the pharmaceutical services utilizing various methods including, but not limited to:

- a unit dose system (i.e.; single unit package, dispensed in most ready to administer form possible),
- individual prescription (i.e.; instruction for a single patient, written by a medical practitioner for a medication or treatment),
- floor stock system (i.e.; storage of pharmaceutical and over-the-counter drugs on the patient care unit), or
- a combination of these systems, as long as they are properly stored.

However, hospitals with only a drug storage area must only use drugs that are pre-packaged and need no further preparation beyond that required at the point of care.

The hospital must develop, implement and periodically review and revise as needed policies and procedures governing provision of pharmaceutical services. The regulation makes the hospital's medical staff responsible for the policies and procedures, but also permits the medical staff to delegate this function to the hospital's pharmaceutical services. The policies and procedures must reflect accepted professional pharmacy principles, and the pharmacy director must be able to identify the source(s) used when developing and adopting the policies and procedures. There must also be a process to train staff on the applicable policies and procedures and to monitor their adherence.

Policies and Procedures for Minimizing Drug Errors

Medication errors are a substantial source of morbidity and mortality risk in the hospitalized setting. Therefore, hospitals must take steps to prevent, identify, and minimize these errors. These steps must be based on accepted professional principles. This includes not only ensuring that the pharmacy processes conform to of accepted standards of pharmacy practice but also proactively identifying and reviewing Adverse Drug Events (ADE) that occur. Pharmacies also need to be aware of external alerts to real or potential pharmacy-related problems in hospitals.

The pharmaceutical services policies and procedures must be designed to minimize drug errors and are expected to address:

- High-alert medications - are considered inherently high risk for adverse drug events. High alert drugs may include controlled medications, medications not on the approved FDA list, medications with a narrow therapeutic range, psychotherapeutic medications, look-alike/sound-alike medications and those new to the market or new to the hospital. Although mistakes may or may not be more common with these drugs, the consequences of errors are often harmful, sometimes fatal, to patients. Examples of ways to minimize high alert medication errors include, but are not limited to, the following: dosing limits, administration guidelines, packaging, labeling and storage.

- Investigational medications - hospitals that conduct research involving investigational medications must have a policy and procedure in place to ensure that investigational

medications are safely controlled and administered. Procedures for the use of investigational medications include, but are not limited to, the following: A written process for reviewing, approving, supervising and monitoring investigational medications specifying that when pharmacy services are provided, the pharmacy controls the storage, dispensing, labeling, and distribution of the investigational medication.

- Adherence to professional standards of practice for all compounding, packaging dispensing and drug disposal activities;

- Standardizing medication-related devices and equipment where feasible. For example, limit the types of general-purpose infusion pumps to one or two;

- Availability of up-to-date medication information and pharmacy expertise on-call when pharmacy does not operate 24 hours a day;

- 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.

    - Prohibition of orders to "resume previous orders;"

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

- Identification of when weight-based dosing for pediatric populations is required; and

- A voluntary, non-punitive, reporting system to monitor and report adverse drug events (including medication errors and adverse drug reactions);

- Monitoring drug alerts and/or recalls. 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 and National Coordinating Council for Medication Error Reporting and Prevention. Governmental agencies may include: Food and Drug Administration, Med Watch Program; and

- The hospital's pharmacy services must be integrated into its hospital-wide QAPI program and therefore, it is important to flag new types of mistakes and continually improve and refine policies and procedures as a result of analyses of errors and adverse events.

Survey Procedures §482.25(a)

- Is the hospital's organized pharmaceutical services responsible for the procurement, distribution and control of all medication products used in the hospital (including medication-related devices) for inpatient and outpatient care?

- If the hospital has a drug storage area instead of a pharmacy, does it use only drugs that are pre-packaged and need no further preparation beyond that required at the point of care?

- Is there evidence that the hospital's medical staff has either adopted pharmaceutical services policies and procedures, or has delegated this task to the pharmaceutical services?

- Can the pharmacy director provide evidence that the policies and procedures are consistent with accepted professional principles?

- Can the pharmacy director provide evidence that policies and procedures address key areas to prevent medication errors?

- Is there evidence of training staff on applicable pharmaceutical policies and procedures?

- Is there a process in place to monitor adherence to policies and procedures?