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### Outline

• Minimum standards for pharmacies in hospitals.

#### **Elements of Care**

- The elements of pharmacy services (*standards*) that are critical to safe, effective, and cost-conscious medication use in a hospital include:
- (1) practice management.

(2) medication-use policy development.

(3) optimizing medication therapy.

- (4) drug product procurement and inventory management.
- (5) preparing, packaging, and labelling medications.
- (6) medication delivery.

- (7) monitoring medication use.
- (8) evaluating the effectiveness of the medication-use system.
- (9) research.

Standard V. Preparing, Packaging, and Labelling Medications

### A. Preparing Medications

### A-1 Compounding.

- > Drug formulations, dosage forms, strengths, and packaging that are not available commercially but are needed for patient care shall be prepared by appropriately trained personnel in accordance with applicable practice standards and regulations.
- > The pharmacy shall provide adequate quality-assurance procedures for these operations.
- ➤ Written master formulas and batch records (including product test results, and a lot number or other method to identify each finished product with its production and control history shall be assigned to each batch.

### **A-2 Sterile Preparations.**

- ➤ The use of sterile medications compounded outside the pharmacy should be avoided to the extent possible.
- There shall be procedures for aseptic preparation, quality assurance, expiration dating, and ongoing competency evaluations for compounding personnel.
- Sterile compounding outside the pharmacy or satellite pharmacies (e.g., on nursing units) should be minimized and occur only in emergency situations.

### A-3 Hazardous Drug Products.

- There shall be policies and procedures that describe special precautions, equipment, and training for preparation, handling, storage, and disposal of hazardous drug products and products used in their preparation.
- > To ensure the safety of staff, patients, visitors, the community, and the environment.

#### **B. Packaging Medications**

#### **B-1 Unit Dose Packaging.**

- ➤ Medications shall be available for inpatient use in single-unit packages and in a ready-to-administer form.
- Manipulation of medications before administration (e.g., withdrawal of doses from containers, reconstitution of powdered drug products, labelling of containers, and splitting of tablets) by final users should be minimized.

#### B-2 Barcoding of Unit Dose Packaging and Point of Care Administration.

- ➤ Unit dose packages should contain a **barcode** and that code should be used in inventory management, dose preparation and packaging, dispensing, and administration.
- It is the responsibility of the pharmacy department to ensure the quality of all aspects of bar-code medication administration, including scan ability of barcodes and database management.

Standard VI. Medication Dispensing and Delivery

### A. Medication Dispensing

### A-1 Prescribing.

- Medications shall be prescribed by individuals who have been granted appropriate clinical privileges in the hospital and are legally permitted to order medications.
- The pharmacy shall advocate and foster practitioners' conformance with standardized, approved, and safe terminology and abbreviations to be used throughout the hospital when prescribing medications and discourage use of nonstandard and unapproved terminology and abbreviations.

#### A-2 Diagnostic or Therapeutic Purpose.

➤ Pharmacists should have immediate access to the patient's diagnosis or the intended therapeutic or medical purpose of medications.

#### A-3 Medication Orders.

- > All patient medication orders shall be contained in the patient's medical record.
- A direct copy of the prescriber's order, either hard copy or prescriber-entered electronic transmission (preferred method), shall be received by the pharmacist.
- > Oral orders should be avoided to the extent possible.
- ➤ When oral orders are necessary, they shall follow the organization's established procedures for their use and documentation.

#### A-4 Review of Medication Orders.

- All medication orders shall be prospectively reviewed by a pharmacist and assessed in relation to pertinent patient and clinical information before the first dose is administered or made available in an automated dispensing device, except in emergent situations in which the treatment of the patient would be significantly compromised by the delay that would result from pharmacist review of the order.
- > There shall be a procedure for retrospective review of these orders.
- Any questions regarding an order shall be resolved with the prescriber prior to administration, and any action taken because of this intervention should be documented in the patient's medical record.
- Information concerning changes shall be communicated to the appropriate health professionals caring for the patient.

### **B. Medication Delivery and Administration**

### B-1 Drug Delivery Systems, Administration Devices, and Automated Distribution Devices.

- > To ensure safety, accuracy, security, and patient confidentiality.
- > To evaluate the potential for medication errors associated with such systems and devices.
- ➤ Pharmacy personnel shall supervise the stocking and documentation of medications in automated dispensing devices.
- ➤ Whenever possible, automated dispensing cabinets should employ profile-based technology integrated with remote medication order-entry capabilities.

#### **B-2 Medication Administration.**

- ➤ Only personnel who are authorized by the hospital in accordance with applicable laws and regulations and appropriately trained shall be permitted to administer medications to a patient.
- All administered, refused, or omitted medication doses should be recorded in the patient's medical record according to an established procedure.
- > All medications that have not been administered should be returned to the pharmacy.
- No medication should be administered to a patient unless medical and nursing personnel have been provided with adequate information about, and are familiar with, its therapeutic use, method of administration, potential adverse effects, and dosage.

### **Standard VII. Monitoring Medication Use**

### A. Reviewing Patient Responses to Medication Therapy.

- By pharmacists.
- Medication therapy monitoring includes a proactive assessment of patient problems and an assessment of the therapeutic appropriateness of the patient's medication regimen.
- > Therapeutic duplication or omissions in the patient's medication regimen.
- The appropriateness of the dose of the medication, as well as the route, method, and frequency of administration of the medication.
- > Patient adherence to the prescribed medication regimen.
- ➤ Medication—medication, medication—food, medication—dietary supplement, medication—laboratory test, and medication—disease interactions.

- > Adverse drug reactions and other undesired effects.
- > Patient medication allergies and sensitivities.
- ➤ Clinical and pharmacokinetic laboratory data to evaluate the efficacy and safety of medication therapy and to anticipate toxicity and adverse effects.
- > Physical signs and clinical symptoms relevant to the patient's medication therapy.
- > Assessment of the effectiveness of the patient's medication therapy.
- B. Educating and Counselling Patients and Family
- ➤ Pharmacists should help to ensure that all patients are given adequate information about the medications they receive.
- ➤ Patient education activities shall be coordinated with the nursing, medical, and other clinical staff as needed.

### Standard VIII. Evaluating the Effectiveness of the Medication-Use System

The program should include routinely evaluating the literature for new technologies or successful practices.

#### Standard IX. Research

#### A. Institutional Review Board.

A pharmacist shall be a member of the hospital's institutional review board (or equivalent body), if one exists.

### **B. Information Regarding Investigational Drugs.**

The pharmacy shall have access to information on all investigational studies and similar research projects involving medications and medication-related devices used in the hospital.

### Thank you

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