

ARTICLE XXIX REGULATIONS GOVERNING INSTITUTIONAL PHARMACY

1. **APPLICABILITY:** The following rules and regulations are applicable to all pharmacies classified and authorized by permit to operate as institutional pharmacies. All rules, regulations and laws which pertain to the practice of pharmacy in the retail setting shall be applied to those aspects of institutional practice which handle, prepare and dispense medications for use outside the confines of the institution, except that none shall be construed to prohibit the extension of a formulary system to outpatient dispensing.
2. **REGISTRATION:** No institutional pharmacy shall be operated before it has been registered with the Mississippi Board of Pharmacy and received an Institutional Permit in conformity with the requirements of ARTICLE VI of the regulations of the Mississippi Board of Pharmacy.
3. **PERSONNEL:**
 - A. **Director.** The Director of Pharmacy shall be responsible for the safe and efficient distribution, control, and accountability for drugs. The responsibilities of the director shall include being responsible for and developing policies and procedures for the following:
 - (1) Preparation of sterile medications prepared within the institutional facility;
 - (2) Admixture of parenteral products;
 - (3) Compounding of drugs, solutions, ointments, lotions, etc.;
 - (4) To assure that no legend medication shall be stored in patient care areas except upon the approval of the Director of Pharmacy;
 - (5) Establishment of specifications for procurement of all materials, including drugs, chemicals and biologicals, subject to approval of the appropriate committee of the institutional facility;
 - (6) Participation in the development of a formulary for the institutional facility where applicable;
 - (7) Dispensing of all drugs dispensed within the institutional facility;
 - (8) Filling and labeling of all containers from which drugs are to be administered;
 - (9) Maintenance of a sufficient inventory of antidotes and other emergency drugs, both in the Pharmacy and in-patient care areas, together with current antidote information, telephone numbers of regional poison control centers and other emergency assistance organizations, and such other materials and information as may be deemed necessary by the appropriate committee of the institutional facility, if any;
 - (10) Maintenance of records of all transactions of the institutional pharmacy as may be required by applicable law, state and federal, and as may be necessary to maintain accurate control and accountability for all pharmaceutical materials;
 - (11) Be responsible for "controlled substances" within the institution from the time of purchase until they have been administered to the patient; although individual pharmacists involved in handling controlled substances share responsibility for control of these drugs;

- (12) Assure that all drugs shall be stored in areas within the institutional pharmacy and satellite storage areas to provide proper sanitation, temperature, light, ventilation, moisture control, segregation and security; that alcohol and flammables shall be stored in areas separate and apart from areas used for storage, compounding or dispensing; that disinfectants and drugs for external use are stored separately and apart from drugs for internal use or ingestion; that outdated or other unusable drugs are identified and stored in a manner that will prevent their distribution or administration prior to disposition; that emergency drugs are in adequate and proper supply at designated locations;
- (13) Assure that all areas occupied by the institutional pharmacy shall be capable of being locked to prevent unauthorized access, and that all areas where drugs are stored or dispensed shall be locked in the absence of pharmacy personnel;
- (14) An institutional pharmacy shall have sufficient floor space allocated to it to assure that drugs are prepared in sanitary, well-lit and enclosed places;
- (15) All drugs dispensed by an institutional pharmacy intended for in-patient use shall be dispensed in appropriate containers and shall be adequately labeled so as to identify, at a minimum, brand or generic name, strength, acceptable route(s) of administration (only if other than oral). The institution will maintain a system with control numbers that will allow for recall of medication products. When a formulary is maintained, a system shall be implemented to cross reference brand name and generic products, and parenteral products that contain added drugs shall be labeled with a distinctive supplementary label indicating the name and amount of the drug added, expiration time, and name of person responsible for compounding the admixture, and all drugs dispensed by an institutional pharmacy for out-patient consumption shall comply with ARTICLE XIV;
- (16) Insure that discontinued and outdated drugs are returned to the pharmacy for proper disposition together with containers with worn, illegible or missing labels. The director or his designee shall properly dispose of such drugs;
- (17) Drugs shall be dispensed from the institutional pharmacy only upon receipt of a written or oral order or a direct copy thereof. These may be in the form of carbon, NCR or electronically transmitted orders (facsimile or computer generated). Orders shall be reviewed by a pharmacist before the medication is initially dispensed except in emergencies or when a pharmacist is unavailable. Medication orders must be reviewed by a pharmacist within 24 hours or as soon thereafter as possible. This regulation shall not be construed to prevent the distribution of drugs for floor stock. Medication orders shall contain: patient name and room number, drug name, strength, dosage, directions for use, date and the signature of the practitioner or an authorized representative;
- (18) Ensure that all requirements of the Controlled Substances Act of 1970 and the requirements set forth in the regulations of the Mississippi Board of Pharmacy in the purchasing, storing, distribution, dispensing, record keeping and disposal of controlled substances are met throughout the institution. The director or his designee shall establish policies and procedures for the control

of these drugs at all times, including those instances when drugs are stored in surgery departments, nursing stations, ambulatory clinics, diagnostic laboratories, etc. Periodic (at least monthly) inspections of the proper storage of these drugs in other areas of the institution is required and deficiencies must be corrected.

When controlled substances are stored in areas of the institution outside the pharmacy, the director shall assure that these drugs are inaccessible to unauthorized personnel.

Records of the administration of controlled substances shall be maintained for a period of not less than two years. Documentation of administration shall include the patient's name, medication, dosage, prescriber, the name of the person administering the drug and the date and time of administration.

A perpetual inventory shall be maintained on Schedule II controlled drugs. A perpetual inventory may be maintained on Schedule III, IV and V controlled drugs. If a perpetual inventory is not maintained on Schedule III, IV and V controlled drugs in the pharmacy, there must be the capability of a computer generated audit trail. Inventory audits shall be performed on a routine (at least daily) basis at all areas where controlled drugs are stocked outside the pharmacy. Records of periodic audits shall be maintained and made available for inspection by an agent of the Mississippi Board of Pharmacy; and

- (19) Employment of pharmacy technicians as required to operate such pharmacy competently, safely and adequately to meet the needs of the patients of the institution; that no pharmaceutical services shall be provided by pharmacy technicians unless supervised by a pharmacist. It has been determined by the Board that three (3) technicians on duty performing technician related work directly related to the dispensing of medications are sufficient for each licensed pharmacist on duty.

4. ABSENCE OF PHARMACIST

- A. General. During such times as an institutional pharmacy may be unattended by a pharmacist, arrangements shall be made in advance by the director for provision of drugs to the medical staff and other authorized personnel of the institutional facility. The pharmacist shall provide on-call services at all times.
- B. Access to Drugs. In the absence of a pharmacist, access shall be by locked cabinet(s) or other enclosure(s) constructed and located outside of the pharmacy area, to which only specifically authorized personnel may obtain access and which is sufficiently secure to deny access to unauthorized persons. The director shall develop inventory listings of those drugs to be included in such area(s) and shall assure that:
- (1) Such drugs are available therein, properly stored and labeled;
 - (2) Only pre-packaged drugs are available therein, in amounts sufficient for immediate therapeutic requirements;
 - (3) Each pre-packaged drug stored outside of the pharmacy area shall be

assigned a "par value" and each addition or withdrawal by authorized persons shall be properly documented. Pharmacy personnel shall audit these areas on a regular basis no less than once per month;

- (4) Written policies and procedures are established to implement the requirements of this Subsection B.
- C. Access to Pharmacy. Whenever any drug is not available from floor supplies or other storage areas and such drug is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, such drug may be obtained from the pharmacy in accordance with the requirements of this subsection. Only designated nurses in any one shift may be given access to the pharmacy and may remove drugs therefrom.

Nurses allowed access to the pharmacy shall receive thorough education and training in the proper methods of access, removal of drugs and records and procedures by the Director of Pharmacy, who shall require at a minimum, the following:

- (1) In the absence of a pharmacist, nursing staff may withdraw a single dose of medication at a time for administration to a patient.
 - (2) Removal of any drug from the pharmacy by an authorized nurse must be recorded on a suitable form showing patient name and room number, name, strength and amount of drug, date, time and signature of nurse;
 - (3) The completed form and a copy of the practitioner's order shall be placed conspicuously so they will be found by a pharmacist and verified promptly;
 - (4) The director or his pharmacist designee shall check and initial the order.
- D. Emergency Medication Supplies.
- (1) Pharmacy. All emergency medication supplies shall be maintained by a pharmacist;
 - (2) Drugs Included. The pharmacist and the appropriate committee of the institutional facility shall jointly determine the drugs, by identity and quantity, to be included in emergency medication supplies.
 - (3) Storage. Emergency medication supplies shall be stored in areas suitable to prevent unauthorized access and to assure a proper environment for preservation of the drugs within them. All emergency medication supplies shall be sealed with a mechanism that must be broken if the container is opened and that will thereby reveal any unauthorized or undocumented access to emergency supplies. All emergency kit drugs shall be provided and sealed by a pharmacist;
 - (4) Labeling - Exterior. The exterior of the emergency medication supplies shall be labeled so as to clearly indicate that it is an emergency medication supply and it is for use in emergencies only; and in addition, the exterior shall indicate the expiration date of the supply, which shall be no later than the earliest expiration date of any drug contained therein, and in facilities operating with a part-time director, the name, address and telephone number of each supplying pharmacy or pharmacist. Upon the occurrence of an expiration date, the supplying pharmacist shall open the supply and replace expired drugs with current dated drugs and reseal it;
 - (5) Labeling - Interior. All drugs contained in emergency medication supplies

shall be listed and properly labeled with any additional information as may be required by the medical staff of the institutional facility to prevent misunderstanding or risk of harm to the patients of the facility;

- (6) Notifications. Whenever an emergency medication supply is opened, the supplying pharmacist shall be notified and the pharmacist shall restock and reseal the supply within a reasonable time so as to prevent risk of harm to patients. In the event the supply is opened in an unauthorized manner, the pharmacist and other appropriate personnel of the facility shall be notified;
- (7) Inspection. Emergency medication supplies shall be routinely inspected. Procedures for the inspection shall assure that the medications are available, in date, properly stored and secured against pilferage or tampering;
- (8) Procedures. The supplying pharmacist shall, in conjunction with the medical staff of the institutional facility, develop and implement written policies and procedures to assure compliance with the provisions of this subsection.

5. DRUGS FROM OUTSIDE SOURCES

- A. Outside Pharmacies. If drugs and/or pharmaceutical services are not available within the institution, they may be obtained from a pharmacist outside the institution provided arrangements shall be made to assure that such outside pharmacists provide services of sufficient quality to protect the safety of the patients and serve the needs of the facility. The pharmacist who develops procedures for these services shall act in the capacity of a (part-time) director (paragraph 4. A. above) and therefore shall make provisions at a minimum for:
 - (1) On-call services at all times;
 - (2) Adequate storage facilities for drugs;
 - (3) Labeling of drugs that will assure that recall can be effected and proper control and supervision of such drugs may be exercised;
 - (4) Written reports to the institution's administrator and/or the medical director as required by law, regulations or institutional policies and procedures.
- B. Patients. Whenever patients bring drugs into an institutional facility such drugs shall not be administered unless authorized by the attending practitioner and unless they can be accurately identified and their quality reasonably assessed. Identification of such drugs from outside sources must be conducted by a pharmacist. The director shall have policy and procedure for the return of patient medication brought into the facility. Drugs not returned to the patient or the patient's family may be disposed of within a reasonable number of days following discharge or death.

6. INVESTIGATIONAL DRUGS

Investigational drugs shall be properly labeled and a pharmacist will assure that procedures are followed regarding use of such medications. A central unit shall be maintained from which essential information regarding such drugs may be obtained. A central file of investigation drug fact sheets together with pertinent articles, correspondence and protocols shall be maintained.

7. UNIT DOSE DISPENSING SYSTEMS

Unit Dose Dispensing shall include a pre-packaging activity and an individual dose selection activity which may be performed within a pharmacy under the supervision of pharmacist according to the following guidelines:

- A. As far as practical, all medications shall be packaged for unit dose dispensing. Such containers shall be packaged for unit dose dispensing. Such containers shall be properly labeled with the name of the drug, dosage form and strength, lot number, expiration date, and the manufacturer's name when the unit dose packaging is not prepared in the institution. Institutions using pre-packaging logs and control procedures may record manufacturer's name and lot numbers in pre-packaging logs provided an institutional lot number is used which will reference such information.
- B. In-house packaging of drugs in unit dose packaging shall be accomplished in a manner that will allow recalls and establish responsibility for packaging and checking of the final product. In-house packaged unit doses shall conform to paragraph 7. A.
- C. Supervision of the compounding, packaging and dispensing of drugs in a total unit dose system shall be pharmacy based.

8. PHARMACY TECHNICIANS

In order to adequately protect the public health and promote the development of innovations in institutional pharmacy practice, pharmacy technicians may be employed subject to the following guidelines:

- A. Prohibited Acts. The following functions require the professional judgment of a pharmacist and may not be performed by pharmacy technicians:
 - (1) Acceptance of oral prescriptions;
 - (2) Certification of filled/finished prescription or drug orders;
 - (3) Weighing or measuring active drug ingredients without a mechanism of verification;
 - (4) Reconstitution of prefabricated medication without a mechanism of verification;
 - (5) Verification of the constituents of final IV admixtures for accuracy, efficacy and patient utilization;
 - (6) Entry of orders on patient medication profiles without verification by a pharmacist;
 - (7) Provision of drug information that has not been prepared or approved by a pharmacist.
- B. Job Descriptions and Procedure Manuals. For each pharmacy technician a job description and procedures manual shall be prepared by the director or his designee. Activities to be specifically addressed shall include the role of the pharmacy technician in bulk compounding or reconstitution, pre-packaging and labeling of multi-dose and unit dose medication; distribution and administration of medication.

The procedures manual must further delineate that such employees may not perform these during such times as there is not a pharmacist in attendance. Job descriptions and procedures shall be on file at the pharmacy and shall be available at all times for

review by institutional personnel and the Board of Pharmacy.

It has been determined by the Board that three (3) technicians on duty performing technician related work directly related to the dispensing of medications are sufficient for each licensed pharmacist on duty.

- C. Performance by pharmacy technicians of tasks outlined in paragraph 8. A. above shall constitute the practice of pharmacy without a license in violation of the Mississippi Pharmacy Practice Act.

9. PROCEDURE MANUAL

Procedure Manual. The director shall be responsible for developing the necessary procedures to carry out the policies spelled out in these regulations and such other policies as may be appropriate to assure the public's health in the handling, storage and dispensing of pharmaceuticals in the institution. These procedures shall be available in a manual for Board of Pharmacy inspection. They shall be reviewed annually and updated as necessary.

10. INITIATION OR MODIFICATION OF DRUG THERAPY

Pharmacists may initiate or modify drug therapy after a written protocol indicating approval by a licensed practitioner has been placed on file at the institutions pharmacy. Such protocol must define the agreement by which the practitioner delegated prescriptive authority and the authority granted must be within the scope of the practitioner's current practice. Any modification shall be treated as a new protocol.

A. Protocols shall include the following:

- (1) Identification of the practitioner and the scope of the practitioner's active practice;
- (2) Specifications of the type of prescriptive authority to be exercised which shall include a description of the types of medical conditions, drugs or drug categories, together with any special condition;
- (3) Mechanism for communication or feedback to the authorizing practitioner;
- (4) Documentation of the prescriptive activities performed;
- (5) Specification of the duration of the protocol agreement not to exceed two years;
- (6) Protocols must be signed by the authorizing practitioner.

11. PATIENT PROFILE

The Director shall develop a system of in-patient medication profiles whereby drug interactions, contraindications, incompatibilities and allergic reactions may be identified and prevented prior to dispensing a medication.

12. PHARMACEUTICAL CARE

The Director shall be responsible for the development of clinical pharmacy practice

policies and procedures which provides optimum pharmaceutical care for in-patients. These programs should include drug therapy by a pharmacist and other pharmaceutical care services intended to achieve outcomes which improve the patient's quality of life as it is related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process.

Clinical pharmacy practice policy and procedures should include but is not limited to the following:

- A. Systems for monitoring and detecting drug interactions, contraindications, incompatibilities and allergic reactions; and
- B. Systems for monitoring dosages and serum blood levels of drugs for correct ranges where appropriate; and
- C. Systems for monitoring, detecting and reporting adverse drug reactions; and
- D. Systems for monitoring and evaluating therapeutic duplications; and
- E. Provision of drug therapeutic consultations and drug information by a pharmacist(s) to patients and health care providers.