

04-05: REGULATIONS REGARDING HOSPITAL PHARMACIES

04-05-0001—HOSPITAL PHARMACEUTICAL SERVICES PERMIT

1. Any pharmacist practicing in an Arkansas Hospital, must so notify the Board of Pharmacy and ascertain that a Hospital Pharmaceutical Services Permit has been issued. The Hospital Pharmaceutical Services Permit shall be issued in the name of the Hospital, showing a pharmacist in charge.
2. Any hospital holding a retail pharmacy permit as of February 15, 1975, upon application for renewal must separate the facilities, stocks, records, etc., in compliance with A.C.A. 17-92-403 -- 17-92-405.

All hospitals shall have adequate provisions for pharmaceutical services regarding the procurement, storage, distribution, and control of all medications. All federal and state regulations shall be complied with.

A. DEFINITIONS:

1. **"Hospital Pharmacy"** means the place or places in which drugs, chemicals, medicines, prescriptions, or poisons are prepared for distribution and administration for the use and/or benefit of patients in a hospital licensed by the Arkansas Department of Health.

The Hospital Pharmacy shall also mean the place or places in which drugs, chemicals, medicines, prescriptions or poisons are compounded for the dispensing to hospital employees, members of the immediate families of hospital employees, patients being discharged, and other persons in emergency situations.

Hospital Pharmacy shall also mean the provision of pharmaceutical services as defined in the Pharmacy Practice Act by a pharmacist to a patient of the hospital.

2. **"Hospital Employee"** means any individual employed by the hospital whose compensation for services or labor actually performed for a hospital is reflected on the payroll records of a hospital.
3. **"Qualified Hospital Personnel"** means persons other than Licensed Pharmacists who perform duties in conjunction with the overall hospital pharmaceutical services for inpatients.
4. **"Licensed Pharmacist"** means any person licensed to practice pharmacy by the Arkansas State Board of Pharmacy who provides pharmaceutical services as

defined in the Pharmacy Practice Act to patients of the hospital.

5. "Unit Dose Distribution System" is a pharmacy-coordinated method of dispensing and controlling medications in hospitals in which medication are dispensed in single unit packages for a specific patient on orders of a physician where not more than 24-hour supply of said medications is dispensed, delivered, or available to the patient.
6. "Unit Dose Distribution System" is a system that meets the requirement of a "Unit Dose Distribution System," provided that up to a 72-hour supply may be sent to the floor once a week if the system has been reviewed and approved administratively by the Board of Pharmacy.

B. COMPOUNDING, DISPENSING, AND DISTRIBUTING

1. **Compounding**--The act of selecting, mixing, combining, measuring, counting, or otherwise preparing a drug or medication.
2. **Dispensing**--A function restricted to licensed pharmacists which involves the issuance of: (a) one or more doses of a medication in containers other than the original, with such new containers being properly labeled by the dispenser as to content and/or directions for use as directed by the prescriber; (b) medication in its original container with a pharmacy prepared label that carries to the patient the directions of the prescriber as well as other vital information; (c) a package carrying a label prepared for nursing station use. The contents of the container may be for one patient (individual prescription) or for several patients (such as a nursing station medication container).
3. **Distributing**--Distributing, in the context of this regulation, refers to the movement of a medication from a central point to a nursing station medication center. The medication must be in the original labeled manufacturer's container or in a prepackaged container labeled according to Federal and State statutes and regulations, by a pharmacist or under his direct and immediate supervision.

C. ADMINISTERING

An act, restricted to nursing personnel as defined in Nurses Practice Act 43 of 1971, in which a single dose of a prescribed drug or biological is given a patient. This activity includes the removal of the dose from a previously dispensed, properly labeled container, verifying it with the prescriber's orders, giving the individual dose to the proper patient and recording

the time and dose given.

D. PHARMACY AND THERAPEUTICS COMMITTEE

There is a committee of the medical staff to confer with the Pharmacist in the formulation of policies, explained as follows:

1. A pharmacy and therapeutics committee (P & T Committee), composed of a least one physician, the administrator or representative, the director of nursing service or representative, and the pharmacist is established in the hospital. It represents the organizational line of communication and the liaison between the medical staff and the pharmacist.
2. The committee assists in the formation of broad professional policies regarding the evaluation, appraisal, selection, procurement, storage, distribution, use, and safety procedures, and all other matters relating to drugs in hospitals.
3. The committee performs the following specific functions:
 - a. Serves as an advisory group to the hospital medical staff and the pharmacist on matters pertaining to the choice drugs.
 - b. Develops and reviews periodically a formulary or drug list for use in the hospital;
 - c. Establishes standards concerning the use and control of investigational drugs and research in the use of recognized drugs;
 - d. Evaluates clinical data concerning new drugs or preparations requested for use in the hospital;
 - e. Makes recommendations concerning drugs to be stocked on the nursing unit floors and emergency drug stocks;
 - f. Prevents unnecessary duplication in stocking drugs and drugs in combination having identical amounts of the same therapeutic ingredients.
4. The committee meets at least quarterly and reports to the medical staff by written report.

E. PHARMACY OPERATIONS

The hospital has a pharmacy directed by a licensed pharmacist. The Pharmacy is administered in accordance with accepted professional principles.

1. Pharmacy Supervision

There is a pharmacy directed by a licensed pharmacist, defined as follows:

- a. The Director of Pharmacy is trained in the specialized functions of hospital pharmacy.

- b. The Director of Pharmacy is responsible to the administration of the hospital and the Board of Pharmacy for developing, supervising, and coordinating all the activities of the pharmacy department and all pharmacists providing professional services in the Hospital.
- c. All licensed pharmacists who provide pharmaceutical services as defined by the Pharmacy Practice Act shall practice under policies, procedures, and protocols approved by the Director of Pharmacy. These policies, procedures, and protocols shall be subject to review and approval by the Board of Pharmacy.

F. PHYSICAL FACILITIES

Facilities are provided for the storage, safeguarding, preparation, and dispensing of drugs, defined as follows:

- 1. Drugs are issued to floor units in accordance with approved policies and procedures.
- 2. Drug cabinets on the nursing units are routinely checked by the pharmacist. All floor stocks are properly controlled.
- 3. A careful determination of the functions of a department will regulate the space to be allocated, the equipment necessary to carry out the functions, and the number of personnel required to utilize the equipment and to render a given volume of service, as these functions relate to the frequency or intensity of each function or activity. Adequate equipment should specifically relate to services rendered and functions performed by the hospital pharmacy. Equipment lists will relate to the following services and functions:
 - a. Medication preparation;
 - b. Library reference facilities;
 - c. Record and office procedures;
 - d. Sterile product manufacturing;
 - e. Bulk compounding (manufacturing);
 - f. Product control (assay, sterility testing, etc.);
 - g. Product development and special formulations for medical staff.
- 4. Equipment and supplies necessary to the hospital pharmacy's safe, efficient and economical operation shall include but not be limited to:
 - a. Graduates capable of measuring from 0.1 ml. up to at least 500ml.
 - b. Mortars and pestles.
 - c. Hot and cold running water.

- d. **Spatulas (steel and non-metallic).**
- e. **Funnels.**
- f. **Stirring rods.**
- g. **Class A balance and appropriate weights.**
- h. **Typewriter, or other label printer.**
- i. **Suitable apparatus for production of small-volume sterile**
- k. **Suitable containers and labels.**
- l. **Adequate reference library to include at least the following:**
 - 1) **American Hospital Formulary Service.**
 - 2) **Pharmacology text.**
 - 3) **Each hospital pharmacy shall have available for personal and patient use a current copy of the U.S.P. DI 3 book set including "Drug Information for the Healthcare Professional" (2 volumes) and "Advice for the Patient" (1 volume), or the two volume set "Facts and Comparisons" (1 volume) and "Patient Drug Facts" (1 volume).**
 - 4) **Text on compatibility of parenteral products.**
 - 5) **Current professional journals, such as:**
 - (a) **Drug Intelligence and Clinical Pharmacy**
 - (b) **Hospital Pharmacy.**
 - (c) **Journal of ASHP.**
- 5. **Special locked storage space is provided to meet the legal requirements for storage of controlled drugs, alcohol, and other prescribed drugs.**

G. PERSONNEL

Personnel competent in their respective duties are provided in Keeping with size and activity of the department, explained as follows:

- 1. **The Director of Pharmacy is assisted by an adequate number of additional licensed pharmacists and such other personnel as the activities of the pharmacy may require to insure quality pharmaceutical services.**
- 2. **The pharmacy, depending upon the size and scope of its operations, is staffed by the following categories of personnel:**
 - a. **Chief Pharmacist (Director of Pharmacy).**
 - b. **One or more assistant chief pharmacists (Assistant Director of Pharmacy).**
 - c. **Staff pharmacists.**
 - d. **Pharmacy residents (where program has been activated).**

- e. Trained non-professional pharmacy helpers (qualified hospital personnel).
- f. Clerical help.

H. EMERGENCY PHARMACEUTICAL SERVICES

Through the administrator of the hospital, the P & T Committee shall establish policies and procedures that include, but are not limited to the following:

1. Upon admission to the Emergency Room on an outpatient basis and when examined by the physician where medications are prescribed to be administered, a record must be kept on file in the Emergency Room admission book or a copy of the Emergency Room medication order must be kept by the pharmacist to be readily accessible, for control and other purposes, as required by these regulations.
2. If the physician wishes the patient to have medication to be taken with them from the Emergency Room Supplies, the amounts to be taken shall be sufficient to last until medication may be obtained by local pharmacies, in any case not to exceed a 48-hour supply. All State and Federal laws must be observed concerning all records, labeling, and outpatient dispensing requirement.
3. Take home prescriptions for anti-infectives issued to patients at the time of discharge from the emergency room, filled by a pharmacist, shall be quantities consistent with the medical needs of the patient.

I. PHARMACY RECORDS AND LABELING

Records are kept of the transactions of the pharmacy and correlated with other hospital records where indicated. All medication shall be properly labeled. Such record and labeling requirements are as follows:

1. The pharmacy establishes and maintains, in cooperation with the accounting department, a satisfactory system of records and bookkeeping in accordance with the policies of the hospital for:
 - a. Maintaining adequate control over the requisitioning and dispensing of all drugs and pharmaceutical supplies, and
 - b. Charging patients for drugs and pharmaceutical supplies.
2. A record of procurement and disbursement of all controlled drugs is maintained in such a manner that the disposition of any particular item may be readily traced.
3. The pharmacist shall receive and provide service pursuant to the perusal of the physician's original order or a direct copy thereof, except in emergency situations

wherein the pharmacist may provide service pursuant to a verbal order or to an oral or written transcription of the physician's order provided that the pharmacist shall receive and review the original or direct copy within twenty-four (24) hours of the time the service is provided.

4. A record shall be maintained by the pharmacy and stored separately from other hospital records for each patient (inpatient or outpatient) containing the name of the patient, the prescribing physician, the name and strength of drugs prescribed, the name and manufacturer (or trademark) of medication dispensed.
5. The label of each medication container prepared for administration to inpatients, shall bear the name and strength of the medication, the expiration date, and the lot and control number. The label on the medication, or the container into which the labeled medication is placed must bear the name of the patient.
6. The label of each outpatient's individual prescription medication container bears the name of the patient, prescribing physician, directions for use, the name and strength of the medication dispensed (unless directed otherwise by the physician).

J. CONTROL OF TOXIC OR DANGEROUS DRUGS

Policies are established to control the administration of toxic or dangerous drugs with specific reference to the duration of the order and the dosage, explained as follows:

1. The medical staff has established a written policy that all toxic or dangerous medications not specifically prescribed as to time or number of doses, will be automatically stopped after a reasonable time limit set by the staff.
2. The classifications ordinarily thought of as toxic or dangerous drugs are controlled sub-stances, anticoagulants, antibiotics, oxytocics, and cortisone products.
3. All deteriorated non-sterile, non-labeled or damaged medication shall be destroyed by the pharmacist, except on controlled drugs, as defined below.
 - a. All controlled drugs (Schedule II, III, IV, and V) should be listed and a copy sent, along with drugs to the Arkansas Department of Health by registered mail or delivered in person for disposition.

K. DRUGS TO BE DISPENSED

Therapeutic ingredients of medications dispensed are included (or approved for inclusion) in the United States Pharmacopoeia,

N.F. and U.S. Homeopathic Pharmacopoeia, or Accepted Dental Remedies (except for any drugs unfavorably evaluated therein) and drugs approved by provisions of the Arkansas Act 436 of 1975, or are approved for use by the P & T Committee of the hospital staff, explained as follows:

- 1. The pharmacist, with the advice and guidance of the P & T Committee, is responsible for specifications as to quality, quantity, and source of supply of all drugs.**
- 2. There is available a formulary or list of drugs accepted for use in the hospital which is developed and amended at regular intervals by the P & T Committee with the cooperation of the pharmacist and the administration.**

L. POLICY AND PROCEDURE MANUAL

- 1. A Policy and Procedure Manual pertaining to the operations of the Hospital Pharmacy with updated revisions adopted by the P & T Committee of each hospital shall be prepared and maintained at the hospital.**
- 2. The Policy and Procedure Manual should include at a minimum the following:**
 - a. Provisions for procurement, storage, distribution and drug control for all aspects of pharmaceutical services in the hospital.**
 - b. Specialized areas such as surgery, delivery, ICU and CCU units and emergency room stock and usage of medication shall be specifically outlined.**
 - c. A system of requisitioning supplies and medications for nurses stations stock shall be in written procedural form as to limits of medications to be stocked in each nursing unit.**
 - d. Detailed job descriptions and duties of each employee by job title working in the Pharmacy Department must be developed and made a part of these policies and procedures.**
 - e. The Pharmacy Policy and Procedure Manual shall be subject to review and approval by the Board of Pharmacy on request from the Board.**

M. EMPLOYEE PRESCRIPTION MEDICATION

- 1. There will be a prescription on file for all prescription drugs dispensed to hospital employees and their immediate families. These records will be kept separate from all inpatient records.**
- 2. The only person(s) entitled to have employee prescriptions filled will be the employee listed on the hospital payroll and members of their immediate family.**

N. PATIENT DISCHARGE MEDICATION

Any take-home prescription dispensed to patients at time of

discharge from the hospital shall be for drugs and quantities consistent with the immediate medical needs of the patient.

O. LICENSED PHARMACIST PERSONNEL REQUIREMENTS

1. The minimum requirements for licensed pharmacists in hospitals is:

- a. A general hospital, surgery and general medical care maternal and general medical care hospital, chronic disease hospitals, psychiatric hospitals, and rehabilitative facilities licensed for greater than 50 beds, as determined by the institution's license issued by the Arkansas Department of Health, shall require the services of one (1) pharmacist on the basis of 40 hours per week, with such additional pharmacists as are necessary, in the opinion of the Arkansas State Board of Pharmacy, to perform required pharmacy duties as are necessary in keeping with the size and scope of the services of the hospital pharmacy's safe and efficient operation. Hospitals, providing specialized or unique patient care services, may request approval from the Arkansas State Board of Pharmacy to be exempt from the requirement of a pharmacist on duty 40 hours per week. The request for exemption must provide adequate written documentation to justify the services of a pharmacist such hours as are necessary to perform required pharmacy services, followed by an appearance before the Board for final approval of the request.**
- b. The above classified hospitals, licensed for 50 beds or less, as determined by the institution's license issued by the Arkansas Department of Health, shall require the services of a pharmacist such hours as, in the opinion of the Arkansas State Board of Pharmacy and the Arkansas State Board of Health, are necessary to perform required pharmacy duties in keeping with the size and scope of the services of the hospital pharmacy's safe and efficient operation. The pharmacist shall be on site at least 5 days per week to perform and review pharmacy dispensing, drug utilization, and drug distribution activities. A pharmacist shall be available to provide emergency services to the staff when the pharmacy is closed.**
- c. Recuperative Centers, Outpatient Surgery Centers, and Infirmaries.**

- 1) If the infirmary, recuperative center or outpatient surgery center has a pharmacy department, a licensed pharmacist must be employed to administer the pharmacy in accordance with all state and federal laws regarding drugs and drug control.
- 2) If the infirmary, recuperative center, or outpatient surgery center does not have a pharmacy department, it has provisions for promptly and conveniently obtaining prescribed drugs and biologicals from a community or institutional pharmacy.
- 3) If the infirmary, recuperative center, or outpatient surgery center does not have a pharmacy department, but does maintain a supply of drugs, a licensed pharmacist shall be responsible for the control of all bulk drugs and maintain records of their receipt and disposition. The pharmacist shall dispense drugs from the drug supply, properly labeled, and make them available to appropriate nursing personnel.
- 4) All medication for patients shall be on individual prescription basis.

d. A pharmacist in charge, who is employed at any facility permitted by the Arkansas State Board of Pharmacy where a 40 hour work week is required, may also be the pharmacist in charge at a hospital licensed for 50 beds or less by the Arkansas Department of Health.

P. RESPONSIBILITY OF A PHARMACIST IN HOSPITAL PHARMACY

1. The pharmacist is responsible for the control of all medications distributed in the hospital where he practices, and for the proper provision of all pharmaceutical services.
2. The following aspects of medication distribution and pharmaceutical service are functions involving professional evaluations of judgments and may not be performed by supportive personnel:
 - a. Selection of the brand and supplier of medication.
 - b. Interpretation and certification of the medication order. This involves a number of professional responsibilities such as the determination of:
 - 1) Accuracy and appropriateness of dose and dosage schedule.

- 2) Such items as possible drug interactions, medication sensitivities of the patient and chemical and therapeutic incompatibilities.
- 3) Accuracy of entry of medication order to patient's medication profile.

c. Final certification of the prepared medication.

Q. OPERATION OF PHARMACY DEPARTMENT WITHOUT A PHARMACIST

At no time will the hospital pharmacy be open and in operation unless a licensed pharmacist is physically present except:

- a. Entrance may be obtained for emergency medication as set forth in the Pharmacy Policy and Procedure Manual when the pharmacy is closed outside its normal operation hours.
- b. When the pharmacist is summoned away from the pharmacy and there are other qualified personnel left in the pharmacy, the personnel left in the pharmacy could perform only those functions authorized within this regulation.

R. THE AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS, GUIDELINES

The American Society of Health-System Pharmacists' most recent statement on hospital drug control systems and Guidelines for Institutional Use of Controlled Substances shall be required reading by hospital pharmacists. (Revised 6/25/83, 4/7/89, 6/15/95)