TITLE 30: PROFESSIONS AND OCCUPATIONS

Part 3001: MISSISSIPPI PHARMACY PRACTICE REGULATIONS

ARTICLE VIII RESPONSIBILITY OF PHARMACIST/PHARMACIST CARE

1. In the dispensing of drugs, the pharmacist shall have the following responsibilities:
   A. In a pharmacy it shall be the responsibility of the pharmacist on duty at the facility to insure that only a pharmacist provides professional consultation with the patients and/or other licensed health care professionals, and that only a pharmacist accepts telephoned prescriptions or gives information in any manner relative to prescriptions or prescription drugs. The provisions of this paragraph shall not apply to an extern or intern working under the supervision of a pharmacist.
   B. In the dispensing of drugs from a pharmacy, it shall be the responsibility of the supervising pharmacist to prevent the pharmacy technician from performing those functions relative to dispensing which are functions based on a judgment for which the pharmacy technician has not been prepared by education or authorized by law or regulation.
   C. In the dispensing of out-patient medications:
      (1) The pharmacist shall be responsible for all activities of the pharmacy technician in the preparation of the drug for delivery to the patient;
      (2) The pharmacist shall be present and personally supervising the activities of the pharmacy technician at all times;
      (3) When a data processor is used, pharmacy technicians may enter information into the system and prepare labels, but it shall be the responsibility of the pharmacist to verify the accuracy of the information entered and the label thus produced;
      (4) When refilling a prescription it shall be the responsibility of the pharmacist to review all appropriate information and make the determination as to whether or not to refill the prescription;
      (5) A pharmacist shall not be assisted by more than <u>three</u> pharmacy technicians;
      (6) Pharmacy Technicians in the dispensing area shall be readily identifiable.

   D. In all instances where the services of pharmacy technicians are utilized in the preparation of a drug for delivery to a patient a pharmacist shall be present and personally supervising the pharmacy technician and shall be responsible for the correct preparation and delivery of the drug to the patient. All drugs dispensed utilizing the services of a pharmacy technician shall be labeled so as to identify the responsible supervising pharmacist.
   E. It is the responsibility of the discovering pharmacist to report losses or suspected losses of controlled substances or prescription drugs directly to the Board.
   F. In the interest of the public health the pharmacist shall, where appropriate, counsel patients and review their medication profiles in order to improve patient understanding and compliance.

2. Patient Records:
    A. A patient record system shall be maintained by all pharmacies for patients for whom prescription drug orders are dispensed. The patient record system shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a prescription drug order is presented for dispensing. The pharmacist or the pharmacist's agent shall make a reasonable effort to obtain, record, and maintain the following information:
        (1) Full name of the patient for whom the drug is intended;
        (2) Address and telephone number of the patient;
        (3) Patient's age or date of birth;
        (4) Patient's gender;
        (5) A record of all Prescription Drug Orders obtained by the patient at the pharmacy maintaining the patient record during the preceding 2 years showing the name of the drug or device, prescription number, name and strength of the drug, the quantity and date received, and the name of the prescriber;
        (6) Pharmacist's comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug; and
    B. The pharmacist or pharmacist's agent shall make a reasonable effort to obtain from the patient or the patient's agent and shall record any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient and the identity of any other drugs, including over-the-counter drugs or devices, currently being used by the patient which may relate to Prospective Drug Use Review (DUR).

3. Prospective Drug Use Review:
    Before a prescription is dispensed, delivered, or distributed, a pharmacist shall review the patient record and each Prescription Drug Order presented for dispensing for purposes of promoting therapeutic appropriateness by screening:
    A. Over-utilization or under-utilization;
    B. Therapeutic duplication;
    C. Drug-disease contraindications;
    D. Drug-drug interactions;
    E. Incorrect drug dosage or duration of drug treatment;
    F. Drug-allergy interactions; and,
    G. Clinical abuse/misuse.

    Upon recognizing any of the above, the pharmacist shall take appropriate steps to avoid or resolve the problem which shall, if necessary, include consultation with the prescriber.

4. Patient Counseling:
    A. Upon receipt of an outpatient prescription drug order and following a review of the

patient's record, it is the pharmacist or the pharmacist's agent's responsibility to make the offer to discuss matters which are deemed significant in the pharmacist's professional judgment. The pharmacist must provide the patient counseling. If patient or caregiver is not available, the pharmacist shall make known the fact that patient counseling is available and how he/she may be reached. Such discussion may include the following:

(1) Name and description of the drug;
(2) Dosage form, dose, route of administration, and duration of therapy;
(3) Intended use of the drug and expected action;
(4) Special directions and precautions for preparation, administration, and use by the patient;
(5) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
(6) Techniques for self-monitoring drug therapy;
(7) Proper storage;
(8) Prescription refill information;
(9) Action to be taken in the event of a missed dose; and
(10) Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

B. Alternative forms of patient information may be used to supplement verbal patient counseling when appropriate, such as written information, leaflets, pictogram labels, video programs, auxiliary labels on the prescription vials, etc.

C. Patient counseling, as described above and defined in the Act, shall not be required for inpatients of a hospital or institution where ~~other~~ licensed health care professionals are authorized to administer the drug(s).

D. A pharmacist that dispenses prescriptions that are to be delivered to the patient or the patient's caregiver by U.S. Mail, UPS, Federal Express, or any other carrier or by any employee or agent of the pharmacy shall comply with the following:
(1) Provide printed information with the delivery which supplies at a minimum the name, address and telephone number of the dispensing pharmacist and all information as outlined in paragraph 4., (A), of this ARTICLE.

E. A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultation.

5. Confidentiality:

Patient information obtained by the pharmacist or his agent is for the purpose of patient record maintenance, prospective drug review, retrospective drug use review and patient counseling shall be considered confidential information (see Definition Section).

Personally identifiable confidential patient information in the patient medication record may be released to the patient, the prescriber, other licensed practitioners then caring for the patient, another licensed pharmacist caring for the patient, the Board or its representatives or any person duly authorized by law to receive such information. This personally identifiable confidential information in the patient medication record may be

released to others only on written release by the patient.

The pharmacist-in-charge shall be responsible for written policies and procedures for maintaining the integrity and confidentiality of prescription and patient health care information. All employees of the pharmacy with access to any such information shall be required to read, sign, and comply with the established policies and procedures.

All pharmacies, pharmacists, pharmacy technicians, and other pharmacy employees shall comply with the provisions of the Health Insurance Portability and Protection Act (HIPPA).

ARTICLE XL PHARMACY TECHNICIANS

1. INTRODUCTION

Section 73-21-83. paragraph (2), Mississippi Code of 1972, Annotated specifies that a license to practice pharmacy shall be obtained by all persons prior to their engaging in the practice of pharmacy. The "Practice of pharmacy" shall mean a health care service that includes, but is not limited to, the compounding, dispensing, and labeling of drugs or devices; interpreting and evaluating prescriptions; administering and distributing drugs and devices; maintaining prescription drug records; advising and consulting concerning therapeutic values, content, hazards and uses of drugs and devices; initiating or modifying of drug therapy in accordance with written guidelines or protocols previously established and approved by the Board; selecting drugs; participating in drug utilization reviews; storing prescription drugs and devices; ordering lab work in accordance with written guidelines or protocols as defined by Section 73-21-73, paragraph (jj), Mississippi Code of 1972, Annotated; providing pharmacotherapeutic consultations; supervising supportive personnel and such other acts, services, operations or transactions necessary or incidental to the conduct of the foregoing.

The only other persons who may perform the above tasks other than a licensed pharmacist, and then only under the direct supervision of a pharmacist, are the following:

A. A pharmacy intern; and
B. A pharmacy extern.

2. PHARMACY TECHNICIAN REGISTRATION

Every person who intends to serves as a pharmacy technician must obtain a pharmacy technician registration from the Board. To obtain a pharmacy technician registration the applicant shall meet the following conditions for each Pharmacy Technician Registration issued after April 1, 2011:

A. Have attained eighteen (18) years of age; and
B. Be a high school graduate or hold GED equivalent and furnish copy of such certificate to the Board; and
C. Be of good moral character as evidenced by having undergone and successfully passed a criminal background check conducted by the Board; and
D. Have submitted a written application including a passport quality photo on a form(s) prescribed by the Board; and
E. Have paid the initial registration fee not to exceed one-hundred dollars ($100.00); and
F. Have paid all fees associated with the criminal background check; and

No Pharmacist whose license has been denied, Revoked, Suspended, or restricted for disciplinary reasons shall be eligible to be registered as a Pharmacy Technician.

3. PHARMACY TECHNICIAN REGISTRATION RENEWAL

Each pharmacy technician shall renew his/her registration annually. To renew his/her registration, a technician shall:

A. Submit an application on the form prescribed by the Board; and
B. Pay a renewal fee not to exceed one-hundred dollars ($100.00) for the registration period April 1, 2011 through March 31, 2012 and annually thereafter.
C. Have successfully passed the Pharmacy Technician Certification Board Exam or a Pharmacy Technician exam approved by the Board if the registration was obtained after April 1, 2011. This Certification must be maintained as specified or required by the examining authority.
D. If the registration was obtained after April 1, 2011, provide proof of a current approved certification.

Any pharmacy technician registration that has not been renewed by March 31 of each registration period becomes null and void after that date. The pharmacy technician shall not perform any pharmacy technician duties in the pharmacy dispensing or drug storage area until such time as the registration is renewed. Any Pharmacy technician renewal application postmarked after March 31 of the renewal period shall be returned and a fifty dollar ($50) late renewal fee shall be assessed prior to renewal

The pharmacist-in-charge shall validate all pharmacy technician registrations on or before March 31 of each year, assuring that all such registrations are current and in good standing.

4. PHARMACY TECHNICIAN RESPONSIBILITIES AND GUIDELINES

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. Support personnel used solely for clerical duties such as filing prescriptions, delivery and general record keeping need not be included in the ratios of the functions performed by a pharmacy technician.

In order to adequately protect the public health, technicians shall not:

A. Communicate, orally or in writing, any medical, therapeutic, clinical, or drug information or communicate any information recorded on a patient profile that requires professional judgment; and
B. Accept by oral communication a new prescription of any nature; and
C. Prepare a copy of a prescription or read a prescription to another person; and
D. Provide a prescription or medication to a patient without a pharmacist's verification as to the accuracy of the dispensed medication. For the purposes of this regulation, verification shall mean that the licensed pharmacist shall be aware of the patient's

medication profile, Drug Utilization Review, computer overrides, and drug interactions as well as the accuracy of the selected medication and labeling; and

E. Counsel a patient on medications or perform a drug utilization review; and
F. Perform any task that requires the professional judgment of a pharmacist; and
G. Perform any task that is in violation of any federal or state pharmacy or drug laws.

Persons registered with the Board as a pharmacy technician, under the direct supervision of a registered pharmacist may perform approved tasks as follows:

A. Packing, pouring or placing in a container for dispensing, sale, distribution, transfer possession of, vending, or barter any drug, medicine, poison, or chemical which, under the laws of the United States or the State of Mississippi, may be sold or dispensed only on the prescription of a practitioner authorized by law to prescribe drugs, medicines, poisons, or chemicals. This shall also include the adding of water for reconstitution of oral antibiotic liquids.
B. Affixing required labels upon any container of drugs, medicines, poisons, or chemicals sold or dispensed upon prescription of a practitioner authorized by law to prescribe those drugs, medicines, poisons, or chemicals.
C. Taking from, and replacing upon shelves in the prescription department of a pharmacy, drugs, medicines, chemicals, or poisons which are required by the law of the United States or the State of Mississippi to be sold or dispensed only on prescription of a practitioner authorized by law to prescribe them.
D. Entering information into the pharmacy computer. The pharmacy technician shall not make any judgemental decisions, which could affect patient care. The final verification of prescription information entered into the computer shall be made by the supervising pharmacist who is then totally responsible for all aspects of the data and data entry.
E. Obtaining prescriber authorization for prescription refills provided that nothing about the prescription is changed.
F. Prepackaging and labeling of multi-dose and unit-dose packages of medication. The pharmacist must establish the procedures, including selection of containers, labels and lot numbers, and must check the finished task.
G. Dose picking for unit dose cart fill for a hospital or for a nursing home patient.
H. Checking and inspecting nursing units in a hospital or nursing home: Pharmacy technicians may check nursing units for proper medication storage and other related floor stock medication issues. Any related medication storage problems or concerns shall be documented and initialed by a pharmacist.
I. Recording patient or medication information in electronic systems for later validation by the pharmacist.
J. Bulk reconstitution of prefabricated non-injectable medication.
K. Bulk compounding. This category may include such items as sterile bulk solutions for small-volume injectables, sterile irrigating solutions, products prepared in relatively large volume for internal or external use by patients, and reagents or other products for the pharmacy or other departments of a hospital.
L. Preparation of parenteral products as follows:
    (1) The pharmacy technician must follow guidelines established by the pharmacist as established by policy and procedures.

(2) Pharmacy technicians may perform functions involving reconstitution of single or multiple dosage units that are to be administered to a given patient as a unit. Pharmacy technicians may perform functions involving the addition of one manufacturer's single dose or multiple unit doses of the same product to another manufacturer's prepared unit to be administered to a patient. The supervising pharmacist must verify the accuracy in all instances.

Every person acting or serving as a pharmacy technician shall wear a name tag, while on duty, identifying him or her as such. When communicating by telephone, the pharmacy technician shall promptly identify him or her as such.

Pharmacy Technicians shall perform such duties as authorized by these regulations and perform other duties as assigned by the pharmacists.

Each technician registered by the Board shall notify the Board in writing within ten (10) days of change of employment or change of address. The notification shall contain his/her name, new mailing address, registration number, the name of the pharmacy where formerly employed and the name of the pharmacy where currently employed or the current employment status. Failure to Notify the Board of any changes may result in disciplinary action by the Board.

In the dispensing of drugs from a pharmacy, it shall be the responsibility of the supervising pharmacist on duty to require that any technician under his/her supervision complies with this Article. Performance by pharmacy technicians of tasks outlined in paragraph 1., above shall constitute the practice of pharmacy without a license and is a violation of the Mississippi Pharmacy Practice Act.

5. REVOCATION, SUSPENSION AND/OR REFUSAL TO ISSUE REGISTRATION

The Board may revoke, suspend, restrict, reprimand, refuse to issue or renew the registration or impose a monetary penalty, in accordance with Section 73-21-103. Mississippi Code of 1972, Annotated, of any person registered as a pharmacy technician, issued under this Article, if such person is found guilty by the Board of any of the following:

A. Violation of any federal or state law or regulation relating to the practice of pharmacy and/or the distribution and dispensing of drugs.
B. Violation of any of the provisions of these regulations.
C. Commission of an act or engaging in a course of conduct which constitutes a clear and present danger to the public health and safety.
D. The theft, unauthorized possession, addiction to, or use of controlled substances or other prescription drugs.
E. The addiction to or dependence on alcohol.
F. The theft or embezzlement of prescription drugs, controlled substances, medical devices, or funds from a permitted facility.
G. Failure to comply with any lawful order of the Board.

H. Disclosure of any patient medical, personal or dispensing information which is deemed confidential.
I. Being found guilty by any competent jurisdiction of the drug laws of this state, any other state or the federal government.
J. Being found guilty by any licensing or registration agency in this state or any other state for violation of the statutes, rules or regulations of that jurisdiction.
K. Obtaining or attempting to obtain a pharmacy technician registration by fraud or intentional misrepresentation.
L. Jeopardizing, compromising or interfering with any lawful investigation conducted by the Board or any state or federal regulatory or law enforcement agency.
M. Destruction, removal or tampering with any prescription drug, controlled substance, or medical device placed under seal, embargoed, or quarantined by the Board or any representative of the Board.
N. Knowing or suspecting that a Pharmacist or Pharmacy Intern is incapable of engaging in the Practice of Pharmacy or that a Pharmacy Technician is incapable of assisting in the Practice of Pharmacy, with reasonable skill, competence, and safety to the public, is diverting or abusing controlled substances or prescription drugs and failing to report any relevant information to the Board of Pharmacy.
O. Failing to pay costs assessed in a disciplinary hearing.
P. Failure to maintain the Certification required by this Article.

Disciplinary action by the Board of any person holding a registration as a pharmacy technician pursuant to this Article shall be in accordance with Section 73-21-99 of the Mississippi Code of 1972, Annotated.

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.

ARTICLE VIII RESPONSIBILITY OF PHARMACIST/PHARMACIST CARE

1. In the dispensing of drugs, the pharmacist shall have the following responsibilities:
   A. In a pharmacy it shall be the responsibility of the pharmacist on duty at the facility to insure that only a pharmacist provides professional consultation with the patients and/or other licensed health care professionals, and that only a pharmacist accepts telephoned prescriptions or gives information in any manner relative to prescriptions or prescription drugs. The provisions of this paragraph shall not apply to an extern or intern working under the supervision of a pharmacist.
   B. In the dispensing of drugs from a pharmacy, it shall be the responsibility of the supervising pharmacist to prevent the pharmacy technician from performing those functions relative to dispensing which are functions based on a judgment for which the pharmacy technician has not been prepared by education or authorized by law or regulation.
   C. In the dispensing of out-patient medications:
      (1) The pharmacist shall be responsible for all activities of the pharmacy technician in the preparation of the drug for delivery to the patient;
      (2) The pharmacist shall be present and personally supervising the activities of the pharmacy technician at all times;
      (3) When a data processor is used, pharmacy technicians may enter information into the system and prepare labels, but it shall be the responsibility of the pharmacist to verify the accuracy of the information entered and the label thus produced;
      (4) When refilling a prescription it shall be the responsibility of the pharmacist to review all appropriate information and make the determination as to whether or not to refill the prescription;
      (5) A pharmacist shall not be assisted by more than ~~two~~ <u>three</u> pharmacy technicians;
      (6) Pharmacy Technicians in the dispensing area shall be readily identifiable.

   D. In all instances where the services of pharmacy technicians are utilized in the preparation of a drug for delivery to a patient a pharmacist shall be present and personally supervising the pharmacy technician and shall be responsible for the correct preparation and delivery of the drug to the patient. All drugs dispensed utilizing the services of a pharmacy technician shall be labeled so as to identify the responsible supervising pharmacist.
   E. It is the responsibility of the discovering pharmacist to report losses or suspected losses of controlled substances or prescription drugs directly to the Board.
   F. In the interest of the public health the pharmacist shall, where appropriate, counsel patients and review their medication profiles in order to improve patient understanding and compliance.

2. Patient Records:
    A. A patient record system shall be maintained by all pharmacies for patients for whom prescription drug orders are dispensed. The patient record system shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a prescription drug order is presented for dispensing. The pharmacist or the pharmacist's agent shall make a reasonable effort to obtain, record, and maintain the following information:
        (1) Full name of the patient for whom the drug is intended;
        (2) Address and telephone number of the patient;
        (3) Patient's age or date of birth;
        (4) Patient's gender;
        (5) A record of all Prescription Drug Orders obtained by the patient at the pharmacy maintaining the patient record during the preceding 2 years showing the name of the drug or device, prescription number, name and strength of the drug, the quantity and date received, and the name of the prescriber;
        (6) Pharmacist's comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug; and
    B. The pharmacist or pharmacist's agent shall make a reasonable effort to obtain from the patient or the patient's agent and shall record any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient and the identity of any other drugs, including over-the-counter drugs or devices, currently being used by the patient which may relate to Prospective Drug Use Review (DUR).

3. Prospective Drug Use Review:
    Before a prescription is dispensed, delivered, or distributed, a pharmacist shall review the patient record and each Prescription Drug Order presented for dispensing for purposes of promoting therapeutic appropriateness by screening:
    A. Over-utilization or under-utilization;
    B. Therapeutic duplication;
    C. Drug-disease contraindications;
    D. Drug-drug interactions;
    E. Incorrect drug dosage or duration of drug treatment;
    F. Drug-allergy interactions; and,
    G. Clinical abuse/misuse.

    Upon recognizing any of the above, the pharmacist shall take appropriate steps to avoid or resolve the problem which shall, if necessary, include consultation with the prescriber.

4. Patient Counseling:
    A. Upon receipt of an outpatient prescription drug order and following a review of the

patient's record, it is the pharmacist or the pharmacist's agent's responsibility to make the offer to discuss matters which are deemed significant in the pharmacist's professional judgment. The pharmacist must provide the patient counseling. If patient or caregiver is not available, the pharmacist shall make known the fact that patient counseling is available and how he/she may be reached. Such discussion may include the following:

(1) Name and description of the drug;
(2) Dosage form, dose, route of administration, and duration of therapy;
(3) Intended use of the drug and expected action;
(4) Special directions and precautions for preparation, administration, and use by the patient;
(5) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
(6) Techniques for self-monitoring drug therapy;
(7) Proper storage;
(8) Prescription refill information;
(9) Action to be taken in the event of a missed dose; and
(10) Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

B. Alternative forms of patient information may be used to supplement verbal patient counseling when appropriate, such as written information, leaflets, pictogram labels, video programs, auxiliary labels on the prescription vials, etc.

C. Patient counseling, as described above and defined in the Act, shall not be required for inpatients of a hospital or institution where ~~other~~ licensed health care professionals are authorized to administer the drug(s).

D. A pharmacist that dispenses prescriptions that are to be delivered to the patient or the patient's caregiver by U.S. Mail, UPS, Federal Express, or any other carrier or by any employee or agent of the pharmacy shall comply with the following:
(1) Provide printed information with the delivery which supplies at a minimum the name, address and telephone number of the dispensing pharmacist and all information as outlined in paragraph 4., (A), of this ARTICLE.

E. A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultation.

5. Confidentiality:

Patient information obtained by the pharmacist or his agent is for the purpose of patient record maintenance, prospective drug review, retrospective drug use review and patient counseling shall be considered confidential information (see Definition Section).

Personally identifiable confidential patient information in the patient medication record may be released to the patient, the prescriber, other licensed practitioners then caring for the patient, another licensed pharmacist caring for the patient, the Board or its representatives or any person duly authorized by law to receive such information. This personally identifiable confidential information in the patient medication record may be

released to others only on written release by the patient.

The pharmacist-in-charge shall be responsible for written policies and procedures for maintaining the integrity and confidentiality of prescription and patient health care information. All employees of the pharmacy with access to any such information shall be required to read, sign, and comply with the established policies and procedures.

All pharmacies, pharmacists, pharmacy technicians, and other pharmacy employees shall comply with the provisions of the Health Insurance Portability and Protection Act (HIPPA).

ARTICLE XL PHARMACY TECHNICIANS

1. INTRODUCTION

Section 73-21-83. paragraph (2), Mississippi Code of 1972, Annotated specifies that a license to practice pharmacy shall be obtained by all persons prior to their engaging in the practice of pharmacy. The "Practice of pharmacy" shall mean a health care service that includes, but is not limited to, the compounding, dispensing, and labeling of drugs or devices; interpreting and evaluating prescriptions; administering and distributing drugs and devices; maintaining prescription drug records; advising and consulting concerning therapeutic values, content, hazards and uses of drugs and devices; initiating or modifying of drug therapy in accordance with written guidelines or protocols previously established and approved by the Board; selecting drugs; participating in drug utilization reviews; storing prescription drugs and devices; ordering lab work in accordance with written guidelines or protocols as defined by Section 73-21-73, paragraph (jj), Mississippi Code of 1972, Annotated; providing pharmacotherapeutic consultations; supervising supportive personnel and such other acts, services, operations or transactions necessary or incidental to the conduct of the foregoing.

The only other persons who may perform the above tasks other than a licensed pharmacist, and then only under the direct supervision of a pharmacist, are the following:

A. A pharmacy intern; and
B. A pharmacy extern.

2. PHARMACY TECHNICIAN REGISTRATION

Every person who intends to serves as a pharmacy technician must obtain a pharmacy technician registration from the Board. To obtain a pharmacy technician registration the applicant shall meet the following conditions for each Pharmacy Technician Registration issued after April 1, 2011:

A. Have attained eighteen (18) years of age; and
B. Be a high school graduate or hold GED equivalent and furnish copy of such certificate to the Board; and
C. Be of good moral character as evidenced by having undergone and successfully passed a criminal background check conducted by the Board; and
D. Have submitted a written application including a passport quality photo on a form(s) prescribed by the Board; and
E. Have paid the initial registration fee not to exceed one-hundred dollars ($100.00); and
F. Have paid all fees associated with the criminal background check; and

No Pharmacist whose license has been denied, Revoked, Suspended, or restricted for disciplinary reasons shall be eligible to be registered as a Pharmacy Technician.

3. PHARMACY TECHNICIAN REGISTRATION RENEWAL

Each pharmacy technician shall renew his/her registration annually. To renew his/her registration, a technician shall:

A. Submit an application on the form prescribed by the Board; and
B. Pay a renewal fee not to exceed one-hundred dollars ($100.00) for the registration period April 1, 2011 through March 31, 2012 and annually thereafter.
C. Have successfully passed the Pharmacy Technician Certification Board Exam or a Pharmacy Technician exam approved by the Board if the registration was obtained after April 1, 2011. This Certification must be maintained as specified or required by the examining authority.
D. If the registration was obtained after April 1, 2011, provide proof of a current approved certification.

Any pharmacy technician registration that has not been renewed by March 31 of each registration period becomes null and void after that date. The pharmacy technician shall not perform any pharmacy technician duties in the pharmacy dispensing or drug storage area until such time as the registration is renewed. Any Pharmacy technician renewal application postmarked after March 31 of the renewal period shall be returned and a fifty dollar ($50) late renewal fee shall be assessed prior to renewal

The pharmacist-in-charge shall validate all pharmacy technician registrations on or before March 31 of each year, assuring that all such registrations are current and in good standing.

4. PHARMACY TECHNICIAN RESPONSIBILITIES AND GUIDELINES

It has been determined by the Board that ~~two (2)~~ three (3) technicians on duty performing technician related work directly related to the dispensing of medications are sufficient for each licensed pharmacist on duty. Support personnel used solely for clerical duties such as filing prescriptions, delivery and general record keeping need not be included in the ratios of the functions performed by a pharmacy technician.

In order to adequately protect the public health, technicians shall not:

A. Communicate, orally or in writing, any medical, therapeutic, clinical, or drug information or communicate any information recorded on a patient profile that requires professional judgment; and
B. Accept by oral communication a new prescription of any nature; and
C. Prepare a copy of a prescription or read a prescription to another person; and
D. Provide a prescription or medication to a patient without a pharmacist's verification as to the accuracy of the dispensed medication. For the purposes of this regulation, verification shall mean that the licensed pharmacist shall be aware of the patient's

medication profile, Drug Utilization Review, computer overrides, and drug interactions as well as the accuracy of the selected medication and labeling; and

E. Counsel a patient on medications or perform a drug utilization review; and
F. Perform any task that requires the professional judgment of a pharmacist; and
G. Perform any task that is in violation of any federal or state pharmacy or drug laws.

Persons registered with the Board as a pharmacy technician, under the direct supervision of a registered pharmacist may perform approved tasks as follows:

A. Packing, pouring or placing in a container for dispensing, sale, distribution, transfer possession of, vending, or barter any drug, medicine, poison, or chemical which, under the laws of the United States or the State of Mississippi, may be sold or dispensed only on the prescription of a practitioner authorized by law to prescribe drugs, medicines, poisons, or chemicals. This shall also include the adding of water for reconstitution of oral antibiotic liquids.
B. Affixing required labels upon any container of drugs, medicines, poisons, or chemicals sold or dispensed upon prescription of a practitioner authorized by law to prescribe those drugs, medicines, poisons, or chemicals.
C. Taking from, and replacing upon shelves in the prescription department of a pharmacy, drugs, medicines, chemicals, or poisons which are required by the law of the United States or the State of Mississippi to be sold or dispensed only on prescription of a practitioner authorized by law to prescribe them.
D. Entering information into the pharmacy computer. The pharmacy technician shall not make any judgemental decisions, which could affect patient care. The final verification of prescription information entered into the computer shall be made by the supervising pharmacist who is then totally responsible for all aspects of the data and data entry.
E. Obtaining prescriber authorization for prescription refills provided that nothing about the prescription is changed.
F. Prepackaging and labeling of multi-dose and unit-dose packages of medication. The pharmacist must establish the procedures, including selection of containers, labels and lot numbers, and must check the finished task.
G. Dose picking for unit dose cart fill for a hospital or for a nursing home patient.
H. Checking and inspecting nursing units in a hospital or nursing home: Pharmacy technicians may check nursing units for proper medication storage and other related floor stock medication issues. Any related medication storage problems or concerns shall be documented and initialed by a pharmacist.
I. Recording patient or medication information in electronic systems for later validation by the pharmacist.
J. Bulk reconstitution of prefabricated non-injectable medication.
K. Bulk compounding. This category may include such items as sterile bulk solutions for small-volume injectables, sterile irrigating solutions, products prepared in relatively large volume for internal or external use by patients, and reagents or other products for the pharmacy or other departments of a hospital.
L. Preparation of parenteral products as follows:
    (3) The pharmacy technician must follow guidelines established by the pharmacist as established by policy and procedures.

(4) Pharmacy technicians may perform functions involving reconstitution of single or multiple dosage units that are to be administered to a given patient as a unit. Pharmacy technicians may perform functions involving the addition of one manufacturer's single dose or multiple unit doses of the same product to another manufacturer's prepared unit to be administered to a patient. The supervising pharmacist must verify the accuracy in all instances.

Every person acting or serving as a pharmacy technician shall wear a name tag, while on duty, identifying him or her as such. When communicating by telephone, the pharmacy technician shall promptly identify him or her as such.

Pharmacy Technicians shall perform such duties as authorized by these regulations and perform other duties as assigned by the pharmacists.

Each technician registered by the Board shall notify the Board in writing within ten (10) days of change of employment or change of address. The notification shall contain his/her name, new mailing address, registration number, the name of the pharmacy where formerly employed and the name of the pharmacy where currently employed or the current employment status. Failure to Notify the Board of any changes may result in disciplinary action by the Board.

In the dispensing of drugs from a pharmacy, it shall be the responsibility of the supervising pharmacist on duty to require that any technician under his/her supervision complies with this Article. Performance by pharmacy technicians of tasks outlined in paragraph 1., above shall constitute the practice of pharmacy without a license and is a violation of the Mississippi Pharmacy Practice Act.

6. REVOCATION, SUSPENSION AND/OR REFUSAL TO ISSUE REGISTRATION

The Board may revoke, suspend, restrict, reprimand, refuse to issue or renew the registration or impose a monetary penalty, in accordance with Section 73-21-103. Mississippi Code of 1972, Annotated, of any person registered as a pharmacy technician, issued under this Article, if such person is found guilty by the Board of any of the following:

A. Violation of any federal or state law or regulation relating to the practice of pharmacy and/or the distribution and dispensing of drugs.
B. Violation of any of the provisions of these regulations.
C. Commission of an act or engaging in a course of conduct which constitutes a clear and present danger to the public health and safety.
D. The theft, unauthorized possession, addiction to, or use of controlled substances or other prescription drugs.
E. The addiction to or dependence on alcohol.
F. The theft or embezzlement of prescription drugs, controlled substances, medical devices, or funds from a permitted facility.
G. Failure to comply with any lawful order of the Board.

H. Disclosure of any patient medical, personal or dispensing information which is deemed confidential.
I. Being found guilty by any competent jurisdiction of the drug laws of this state, any other state or the federal government.
J. Being found guilty by any licensing or registration agency in this state or any other state for violation of the statutes, rules or regulations of that jurisdiction.
K. Obtaining or attempting to obtain a pharmacy technician registration by fraud or intentional misrepresentation.
L. Jeopardizing, compromising or interfering with any lawful investigation conducted by the Board or any state or federal regulatory or law enforcement agency.
M. Destruction, removal or tampering with any prescription drug, controlled substance, or medical device placed under seal, embargoed, or quarantined by the Board or any representative of the Board.
N. Knowing or suspecting that a Pharmacist or Pharmacy Intern is incapable of engaging in the Practice of Pharmacy or that a Pharmacy Technician is incapable of assisting in the Practice of Pharmacy, with reasonable skill, competence, and safety to the public, is diverting or abusing controlled substances or prescription drugs and failing to report any relevant information to the Board of Pharmacy.
O. Failing to pay costs assessed in a disciplinary hearing.
P. Failure to maintain the Certification required by this Article.

Disciplinary action by the Board of any person holding a registration as a pharmacy technician pursuant to this Article shall be in accordance with Section 73-21-99 of the Mississippi Code of 1972, Annotated.

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 ~~two (2)~~ 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 ~~two~~ three (~~2~~ 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.