TITLE 30: PROFESSIONS AND OCCUPATIO NS

PART 3001: MISSISSIPPI PHARMACY PRACTICE REGUALTIONS

MISSISSIPPI PHARMACY PRACTICE REGULATIONS

Mississippi Board of Pharmacy
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Effective January 24, 2013

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www.mbp.state.ms.us

MISSISSIPPI BOARD OF PHARMACY

PHARMACY PRACTICE REGULATIONS

AND

PHARMACY PRACTICE ACT

PART 3001
BOARD REGULATIONS
(Effective January 31, 2011)

PART 3002

ADMINISTRATIVE RULES

PHARMACY PRACTICE REGULATIONS

Whereas, the Mississippi Board of Pharmacy in accordance with Section 73-21-81, Mississippi Code of 1972, finds it necessary to adopt new regulations governing the practice of pharmacy and the distribution and sale of prescription drugs, and

Whereas, the Mississippi Board of Pharmacy having given careful consideration to the needs of the public in the preparation of these regulations, and having complied with Title 25, Chapter 43, Mississippi Code of 1972, annotated, the Mississippi Board of Pharmacy, on November 15, 2012, adopted these regulations to become effective January 1, 2013. In these regulations, any reference to the "Code" or a section thereof, refers to the Mississippi Code of 1972, annotated.

All regulations in effect prior to the effective date of these regulations are rescinded effective December 31, 2012. Individuals who are charged with a violation during the time of the effective dates of previous regulations will be charged under the regulations in effect at the time of the violation.

GENERAL INFORMATION
PHARMACISTS

CHANGE OF ADDRESS

A pharmacist must notify the Board in writing by mail or fax of change of address within ten (10) days of the change. To ensure the correct changes are made to the Board records, a pharmacist should include the following information:

(1) Name and license number of pharmacist;
(2) New address;
(3) Former address;
(4) Current telephone number.

Keeping this information current with the Board office will assure pharmacists of receiving license renewal and controlled substance registration applications and their *Board of Pharmacy Newsletter*.

CHANGE OF EMPLOYMENT

Pharmacists must notify the Board in writing by mail or fax within ten (10) days of a change of employment. To ensure the correct changes are made to the Board records, a pharmacist should include the following information:

(1) Name and license number of pharmacist;
(2) Name, address and permit number of the pharmacy where presently employed;
(3) Name, address and permit number of the pharmacy where he/she was formerly employed.

CHANGE OF LEGAL NAME

The Board's records and a pharmacist's renewal certificate must accurately reflect the legal name used in pharmacy practice by that pharmacist. Pharmacists who change the legal name, under which they practice, through a legal name change, e.g., marriage or divorce, must notify the Board within ten (10) days of receipt of the legal document effecting the change. The following must be included in the notification of change of pharmacist's name:

(1) A letter of explanation which includes the new name, clearly printed or typed as it is to appear on the renewal card and in the Board records;
(2) A copy of the legal document that changed the name, e.g., marriage license, divorce decree or court order;
(3) The current renewal card (wallet card);
(4) A check or money order in the amount of fifteen dollars ($15.00) for each wallet card.

Changing your name on the wall certificate is optional. If you desire a new wall certificate reflecting your new legal name, you must send the following additional information:

(1) A check or money order for twenty-five ($25.00).

OBTAINING DUPLICATE DOCUMENTS

The Board will replace, under certain conditions e.g., lost or stolen, a pharmacist's wall certificate and/or wallet registration card. To obtain duplicates of these documents, the following should be observed:

(1) A written statement signed by the pharmacist outlining the circumstances under which the card(s) was lost or stolen;
(2) The name, address and license number on the lost or stolen card(s);
(3) A check or money order in the amount of fifteen ($15.00) for each wallet card;
(4) A check or money order in the amount of twenty-five dollars ($25.00) for a duplicate wall certificate.

PHARMACIES

LOSS OF CONTROLLED SUBSTANCES

When a pharmacy has a loss of controlled substances or suspected loss, the pharmacist-in-charge must comply with the following:

(1) Any loss or suspected loss must be reported directly to the office of the Board by telephone (601-605-5388) immediately on discovery;
(2) Within forty-eight hours of the discovery of the loss, a complete inventory of controlled substances shall be made. This inventory must be dated and signed by the pharmacist-in-charge;
(3) Within fifteen days of the discovery of the loss, a written report shall be forwarded to the office of the Board. This written report shall include a copy of the controlled substance inventory as required by paragraph (2) above.

FAILURE TO REPORT ANY LOSS OR SUSPECTED LOSS DIRECTLY TO THE BOARD MAY BE GROUNDS FOR DISCIPLINARY ACTION BY THE BOARD.

CHANGE OF PHARMACIST-IN-CHARGE

If the employment of a pharmacist-in-charge is terminated or if for any other reason he/she wishes to be relieved of the responsibilities of the pharmacist-in-charge, he/she must:

(1) Return the pharmacy permit to the office of the Board with written notice that he/she is no longer the pharmacist-in-charge at that facility. Advise the Board of the effective date of the change;
(2) The pharmacist-in-charge shall conduct a complete inventory of controlled substances and send it to the Board along with the pharmacy permit.

When the relinquishing pharmacist-in-charge cannot or does not comply with paragraphs (1) and (2) as listed above, it shall be the responsibility of the new pharmacist-in-charge to send to the Board an inventory of controlled substances on hand at the time he/she assumes responsibility as pharmacist-in-charge.

PROCEDURES FOR PERMANENT CLOSURE OF BUSINESS

Requirements under Board regulations:

(1) The pharmacist-in-charge shall give notice to the Board of the effective date of closure at least fourteen (14) days prior to the closure and shall notify the Board in writing fourteen (14) days by what means and as to whom controlled substances were transferred or disposed of; and

(2) Take a complete inventory of any controlled substances on hand, including out-of-date drugs; and

(3) Send the pharmacy permit, controlled substances registration and a copy of the controlled substances inventory to the Board; and

(4) Remaining controlled substances may be transferred to another registrant. Schedule II drugs must be transferred by use of DEA form 222 Narcotic Order Blank. Schedule III, IV and V drugs may be transferred between registrants by an inventory listing agreed upon between registrants. The closing business PIC should maintain a copy of the inventory and a copy should be maintained by the business receiving the inventory.

Requirements under DEA regulations:

(1) Return for cancellation the DEA registration Certificate and any unexecuted DEA 222 order forms to:
Registration Unit
DEA, Department of Justice
P. O. Box 28083
Central Station
Washington, DC 20005

(2) Submit notice fourteen (14) days in advance of closure in person or by Registered or Certified Mail return receipt requested to:
Special Agent in Charge
DEA- U.S. Department of Justice
3838 N. Causeway Blvd., Suite 1800
Three Lakeway Center
Metarie, LA 70002
Include the following information:

(A) Name, address, DEA registration number and authorized business activity of registrant closing business; and

(B) Name, address, DEA Registration Number and authorized business activity of person acquiring the business; and

(C) Whether the business activity will be continued at the location registered by the person discontinuing the business, or moved to another location; and

(D) The date on which the transfer of controlled substances will occur.

OTHER AGENCIES

DRUG ENFORCEMENT ADMINISTRATION (DEA)

Drug Enforcement Administration
Registration Unit
P. O. Box 28083
Central Station
Washington, DC 20038-8083
telephone: (800)-882-9539 (24 hour automated system)

New Orleans Divisional Office

Drug Enforcement Administration
3838 North Causeway Blvd.
Suite 1800
3 Lakeway Center
Metairie, LA 70002
telephone: 504-840-1100

MISSISSIPPI BUREAU OF NARCOTICS

6090 I-55 South
Jackson, MS 39272
telephone 601-371-3600
toll free: 800-844-6272

MISSISSIPPI BOARD OF NURSING

Mississippi Board of Nursing
1080 River Oaks Drive Suite A100
Flowood, MS 39232
telephone: 601-664-9303------fax: 601-664-9304

MISSISSIPPI STATE BOARD OF DENTAL EXAMINERS

Mississippi State Board of Dental Examiners
600 East Amite Street
Jackson, MS 39201-2801
telephone: 601-944-9622------fax: 601-944-9624

MISSISSIPPI STATE BOARD OF MEDICAL LICENSURE

Mississippi State Board of Medical Licensure
1867 Crain Ridge Dr.
Suite 200B
Jackson, MS 39216
telephone: 601-987-3079 fax: 601-987-4159

U. S. FOOD AND DRUG ADMINISTRATION

Food and Drug Administration
100 West Capitol
Suite 340
Jackson, MS 39269
telephone: 601-965-4581------fax: 601-965-4584

DIVISION OF MEDICAID

550 High Street Suite 1000
Jackson, MS 39201
telephone: 601-359-6050
toll free: 800-421-2408

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DEFINITIONS:

As used in these regulations unless the context requires otherwise:

1. "Administer" shall mean the direct application of a prescription drug pursuant to a lawful order of a practitioner to the body of a patient by injection, inhalation, ingestion or any other means.

2. “Advisory Board” shall mean the advisory board established in conjunction with the Prescription Monitoring Program.

3. “Application” shall mean a document either paper or electronic required to be completed by an application for initial licensure, permit, registration or renewal of said licensure, permit or registration..

4. "Authentication of Product History" means but is not limited to, identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical.

5. “Automated Pharmacy Systems” include, but are not limited to, mechanical systems which perform operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing, or distribution of medications, and which collect, control, and maintain all transaction information.

6. "Biological Safety Cabinet" shall mean a containment unit suitable for the preparation of low to moderate risk agents where there is a need for protection of the product, personnel, and environment, according to National Sanitation Foundation (NSF) Standard 49.

7. "Board of Pharmacy", "Pharmacy Board", "Board" or "M~~S~~BP", shall mean the Mississippi Board of Pharmacy.

8. “Cease and Desist” is an order of the Board prohibiting a licensee or other person or entity from continuing a particular course of conduct which violates the Pharmacy Practice Act or its rules or regulations.

9. “Centralized Prescription Processing” shall mean the processing by a pharmacy of a request from another pharmacy to fill or refill a prescription drug order or to perform processing functions such as dispensing, DUR, claims adjudication, refill authorizations, and therapeutic interventions.

10. “Certified Pharmacy Technician” shall mean those supportive persons, registered with the Mississippi Board of Pharmacy, who have successfully completed the Pharmacy Technician

Certification Board Examination or a Board approved pharmacy technician examination

11. "Class 100 Environment" shall mean an atmospheric environment which contains less than 100 particles 0.5 microns in diameter per cubic foot of air, according to Federal Standard 209B.

12. “Collaborative Pharmacy Practice” is that practice of pharmacy whereby one or more pharmacists have jointly agreed, on a voluntary basis, to work in conjunction with one or more practitioners under protocol whereby the pharmacist may perform certain patient care functions authorized by the practitioner or practitioners under certain specified conditions and or limitations.

13. “Collaborative Pharmacy Practice Agreement” is a written and signed agreement between one or more pharmacists and one or more practitioners that provides for Collaborative Pharmacy Practice for the purpose of Drug Therapy Management of patients.

14. "Component" is any ingredient intended for use in the compounding of a medication.

15. "Compounding" means (1) the production, preparation, propagation, conversion, or processing of a sterile or non-sterile drug or device either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis or from bulk chemicals or the preparation, mixing, measuring, assembling, packaging, or labeling of a drug or device as a result of a practitioner's prescription drug order or initiative based on the practitioner/patient/pharmacist relationship in the course of professional practice or (2) for the purpose of, as an incident to, research, teaching or chemical analysis and not for sale or dispensing. Compounding also includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine regularly observed prescribing patterns.

16. "Confidential Information" shall mean information obtained and/or maintained by the pharmacist, which is privileged and released only to the patient or, as the patient directs; to those health care professionals where, in the pharmacist's professional judgment, such release is necessary to protect the patient's health and well being; and to such other persons or governmental agencies authorized by law to receive such confidential information.

17. "Consultant Pharmacist" shall mean a pharmacist who provides services which includes but is not limited to; providing consultation on matters related to drugs, reviewing patients drug therapy regimen, serving on appropriate committees, disposing of drugs which are no longer needed, ensuring complete and accurate records of acquisition and disposition of controlled substance medications and who has attended, within the last two years, a qualifying seminar which has been approved by the Board of Pharmacy.

18. "Continuing Education Unit" shall mean ten (10) clock hours of study or other activity and shall include either of the following:

A. Programs which have been approved by the American Council on Pharmaceutical Education. (A.C.P.E.)

B. Programs which have been approved by the Mississippi Board of Pharmacy prior to presentation.

19. "Cytotoxic" shall mean a pharmaceutical that has the capability of killing living human cells.

20. "Deliver" or "Delivery" shall mean the actual, constructive or attempted transfer of a drug or device from one person to another, whether or not for a consideration.

21. “Digital Signature” shall mean an electronic signature based upon cryptographic methods of originator authentication, and computed by using a set of rules and a set of parameters so that the identity of the signer and the integrity of the data can be verified.

22. "Dispense" or "Dispensing" shall mean the interpretation of a valid prescription or order of a practitioner by a pharmacist and the subsequent preparation of the drug or device for administration to or use by a patient or other individual entitled to receive the drug.

23. “Dispenser” shall mean, as it pertains to the Prescription Monitoring Program, a person authorized in this state to distribute to the ultimate user a substance monitored by the prescription monitoring program, but does not include:
(a) a licensed hospital pharmacy that distributes such substances for the purposes of inpatient hospital care or the dispensing of prescriptions for controlled substances at the time of discharge from such a facility.
(b) a licensed nurse or medication aide who administers such substances at the direction of a licensed physician; or
(c) a wholesale distributor of a substance monitored by the prescription monitoring system.

24 ."Device" shall mean an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component part or accessory, that is required under federal or state law to be ordered or prescribed by a practitioner and dispensed by a pharmacist.

25. "Distribute" shall mean the delivery of a drug or device other than by administering or dispensing to persons other than the ultimate consumer.

26. “Drug” shall mean:

(1) articles recognized as Drugs in any official compendium, or supplement thereto, designated from time to time by the Board for use in the diagnosis, cure, mitigation,

treatment, or prevention of disease in humans or other animals;

(2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals;

(3) articles (other than food) intended to affect the structure or any function of the body of humans or other animals; and

(4) articles intended for use as a component of any articles specified in item (1), (2), or (3) of this definition.

27. “Electronic Signature” shall mean an electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record.

28. “Electronic Transmission” shall mean a transmission of information in electronic form or the transmission of the exact visual image of a document by way of electronic equipment.

29. "Emergency Medication Supplies", "Boxes", "Kits" or "Carts" are those drugs which may be required to meet the immediate therapeutic needs of patients and which are not available from any other authorized source in sufficient time to prevent risk of harm to patients.

30. "Enteral" shall mean within or by way of the intestine.

31. “Embargo” shall mean to restrict prescription drugs or devices from being dispensed by placing them under seal or in a secure area.

32 ."Foreign pharmacy graduate" shall mean a person whose undergraduate pharmacy degree was conferred by a recognized school of pharmacy outside of the United States, the District of Columbia and Puerto Rico. Recognized schools of pharmacy are those colleges and universities listed in the World Health Organization's World Directory of Schools of Pharmacy, or otherwise approved by the Foreign Pharmacy Graduate Examination Committee (FPGEC) certification program as established by the National Association of Boards of Pharmacy.

33. "Generic Equivalent Drug" shall mean a drug product which contains the identical active chemical ingredient of the identical strength, quantity and dosage form and which can be expected to have the same therapeutic effect when administered to the patient under the conditions specified in the labeling.

34. “Good Moral Character” shall mean an applicant for licensure or registration has not been adjudicated guilty of any act which would provide grounds for disciplinary action by the Board as evidenced by having undergone and successfully passed a criminal background check conducted by the Board.

35. “Home Health/Hospice” shall mean a business, which does not require the services of a pharmacist and where certain prescription drugs or prescription devices as approved by the Board are bought, sold, maintained or provided to consumers.

36. “Home Infusion Pharmacy” shall mean a pharmacy which compounds solutions for direct administration to a patient in a private residence, long-term care facility, or hospice setting by means of parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion.

37. "In-patient" is one who receives treatment or undergoes tests as a resident of an institutional facility.

38. "Inpatient Medication" shall mean medication dispensed for a person who is a patient in the facility where the medication is dispensed.

39. "Institutional Facility" or "Organized Health Care Setting" is defined as:

    (1) Hospital;
    (2) Convalescent Home;
    (3) Nursing Home;
    (4) Extended Care Facility;
    (5) Mental Institution;
    (6) Rehabilitation Center;
    (7) Psychiatric Center;
    (8) Developmental Disability Center;
    (9) Drug Abuse Treatment Center;
    (10) Retardation Center;
    (11) Correctional Facility;
    (12) Hospice;
    (13) Out-patient surgery facilities;
    (14) Any other such organization whose primary purpose is to provide a residential environment for patients to obtain health care services, and shall not include those places where physicians, dentists, veterinarians or other practitioners of the healing arts, who are duly license, engage in private practice.

40. "Institutional Pharmacy" is defined as that portion of an institutional facility which is engaged in the compounding, production, storage, sale, dispensing or distribution of drugs, medications, devices and other materials used in the diagnosis and treatment of injury, illness and disease, and registered with the Mississippi Board of Pharmacy and operating under a valid institutional permit issued thereby.

41. "Internal Test Assessment" means, but is not limited to, conducting those tests of quality assurance necessary to ensure the integrity of the test.

42. "IV Additive Program" is a pharmacy based program in which the addition of drugs to IV fluids and the preparation of small volume parenterals are under the supervision of a pharmacist.

43. “Long Term Care Facility (LTCF)” shall mean any nursing home, convalescent home, extended care facility, personal care home, or inpatient hospice, which has been issued a permit by the Board but does not include a Hospital.

44. "Manufacturing" of prescription products shall mean the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from substances from natural origin or independently by means of chemical or biological synthesis, or from bulk chemicals and includes any packaging or repackaging of the substance(s) or labeling or relabeling of its container, if such actions are associated with promotion and marketing of such drug or devices.

45. “Non-Resident Pharmacy” means a Pharmacy located outside this State.

46. "Nuclear Pharmacy" is a pharmacy providing the services of storing, compounding, dispensing, labeling or distributing radiopharmaceuticals.

47. "Out-patient" is one who receives treatment or undergoes tests without in-patient admission to an institutional facility.

48. "Outpatient Medication" shall mean medication which is dispensed for a person who is not a patient in the facility where the medication is dispensed.

49. "Parenteral" means sterile preparations of drugs for injection through one or more layers of skin.

50. "Patient Counseling" shall mean the oral communication by a pharmacist of information to the patient or care giver to improve therapeutic outcomes by optimizing proper use of prescription drugs or devices. Alternative forms of patient information may be used to supplement verbal patient counseling when appropriate. Examples to include written information leaflets, pictogram labels, video programs, auxiliary labels on the prescription vial, etc.

51. "Patient Med-Pak" is a package prepared by a pharmacist for a specific patient comprising a series of containers or cells and containing two or more prescribed solid oral dosage forms. The med-pak is designed and labeled to indicate the day and time or period of time that the contents within each container or cell are to be taken.

52. "Person" shall mean an individual, corporation, partnership, association, or any other legal entity.

53. "Pharmaceutical Care/Pharmacist Care" is the provision of drug therapy by a pharmacist and other pharmacist 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.

54. "Pharmacist" shall mean an individual health care provider licensed by this state to engage in the practice of pharmacy. This recognizes a pharmacist as a learned professional who is authorized to provide patient services.

55. “Pharmacist-in-Charge” shall mean a Pharmacist currently licensed in this state who accepts responsibility for the operation of a Pharmacy in conformance with all laws and rules pertinent to the Practice of Pharmacy and the Distribution of Drugs and Devices, and who is personally in full and actual charge of such Pharmacy and personnel.

56. "Pharmacy" shall mean any location for which a pharmacy permit is required and in which prescription drugs are compounded, maintained and/or dispensed for patients by a pharmacist. This definition includes any location where pharmacy related services are provided by a pharmacist.

57. “Pharmacy Extern" shall mean a student in the professional program of a school of pharmacy who is making normal progress toward completion of a degree in pharmacy.

58. “Pharmacy Intern” means an individual who is:

(1) currently licensed by this State to engage in the Practice of Pharmacy while under the personal supervision of a Pharmacist and is satisfactorily progressing toward meeting the requirements for licensure as a Pharmacist; or
(2) a graduate of an approved college of Pharmacy or a graduate who has established educational equivalency by obtaining a Foreign Pharmacy Graduate Examination Committee (FPGEC) Certificate, who is currently licensed by the Board of Pharmacy for the purpose of obtaining practical experience as a requirement for licensure as a Pharmacist; or
(3) a qualified applicant awaiting examination for licensure.

59. "Pharmacy Technician" shall mean those supportive persons, registered with the Mississippi Board of Pharmacy, utilized in pharmacies whose responsibilities are to provide non-judgemental technical services concerned with the preparation for dispensing of drugs under the direct supervision and responsibility of a pharmacist.

60. “Physician/Patient Relationship” shall mean that a practitioner has obtained a thorough medical history and has conducted an appropriate physical and/or mental examination of a patient prior to the prescribing of any medication.

61. "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; proper and safe storage of Drugs and 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.

62. "Practitioner" shall mean a physician, dentist, veterinarian, or other health care provider authorized by law to diagnose and prescribe drugs.

63. “Preceptor” shall mean an individual who is currently licensed as a Pharmacist by the Board of Pharmacy and participates in the instructional training of Pharmacy externs.

64. "Prepackaging" shall mean the act of placing small precounted quantities of drug products in containers suitable for dispensing or administering in anticipation of prescriptions or orders.

65. “Prescriber” means a licensed health care professional with prescriptive authority.

66. "Prescription" shall mean a written, verbal or electronically transmitted order issued by a practitioner for a drug or device to be dispensed for a patient by a pharmacist. An electronically transmitted order for a prescription drug or controlled substance is considered to be a written order.

67. "Prescription Drug" or "Legend Drug" shall mean a drug which is required under federal law to be labeled with either of the following statements prior to being dispensed or delivered:
(1) “Rx Only” or
(2) "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian";
or a drug which is required by an applicable federal or state law or regulation to be dispensed on prescription only or is restricted to use by practitioners only.

68. "Prescription Drug Order" shall mean a prescription as defined in the pharmacy laws and regulations of the State of Mississippi.

69. “Prescription Monitoring Information” means information submitted to and maintained by the Prescription Monitoring Program.

70. “Prescription Monitoring Program (PMP)” means a program established for the purpose of monitoring the dispensing and appropriate use of certain controlled substances and specified drugs within the state.

71. “Probation” shall mean the restriction of a license, permit or registration for a specified period of time.

72. "Product Selection" shall mean the dispensing of a generic equivalent drug product in lieu of the drug product ordered by the prescriber.

73. "Prospective Drug Review" shall mean the monitoring by a pharmacist, for therapeutic appropriateness, over-utilization and under-utilization, appropriate use of generic products, therapeutic duplications, drug-disease contraindications, drug-drug interaction(s), incorrect dosage or duration of drug treatment, and clinical abuse/misuse by a pharmacist prior to the drug being dispensed.

74. "Qualified Licensed Professional" means an individual (such as a physician, nurse, or technologist) who possesses a current state license if applicable, and who has sufficient training and experience to safely handle radiopharmaceuticals as defined by the Mississippi State Department of Health, Division of Radiological Health.

75. "Qualified Nuclear Pharmacist" means a currently licensed pharmacist in the state of Mississippi who is certified by the Mississippi State Department of Health, Division of Radiological Health, or who meets the following standards:
    (1) Minimum standards of training for "authorized user status" of radioactive materials as defined by Mississippi State Department of Health, Division of Radiological Health.
    (2) Completed a minimum of two hundred (200) contact hours of instruction in nuclear pharmacy and the safe handling and the use of radioactive materials from a program approved by the Mississippi Board of Pharmacy, with emphasis in the following areas:
        (i) Radiation Physics and Instrumentation;
        (ii) Radiation Protection;
        (iii) Mathematics of Radioactivity;
        (iv) Radiation Biology; and
        (v) Radiopharmaceutical Chemistry.
    (3) Attain a minimum of five hundred (500) hours of clinical nuclear pharmacy training under the supervision of a qualified nuclear pharmacist.

76. “Quarantine” shall mean the act of isolating prescription drugs or devices for the purpose of preventing dispensing or introduction into or intermingling with other prescription drug stock or devices at a permitted location.

77. "Radiopharmaceutical" is any substance defined as a drug in Section 201(g) (1) of the Federal Food, Drug and Cosmetic Act which also contains unstable nuclei which undergo

spontaneous disintegration with the emission of nuclear radiation. Radiopharmaceuticals also include any non-radioactive reagent kit or radionuclide generator which is intended to be used in the preparation of radiopharmaceutical doses.

78. "Radiopharmaceutical Service" means, but shall not be limited to the procurement, storage, handling, preparation, labeling, quality assurance testing, dispensing, delivery, record keeping, and disposal of radiopharmaceutical and other drugs.

79. "Radiopharmaceutical Quality Assurance" means, but is not limited to, the performance of appropriate chemical, biological and physical tests on potential radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans including internal test assessment, authentication of product history and the keeping of proper records.

80. "Registrant" shall mean a pharmacy or other entity which is registered with the Mississippi Board of Pharmacy to buy, sell, destroy or maintain controlled substances.

81. "Repackager" means a person registered by the Federal Food and Drug Administration as a repackager who removes a prescription drug product from its marketed container and places it into another, usually of smaller size, to be distributed to persons other than the consumer.

82. “Reprimand” shall mean the formal reproof of a licensee for violation of the Pharmacy Practice Act or Rules and Regulations of the Board.

83. "Retrospective Drug Review" shall mean the monitoring for therapeutic appropriateness, over-utilization and under-utilization, appropriate use of generic products, therapeutic duplications, drug-disease contraindications, drug-drug interaction(s), incorrect dosage or duration of drug treatment, and clinical abuse/misuse after the drug has been dispensed.

84. “Reverse Distributor” shall mean those business operations which are responsible for the receipt and appropriate disposal of un-wanted and un-needed stocks of controlled and non-controlled medications.

85. “Revocation” shall mean the withdrawal of the license to practice Pharmacy. The individual no longer has the privilege of practicing Pharmacy in this state.

86. "Sterile Pharmaceuticals" shall mean a dosage form free from living micro-organisms (aseptic).

87. “Summary Suspension” shall mean the Suspension of a license or permit which requires a licensee to cease Pharmacy Practice immediately pending the results of a timely hearing.

88. “Suspension” shall mean the withdrawal of the license to practice Pharmacy in the state for

a specified period of time.

89. “Telemedicine” shall mean the practice of medicine using electronic communication, information technology or other means between a physician in one location and a patient in another location with or without an intervening health care provider. This definition does not include the practice of medicine through postal or courier services.

90. "Unit Dose Packaging" is the packaging of individual doses of medication in containers which will preserve their identity and integrity from the point of packaging to patient consumption.

91. "Unlawful" or "Unauthorized Possession" shall mean physical holding or control by a pharmacist, pharmacy technician, or other person, of a controlled substance or other habit forming prescription drug outside the usual and lawful course of employment.

92. "Valid Prescription" or "Valid Order" shall mean one issued in compliance with applicable rules and regulations of the regulatory authority by an individual licensed or authorized to prescribe a product to be used by a named and identifiable individual for a bona fide medical purpose. To be valid in Mississippi, a prescription written in another state must be written so as to comply with the requirements of the regulatory authority of that state and with the requirements of the regulatory authority of this state. A prescription which is written in code or for any other reason does not provide adequate information for the interpretation of the prescription and the safe dispensing of the drug product is not a valid prescription. The dispensing of prescription drugs or controlled substances pursuant to prescription documents which the pharmacist knows or should know were issued by a practitioner when a valid practitioner/patient relationship did not exist are not valid prescriptions. A valid practitioner/patient relationship shall mean that the practitioner has obtained a thorough medical history and has conducted an appropriate physical and/or mental examination prior to the prescribing of any medication. Prescriptions or orders issued for the dispensing of medications on an out-patient basis in the absence of a physician/patient relationship in which a practitioner has not conducted an appropriate examination of the patient and established a diagnosis are not valid prescriptions.

93. "Wholesaler" shall mean a person who buys/acquires prescription drugs or prescription devices for resale or distribution, or for repackaging for resale or distribution, to persons other than consumers.

94. "Written guideline or protocol" shall mean an agreement in which any practitioner authorized to prescribe drugs, delegates to a pharmacist authority to conduct specific prescribing functions in an institutional setting, or with individual patients, provided that a specific protocol agreement is signed on each patient and is filed as required by law or by rule or regulation of the Board.

ARTICLE I LICENSURE

A license for the practice of pharmacy shall be obtained from the Mississippi Board of Pharmacy by all persons prior to their engaging in the practice of pharmacy in this state and every pharmacist licensed in this state shall keep the Board informed as to his/her current mailing address and place of employment.

1. To obtain a license to engage in the practice of pharmacy by examination, the applicant shall:
   A. Have submitted a written application on the form prescribed by the Board;
   B. Be of good moral character as evidenced by having undergone and successfully passed a criminal background check conducted by the Board;
   C. Have graduated and received a degree from a school or college of pharmacy accredited by the American Council on Pharmaceutical Education or as approved by the Board;
   D. Have successfully passed an examination approved by the Board;
   E. Have submitted documented evidence of the required practical experience;
   F. Have paid the initial licensure fee (not to exceed two-hundred dollars ($200.00).

2. To obtain a license to engage in the practice of pharmacy by licensure transfer, the applicant shall:
   A. Have submitted a written application on the Official Application for Transfer of Pharmaceutic Licensure Form of the National Association of Boards of Pharmacy;
   B. Have graduated and received a degree from a school or college of pharmacy accredited by the American Council on Pharmaceutical Education or as approved by the Board;
   C. At the discretion of the Board, appear before the Board of Pharmacy for a personal interview;
   D. Have successfully passed an examination approved by the Board;
   E. Be of good moral character as evidenced by having undergone and successfully passed a criminal background check conducted by the Board;
   F. Present to the Board proof that the license(s) granted to the applicant by any other state has not been suspended, revoked, canceled, surrendered, or otherwise restricted for any reason;
   G. Have paid the initial licensure fee not to exceed two-hundred dollars ($200.00).

   No applicant shall be eligible for license transfer unless the state in which the applicant was licensed as a Pharmacist also grants licensure transfer to Pharmacists duly licensed by examination in the State, under like circumstances and conditions.

3. To obtain a license to engage in the practice of pharmacy, a foreign pharmacy graduate applicant shall obtain the National Association of Boards of Pharmacy's Foreign Pharmacy Graduate Examination Committee's certification which shall include, but not be limited to, successfully passing the Foreign Pharmacy Graduate Equivalency Examination and

attaining a total score of at least 550 on the Test of English as a Foreign Language (TOEFL); and

A. Have submitted a written application on the form prescribed by the Board; and
B. Be of good moral character as evidenced by having undergone and successfully passed a criminal background check conducted by the Board; and
C. Have graduated and been granted a pharmacy degree from a college or school of pharmacy recognized and approved by the National Association of Boards of Pharmacy's Foreign Pharmacy Graduate Examination Committee; and
   May at the discretion of the Board appear before the Board of Pharmacy and demonstrate adequate spoken English Language skills; and
D. Have paid all fees specified by the Board for examination; and
E. Have successfully passed an examination approved by the Board; and
F. Have completed sixteen hundred hours of extern/internship hours approved by the Board; and
G. Have paid the initial licensure fee, not to exceed two-hundred dollars ($200.00).

ARTICLE II PHARMACY BOARD EXAMINATION

The examination shall consist of the North American Pharmacist Licensure Examination (NAPLEX) and the Multi-State Pharmacy Jurisprudence Examination (MPJE) or a test on Mississippi Pharmacy Law and Pharmacy Board Regulations administered by the Board.

To be eligible to take the NAPLEX examination, a person shall be a graduate of a school of pharmacy which is accredited by the American Council on Pharmaceutical Education or which has been approved by the Board.

A person desiring to take the examination for licensure as a pharmacist must make application for the examination on the form prescribed by the Board. The required fee for the examination must accompany the application.

To successfully complete the examination, the candidate must make a score of at least seventy five (75) on the NAPLEX part of the examination, a score of at least seventy five (75) on the MPJE part of the examination, or a score of at least seventy five (75) on the test of Mississippi Pharmacy Law and Pharmacy Board Regulations.

A person who takes the examination and fails the examination may repeat the examination; however, a person may not take the examination more than four (4) times without permission from the Board. A person who is not eligible to take the Mississippi Board of Pharmacy examination may not practice as an intern. A person who takes the examination and successfully completes the examination must become licensed within two (2) years of the examination date or the results of the examination become invalid.

ARTICLE III PRACTICAL EXPERIENCE REQUIREMENT

1. The externship/internship practical experience required for licensure is defined as a total of sixteen hundred (1,600) hours of pharmacy experience. The said sixteen hundred (1,600) hours of practical experience shall be obtained after the student is enrolled in the professional program of a school of pharmacy. Practical experience hours gained through clerkships and externships, while enrolled in a school of pharmacy whose externship rotations are approved by the Board, may be used to satisfy these requirements. In order for a pharmacy student to be considered as a valid extern in such a program, he/she must be certified by a school of pharmacy as a bona fide student making normal progress toward completion of either a Bachelor of Science or a Doctor of Pharmacy degree in pharmacy.

   Any remaining practical experience required for licensure, not obtained by the extern through externship rotations, may be obtained during official vacation periods when the extern is not enrolled as a full time student or as an intern after graduation. No more than fifty (50) hours per week of practical experience shall be credited during any of these periods.

2. All practical experience gained in Mississippi, which is related to the dispensing of drugs, must be under the direct and immediate supervision of a pharmacist registered in Mississippi and in good standing with the Mississippi Board of Pharmacy. The direct and immediate supervision by the pharmacist requires the physical presence of the supervising pharmacist at all times and includes the constant personal supervision and monitoring of the extern or intern by the supervising pharmacist. The supervising pharmacist shall be responsible for the activities of the extern or intern.

3. No practical experience obtained in this state shall be credited to an extern or intern unless such extern or intern be registered with the Mississippi Board of Pharmacy as a pharmacy extern/intern and be issued a registration to dispense controlled substances by the Board.

4. For practical experience obtained in another state and for which the Mississippi Board of Pharmacy is requested to grant credit toward the experience requirements, the applicant shall:
   A. Submit the affidavits certifying the work experience to the Board of pharmacy in the state in which the experience was obtained;
   B. Request that Board of Pharmacy to send copies of the affidavits to the Mississippi Board of Pharmacy along with certification that the hours of experience claimed are acceptable to that Board.

Upon receipt of copies of the affidavits and the statement of their acceptance by the Board of Pharmacy in the state in which the experience was obtained, the Mississippi Board of Pharmacy may grant the same credit toward practical experience requirements.
For purposes of these Regulations the term "practical experience" shall include, but not be limited to, the compounding, dispensing and labeling of drugs, interpreting and evaluating

prescriptions, maintaining prescription drug records and any other activity included in the practice of pharmacy.

ARTICLE IV LICENSE RENEWAL AND CONTINUING EDUCATION

Each pharmacist shall renew his/her license annually.

1. To renew his/her license, a pharmacist shall:
   A. Submit an application for renewal on the form prescribed by the Board or through the online process found at the Mississippi Board of Pharmacy webpage;
   B. On the application, indicate and certify the number of continuing education hours earned for Licensure:
   One (1) continuing education unit~~s~~ (10 hours) is required for each licensure period.
   C. Pay renewal fees as follows:
   One-hundred dollars ($100.00) for the annual licensure period January 1, 2011 through December 31, 2011, and each annual licensure period thereafter, plus a surcharge of five dollars ($5.00) to fund a program to aid impaired pharmacists and pharmacy students for a total fee of one-hundred and five dollars ($105.00) .
   D. Any pharmacist license renewal application postmarked after December 31 of the renewal period or submitted online after 11:59 P.M. CST shall be returned or rejected and a fifty dollar ($50.00) late renewal fee shall be assessed prior to renewal.
   E. Any license not renewed by January 15th may be considered invalid and may be subject to disciplinary action by the Board.

2. Any person who has not renewed or possessed a valid license to practice pharmacy in Mississippi for a current period of time exceeding two years must:
   A. Petition the Board for license reinstatement;
   B. Appear before the Board in support of said petition;
   C. Work as an intern for a Board approved pharmacist and site for twenty (20) clock hours for each year that the person was without a valid license;
   D. Provide a record from the supervising pharmacist showing the satisfactory completion of the intern hours;
   E. Provide proof of ten (10) hours of continuing education for the current licensing period;
   F. Pay all license renewal fees in arrears; and
   G. Satisfactorily pass an examination on Pharmacy Law and Board regulations approved by the board.

3. Those persons who have been actively engaged in the practice of pharmacy pursuant to a license issued by another state, but who have not renewed the Mississippi Pharmacist License for a period of time exceeding two years must:
   A. Petition the Board for reinstatement;
   B. May appear before the Board in support of said petition, or furnish proof of a continuing valid pharmacy license in another state during the period of license lapse in Mississippi;
   C. Provide proof of ten (10) hours of continuing education for the current licensing period; and

D. Pay all license renewal fees in arrears; and
E. Satisfactorily pass an examination on Pharmacy Law and Board regulations approved by the Board.

4. For purposes of these regulations, one (1) continuing education unit shall consist of ten (10) clock hours of study or other activity and shall include either of the following:
   A. Programs, which have been approved by the American Council on Pharmaceutical Education (A.C.P.E.);
   B. Programs, which have been approved by the Mississippi Board of Pharmacy prior to presentation.

5. The continuing education required for license renewal shall be obtained in the licensure period preceding the renewal date. Evidence of continuing education shall be submitted to the Board of Pharmacy on request by audit or at any time on request by any agent of the Board of Pharmacy. Documentation of evidence of continuing education should indicate the name and address of the participant, date of the continuing education, the program title, the amount of continuing education credit received and the signature of the person authorized to issue certification of continuing education credit. Documentation of continuing education credit must be received within five (5) working days of a request. Failure to submit evidence of continuing education credit will result in disciplinary action by the Board.

6. Continuing education obtained in another state may be accepted by the Mississippi Board of Pharmacy provided that it is acceptable to the Board of Pharmacy in the state where it was obtained.

7. A request for Pharmacy Board approval of a program as continuing education shall be made on a form prescribed by the Board.

8. The subject matter of the program, the objectives of the program and the qualifying credentials of the person or persons presenting the program must be sufficiently detailed in the request for Board approval so as to give the Board a sound basis for evaluating the merits of the program.

9. In approving programs for continuing education the policy of the Board shall be that no program will be approved:
   A. After the program has been presented;
   B. If program attendance is expected or required as part of a person's employment (an example would be an inservice or training seminar);
   C. That is not made available to all pharmacists who wish to attend (an exception may be a program that is specifically directed to a particular group such as hospital pharmacists, retail pharmacists or consultant pharmacists).

10. Continuing education obtained by a pharmacist who is also licensed by another approved

health care regulatory agency shall be acceptable to the Board provided the continuing education is approved by that respective regulatory agency. A pharmacist enrolled full time in any recognized school of the healing arts may receive credit for the continuing education requirements of this ARTICLE upon submitting proof of full time enrollment.

11. The Board, at its discretion, may grant extension periods and waivers for the completion of license renewal and continuing education requirements for ACTIVE Military Service members.

ARTICLE V ACTION AGAINST PHARMACIST LICENSE

1. The Board of Pharmacy may refuse to issue or renew, or may suspend, summarily suspend, place on probation, revoke, reprimand or restrict the license of any pharmacist and/or impose a monetary penalty upon one or more of the following grounds:
   - A. Violation of the rules and regulations of the Board of Pharmacy;
   - B. Violation of any of the provisions of the Mississippi Pharmacy Practice Act or the Mississippi Uniform Controlled Substances Law;
   - C. Violation of pharmacy or drug laws of any other state or the federal government or rules or regulations pertaining thereto;
   - D. Fraud or intentional misrepresentation by a licensee in securing the issuance or renewal of a license or failing to report to the Board any adverse action taken by another licensing jurisdiction, government agency, law enforcement agency, or court that would constitute grounds for action;
   - E. Aiding and abetting an individual to engage in the practice of pharmacy without a license;
   - F. Addiction to or dependence on alcohol, controlled substances or other habit forming legend drugs or the unauthorized use, possession, or theft of controlled substances or other habit forming legend drugs;
   - G. Unprofessional conduct. Unprofessional conduct shall include, but is not limited to:
     - (1) Condoning or assisting in the dispensing, promotion or distribution of drugs:
       - (a)Which do not meet the standards required by law;
       - (b)Which the pharmacist knows, or should know, are not obtained for a legitimate medical need.
     - (2) Committing any fraudulent act including, but not limited to:
       - (a)Destruction or alteration of any records such as prescriptions, profiles, purchase invoices, third-party vouchers and receipts required to be kept;
       - (b)The placement of any advertisement which is false or misleading;
       - (c)Filing a claim or assisting in the filing of a claim for reimbursement for drugs or professional services which were not provided or which were not authorized to be provided.
     - (3) Dispensing, selling, bartering, receiving, or maintaining drugs which the pharmacist knows, or should know, have been stolen or diverted from the purpose for which they were distributed by a legitimate source;
     - (4) Practicing in a location which is not properly permitted or registered by the Mississippi Board of Pharmacy;
     - (5) Selling or bartering a prescription drug sample;
     - (6) Receiving, dispensing, or maintaining a prescription drug sample unless the pharmacy is owned by a charitable organization and is not operated for profit and has prior approval in writing by the Board. Institutional pharmacies may receive, dispense and maintain prescription drug samples that are provided by a practitioner and intended solely for administration to his/her patients confined to the institution provided no charge is made to the patient by the

institution for the sample;

(7) No pharmacist shall have possession of a prescription drug sample unless such sample is for treatment of a diagnosed personal medical condition;

(8) Denying a patient freedom of choice in selecting who will fill their prescription needs;

(9) Willfully and knowingly failing to maintain complete and accurate records of all prescription drugs received, disposed of or dispensed at a permitted facility.

(10) Failure to report fraudulent prescription activity to the appropriate authorities.

H. Physical or mental incapacity that prevents a pharmacist from practicing pharmacy with reasonable skill and safety to the public.

I. Failure to comply with any lawful order of the Board.

J. Being found guilty by the licensing agency in another state or violating the statutes, rules or regulations of that jurisdiction.

K. Divulging or revealing patient confidential or protected health information to any person other than as authorized by Board regulations.

L. Termination of employees suspected of theft of pharmaceuticals or merchandise without contacting the Board prior to termination.

M. Failure to report directly to the Board, losses or suspected losses of controlled substances or prescription drugs.

N. Theft from a permitted facility.

O. Theft or embezzlement of prescription drugs, controlled substances or medical devices from a permitted facility.

P. Jeopardizing, compromising, interfering or failing to cooperate with any lawful investigation conducted by the Board or any state or federal regulatory or law enforcement agency.

Q. 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.

R. 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 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.

S. Failure to furnish to the Board, its investigators, or representatives any information legally requested by the Board.

T. Failing to pay costs assessed in a disciplinary hearing.

U. Failing to submit prescription monitoring information to the Prescription Monitoring Program within the time interval prescribed.

V. The unlawful disclosure of information from the Prescription Monitoring Program or using information obtained from the Prescription Monitoring Program for unlawful or unethical purposes.

W. Failure to produce continuing educations credits within required time period set forth in these regulations.

X. The Board may issue a cease and desist order to prevent a person from engaging in the practice of pharmacy which endangers the public.

ARTICLE VI PHARMACY PERMITS

1. Every business or location in this state where prescription drugs are maintained and/or pharmacy services are provided shall obtain a permit as a pharmacy from the Mississippi Board of Pharmacy. Effective January 31, 2011, every pharmacy issued a permit by the Board shall renew this permit biennially. The Board shall identify written criteria and issue permits accordingly in one of the following general classifications:
   A. Community Pharmacy; or
   B. Institutional Pharmacy; or
   C. Limited Closed Door Pharmacy; or
   D. Nonresident Pharmacy.

2. For purposes of this ARTICLE, definitions are as follows:
   A. A Community Pharmacy shall mean any place, other than an Institutional Pharmacy or a Limited Closed Door Pharmacy, which is accessible to the general public and where pharmacy services are offered. These pharmacies may include but are not limited to independent retail or chain retail pharmacies.

      A Specialty Community Pharmacy shall mean any place other than an Institutional Pharmacy, Limited Closed Door Pharmacy or a Community Pharmacy where the practice of pharmacy occurs and pharmacy services are provided to patients. These services may include, but are not limited to the following: dispensing sterile pharmaceuticals for home infusion, nuclear pharmacy services, compounding, consulting pharmacist services, disease state management, respiratory services and dispensing of nursing home medications. These pharmacies may be open on a full or part time basis.
   B. An Institutional Pharmacy shall mean that portion of an institutional facility where the practice of pharmacy occurs and where medications, devices and other materials are dispensed to their patients.
      (1) An Institutional I Pharmacy shall mean that portion of a hospital where the practice of pharmacy occurs and which is engaged in the compounding, production, and dispensing of drugs, medications, devices and other materials which are used in the diagnosis and treatment of injury, illness and disease. For purposes of these regulations a hospital shall mean any institution for the care and treatment of the sick and injured which is licensed and approved by the Mississippi State Department of Health, Health Facilities, Licensure and Certification.
      (2) An Institutional II Pharmacy shall mean that portion of an institution, other than a hospital, where the practice of pharmacy occurs and which is engaged in the compounding, production and dispensing of drugs, medications, devices and other materials used in the diagnosis and treatment of injury, illness and disease.

      Various categories of Institutional Pharmacies are recognized as follows:

"Institutional Facility" or "Organized Health Care Setting" is a:

(1) Hospital;
(2) Convalescent Home;
(3) Nursing Home;
(4) Extended Care Facility;
(5) Mental Institution;
(6) Rehabilitation Center;
(3) Retardation Center;
(8) Correctional Facility;
(9) Hospice;
(10) Out-patient surgery facilities;
(11) Any other such organization whose primary purpose is to provide a residential environment for patients to obtain health care services, and shall not include those places where physicians, dentists, veterinarians or other practitioners of the healing arts, who are duly licensed, engage in private practice.

C. Limited Closed Door Pharmacy shall mean any place where pharmacy services are provided and where preferentially priced prescription drugs are purchased for the pharmacy's own use to dispense only to their own patients. These pharmacies are not accessible to the general public and may or may not provide full time pharmacy services.

A Limited Closed Door Pharmacy may include, but is not limited to, pharmacies owned by any city, county or state government and federally, state or privately funded non-profit community health clinics.

D. A Nonresident Pharmacy shall mean any pharmacy that is located outside the State of Mississippi which ships, mails or delivers prescription or legend drugs or devices to patients residing in this state.

3. To obtain a pharmacy permit or renew a pharmacy permit, the applicant shall have:
   A. Submitted a written application on a form(s) prescribed by the Board;
   B. Submitted the required fees as follows:
   Three hundred dollars ($300.00) for the registration period January 1, 2011 through December 31, 2012, and each biennial registration period thereafter.
   C. Any Pharmacy permit renewal application postmarked after December 31 of the renewal period shall be returned and a fifty ($50.00) late renewal fee shall be assessed prior to renewal.

4. Newly issued permits which do not coincide with the registration period shall be valid for the following periods of time: If the permit is issued in the first half of the registration period, it must be renewed at the end of the registration period. If the permit is issued in the second half of the registration period, it must be renewed at the end of the next registration period.

5. Permits issued to any type facility become null and void sixty (60) days from the date of

issuance if inspection reveals a lack of legitimate business activity.

6. A permit for a pharmacy shall not be issued or renewed on the application of any person unless such person be a pharmacist licensed in this state.

7. Original permits, once issued for a new facility, may be returned to the Board and a new permit issued without being assessed an additional permit fee provided:
   A. The change is on a one time basis and is within sixty (60) days of original issuance; and
   B. Controlled substance inventory requirements are met; and
   C. A twenty-five dollar ($25.00) processing fee is paid to the Board.

ARTICLE VII RESPONSIBILITY OF PHARMACIST-IN-CHARGE (PIC)

1. The person who signs the application for a pharmacy permit or the renewal of a pharmacy permit shall be the pharmacist-in-charge (PIC) for that facility.
   A. Authority. The PIC of the pharmacy shall be responsible for complete supervision, management and compliance with all federal and state pharmacy laws and regulations pertaining to the practice of pharmacy in the entire prescription department. He/She shall have the cooperation and support of all pharmacy staff in carrying out these responsibilities. The pharmacist-in-charge is responsible for assuring that all personnel are properly registered or licensed with the Board and, that all pharmacy permits are current and appropriate for the type of pharmacy operation being conducted.
   A pharmacist shall not be the PIC at more than one Community Pharmacy or Institutional I Pharmacy and shall not be the pharmacist-in-charge or have personal supervision of more than one facility which is open to the general public on a full time basis.
   B. Recommended Guidelines:
      (1) That each individual work space is designed to provide space and a work flow design that will accommodate the workload in an organized fashion; and
      (2) That the computer's software should be of a design so that drug interactions and contraindications must be reviewed by the pharmacist. Further, the computer system should support counseling and drug utilization review documentation; and
      (3) That trained supportive staff should be maintained to meet the demands of the practice site, workload and the clientele served; and
      (4) That all staff should have the opportunity to take periodic breaks and/or meal periods to relieve fatigue and mental and physical stress. Nothing in this paragraph suggests closing the pharmacy; and
      (5) That all staff should be afforded and encouraged to participate in training and continuing education in order to keep them abreast of new information and changes in the field; and
      (6) That if quotas or formulas such as prescription volume are used to set staffing, conditions such as peak workload periods, workplace design and the training of staff must be taken into consideration.

   C. Circumvention. It is a violation of this section for any person to subvert the authority of the pharmacist-in-charge by impeding the management of the prescription department for the compliance with federal and state drug or pharmacy laws and regulations. Any such circumvention may result in charges being filed against the pharmacy permit.

2. A permit for a pharmacy located within the state shall not be issued or renewed unless such person be a pharmacist-licensed in this state.

If the pharmacist license of the pharmacist-in-charge becomes void or inactive due to surrender, revocation, suspension, restriction or for any other reason, application must be made for a new pharmacy permit by another pharmacist within ten (10) days.

3. If the employment of a pharmacist-in-charge is terminated or if for any other reason he/she wishes to be relieved of the responsibilities of the PIC, he/she must:
   A. Return the permit to the Mississippi Board of Pharmacy with written notice that he/she is no longer the pharmacist-in-charge for that facility and;
   B. In accordance with the provision of paragraph 2 of ARTICLE XXV of the Regulations, send to the Board of Pharmacy an inventory of any controlled substances on hand at the facility at the time of his/her termination as pharmacist-in-charge.
   C. When the relinquishing PIC cannot or does not comply with the inventory requirements of this paragraph it shall be the responsibility of the new PIC to send to the Board of Pharmacy an inventory of any controlled substances on hand at the time he/she assumes responsibility as PIC.
   D. The relinquishing PIC is responsible for notification of appropriate supervisors or owners of the surrender of the permit.

   When a permit is thus returned for a facility, application for a new permit for that facility must be made to the Mississippi Board of Pharmacy within ten (10) days.

4. If a permitted facility is permanently closed or has a change of ownership, the pharmacist-in-charge for that facility shall give notice to the Board of the effective date of closure or change in ownership and include the storage location of the businesses records and appropriate contact information. If a permitted facility has a change in name or location, application for a new permit must be made to the Board at least ten (10) days prior to the change in name or location. Once issued, a permit cannot be amended, transferred or assigned to another person.

5. On the premises where a pharmacy is maintained in conjunction with other services or business activities, the pharmacy shall be physically secured from such other services or activities during those times a pharmacist is not present and the pharmacy is not open and other services or activities are being provided on the premises.
   A. The Pharmacy shall be secured by a physical barrier to detect entry at a time when the Pharmacist is not present.
   B. Each pharmacist while on duty shall be responsible for the security of the Pharmacy, including provisions for effective control against theft or diversion of Drugs and/or Devices.
   C. The pharmacist-in-charge shall be responsible for adequate security being maintained on drugs in all areas of the permitted facility at all times and is responsible for reporting any loss or suspected loss of controlled substances or legend drugs directly to the Board immediately (this does not relieve any pharmacist who discovers a loss from the requirement of reporting the loss directly to the Board).

6. Each facility issued a pharmacy permit by the Mississippi Board of Pharmacy shall maintain:
   A. An area of sufficient size to accommodate the dispensing functions of the facility and which is adequately equipped to provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation and security. All areas where Drugs and Devices are stored shall be dry, well lighted, well ventilated, and maintained in a clean and orderly condition. Storage areas shall be maintained at temperatures which will ensure the integrity of the Drugs prior to their dispensing as stipulated by the USP-NF and/or the Manufacturer's or Distributor's labeling.
   B. A sink with hot and cold running water which is convenient to the dispensing area;
   C. An inventory which shall include such drugs, chemicals and preparations as may be necessary to fill ordinary prescriptions as indicated by experience in the area where the pharmacy is located;
   D. Technical equipment which may include measuring graduates, mortar and pestle, spatulas, funnels, ointment slab or paper, balance and such other items of equipment found to be necessary for the filling of prescriptions or rendering of other pharmacist services; and,
   E. Current reference material adequate for professional and consumer information.
   F. Pharmacy permits, facility controlled substance registrations, and DEA registrations must be conspicuously posted. Evidence of current pharmacist licensure and pharmacy technician registration must be provided on request by any agent of the Board.
   G. A current and updated copy of the Mississippi Board of Pharmacy Practice Regulations and Pharmacy Practice Act.

7. It is the responsibility of the Pharmacist-in-charge to establish and implement procedures to ensure compliance with the Article entitled Prescription Monitoring Program.

8. 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.

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 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 IX ACTION AGAINST PERMITS

1. The Board of Pharmacy may refuse to issue or renew, or may suspend, summarily suspend, place on probation, revoke, reprimand, or restrict the permit of any permitted facility and/or impose a monetary penalty upon one or more of the following grounds:
   - A. Any act by any person in the conduct of the activities of the facility which is a violation of any of the provisions of the Mississippi Pharmacy Practice Act or the Mississippi Uniform Controlled Substances Law. Further, that any act by any person which subverts the authority of the pharmacist-in-charge by impeding the management of the prescription department or the practice of pharmacy in the compliance with federal and state drug or pharmacy laws and regulations shall be deemed a violation of this section. Any such circumvention may result in charges being filed against the pharmacy permit.
   - B. Any act by any person in the conduct of the activities of the facility which is a violation of the rules and regulations of the Board of Pharmacy.
   - C. Fraud or intentional misrepresentation in securing the issuance or renewal of a permit.
   - D. Failure to comply with any lawful order of the Board.
   - E. Engaging in or aiding and abetting an individual to engage in the practice of pharmacy without a license.
   - F. Unprofessional conduct by any person in any activity relating to the operation of a pharmacy. Unprofessional conduct includes, but is not limited to:
     - (1) Condoning or assisting in the dispensing, promotion or distribution of drugs which do not meet the standards required by law.
     - (2) Committing any fraudulent act including, but not limited to:
       - (a) Destruction or alteration of any records such as purchase invoices, prescriptions, patient profiles, third-party vouchers and receipts required to be kept;
       - (b) The placement of any advertisement which is false or misleading;
       - (c) Filing a claim or assisting in the filing of a claim for reimbursement for drugs or professional services which were not provided.
     - (3) Dispensing, selling, bartering, receiving, or maintaining drugs which the pharmacist knows, or should know, have been stolen or diverted from the purpose for which they were distributed by a legitimate source.
     - (4) Selling or bartering a prescription drug sample.
     - (5) Receiving, dispensing, or maintaining a prescription drug sample unless the pharmacy is owned by a charitable organization, and is not operated for profit and has prior approval in writing by the Board. Institutional pharmacies may receive, dispense and maintain prescription drug samples that are provided by a practitioner and intended solely for administration to his/her patient confined to the institution provided no charges made to the patient by the institution for the sample.
     - (6) No pharmacist shall have possession of a prescription drug sample unless such sample is for treatment of a diagnosed personal medical condition.
     - (7) Willfully and knowingly failing to maintain complete and accurate records of

all prescription drugs received, disposed of or dispensed at a permitted facility.

(8) Divulging or revealing confidential patient information to any person other than as authorized by Board regulations.

G. Termination of employees suspected of theft of pharmaceuticals or merchandise without contacting the Board prior to termination.

H. Failure to report directly to the Board, losses or suspected losses of controlled substances or prescription drugs.

I. Jeopardizing, compromising, interfering or failing to cooperate with any lawful investigation conducted by the Board or any state or federal regulatory or law enforcement agency.

J. 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.

K. 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.

L. Failure to furnish to the Board, its investigators, or representatives any information legally requested by the Board within the required time frame.

M. Failing to pay costs assessed in a disciplinary hearing as directed by a lawful order of the Board.

N. Knowingly failing to submit Prescription Monitoring Information to the Prescription Monitoring Program within the time interval prescribed.

O. The unlawful disclosure of information from the Prescription Monitoring Program. Using information obtained from the Prescription Monitoring Program for unlawful or unethical purposes.

P. Retaliation against pharmacy employees for providing information to the Board.

Q. Hindering, interfering with, or restriction the reporting of suspected unlawful activity to the appropriate authorities.

R. Failure by any representative of a permitted facility to acknowledge completion of an inspection by placement of a signature on the inspection form.

ARTICLE X DRUG PRODUCT SELECTION

When a generic equivalent drug product is available, drug product selection by the pharmacist shall be made in accordance with this regulation.

For purposes of this ARTICLE, "drug product selection" shall mean the dispensing of a generic equivalent drug product in lieu of the brand name drug product ordered by the prescriber.

1. Each prescription written in this state shall contain two signature lines, either of which, when signed by the prescriber, shall validate the prescription and, depending upon which line the prescriber's signature appears, will indicate the prescriber's approval or denial of drug product selection by the pharmacist. The two line provision of the prescription and the prescriber's approval or denial of drug product selection shall be as follows:
   A. There shall be a signature line in the lower right-hand corner of the prescription form beneath which shall be imprinted the words "Substitution Permitted".
   B. There shall be a signature line in the lower left-hand corner of the prescription form beneath which shall be imprinted the words "Dispense as Written".

      If the prescriber utilizes a prescription form which does not contain the two signature lines, the prescriber must write in his own handwriting the words "Dispense as Written", otherwise the pharmacist may select a generic equivalent drug product.

      On electronically transmitted prescriptions, the prescriber must specify if the brand name drug must be dispensed.

   The requirements of this paragraph shall not apply to the dispensing of medication for Medicaid recipients. Pharmacists must comply with current Division of Medicaid guidelines regarding the dispensing of medications for Medicaid recipients.

2. When drug product selection is made under the provisions of this ARTICLE, the purchaser shall be informed of the drug product selection.

3. If a generic equivalent drug product is available, a pharmacist may select and dispense a generic equivalent drug product when the following three conditions are present:
   A. The purchaser requests the selection of a generic equivalent drug product;
   B. The prescriber has not prohibited drug product selection;
   C. Drug product selection will result in a lower cost to the purchaser.

4. Unless the prescriber indicates that the name of the drug product shall not appear on the label of the dispensed medication container, the pharmacist, having made product selection of a drug, shall place on the label of the finished dispensed container one of the following:
   A. The proprietary name of the generic product dispensed; or
   B. The generic name of the product dispensed and the name of the manufacturer or repackager, either written in full or appropriately abbreviated.

5. In addition to the labeling described in A. and B. of the previous paragraph, the pharmacist may add a statement such as "Substituted for _____" and add to this statement the brand name of the prescribed drug product.

6. The pharmacist shall not select a generic equivalent drug product when the purchaser requests the drug product to be dispensed as ordered by the prescriber. Pharmacists must abide by Medicaid regulations concerning Brand and generic drugs for Medicaid Recipients.

7. A pharmacist may not select a drug product to substitute for a prescribed brand name drug unless such drug product is the generic equivalent of the prescribed brand name and has been manufactured under the Federal Food and Drug Administration's current Good Manufacturing Practice Regulations and meets U.S.P. or other official specifications, and has an approved New Drug Application (NDA) or Abbreviated New Drug Application (ANDA), or Antibiotic Form 5 or 6 Application approved by the U. S. Food and Drug Administration under the provisions of Section 505 and 507 of the Federal Food, Drug and Cosmetic Act (21 U.S.C.A., 301, et seq.).

   Generic equivalent drugs shall include, but not be limited to, any drug listed by the Food and Drug Administration list of therapeutically equivalent drugs as contained in APPROVED DRUG PRODUCTS.

   For purposes of this ARTICLE, the term "if available" means if the generic drug product is available in the pharmacy at the time the prescription is presented.

   Nothing in this ARTICLE shall be construed to prohibit the implementation of a drug formulary system within an institution.

ARTICLE XI STOCK CONTAINER LABELING, OUTDATED MERCHANDISE, SANITATION, DISPENSING AND STORAGE REQUIREMENTS

1. All drug products which are stored or maintained in a facility permitted by the Board of Pharmacy shall remain in the manufacturer's or repackager's original container. The label of any container in which drugs are maintained must bear the drug name, strength, the manufacturer's control lot number and the expiration date.

   Drugs which are precounted and prepackaged, or placed in automatic tablet counting machines, for purposes of dispensing shall be identifiable as to expiration date and manufacturer's control lot number. The containers in which drug products are maintained shall not be labeled in any false or misleading manner. The labeling requirements of this ARTICLE are in addition to, and not in lieu of, other labeling requirements of the laws of the state of Mississippi, rules and regulations of the Mississippi Board of Pharmacy, and laws of the United States, or federal regulations.

2. A pharmacist shall not dispense out-of-date drugs and a pharmacy shall not maintain out-of-date drugs intermixed with the stock of current drugs. Out-of-date drugs shall be promptly removed from current stock and stored separately until proper disposal shall be made.

   The Board or its representative may seize, embargo, quarantine, or place under seal, any prescription drug, controlled substance, or medical device which may constitute an imminent danger to the public health and safety.

   At the conclusion of proceedings, the Board may asses fees associated with the storage of, destruction, or disposal of any seized, embargoed, or quarantined prescription drugs, controlled substances or medical devices

   The Board may place under seal all Drugs or Devices that are owned by or in the possession, custody, or control of a licensee at the time his or her license is Suspended or Revoked or at the time the Board refuses to renew his or her license. Drugs or devices so sealed shall not be disposed of until appeal rights have expired or disposal is ordered by the Board.

3. Pharmacies shall be maintained in an orderly and sanitary fashion.

4. A pharmacist or a pharmacy shall not accept the return for subsequent resale or exchange any drug after such drug has been taken from the premises where sold, distributed or dispensed and from the control of the pharmacist.

5. All drug products shall be maintained, stored and dispensed in such a manner as to maintain the integrity of the product.

6. Unless requested not to do so, all medication dispensed in a liquid or solid dosage form shall be dispensed in child resistant packaging.

7. Disasters, accidents or emergencies which may affect the strength, purity or labeling of drugs shall be immediately reported to the Board.

8. Customized Patient Medication Packages:
   In lieu of dispensing two or more prescribed drug products in separate containers, a pharmacist may, with the consent of the patient, a patient's care giver, or the prescriber, provide a customized package, known as a patient med-pak provided:
   A. Patient med-paks shall bear a label (or labels) including all information required on a traditional prescription label. In addition, the med-pak shall bear an identification number unique to that patient med-pak, the date of preparation and the beyond-use date of the patient med-pak (not to exceed ninety(90) days from the date of preparation). If the patient med-pak allows for the removal or separation of individual cells within the med-pak, each cell shall bear a label identifying each of the drug products contained.
   B. It is the responsibility of the dispensing pharmacist when preparing the med-pak, to take into account any applicable compendia requirements or guidelines and the physical and chemical compatibility of the dosage forms placed within each cell of the med-pak, as well as any therapeutic incompatibilities that may attend the simultaneous administration of the drugs.
   C. In addition to individual prescription filing requirements, a record of each patient med-pak shall be made and filed. Each record shall contain at a minimum:
      (1) The name and address of the patient;
      (2) The unique identification number of the patient med-pak;
      (3) The prescription number for each drug product contained;
      (4) The drug name, manufacturer or distributor name and lot number of each drug product contained;
      (5) Any special labeling instructions;
      (6) Information identifying or describing the design, characteristics, or specifications of the med-pak, sufficient to allow subsequent preparation of the med-pak for the patient;
      (7) The date of preparation of the patient med-pak and the beyond-use date that was assigned; and
      (8) The name or initials of the pharmacist responsible for preparing the med-pak.

ARTICLE XII PRESCRIPTION/ORDER REQUIRED AND REFILL AUTHORIZATION/RECORD KEEPING

1. Prescription drugs shall be dispensed only pursuant to a valid prescription or a valid order. A pharmacist shall not dispense a prescription which the pharmacist knows or should know is not a valid prescription. A Prescription Drug Order, to be effective, must be issued for a legitimate medical purpose by a Practitioner acting within the course of legitimate professional practice.

   A Prescription Drug Order shall contain the following information at a minimum:
   (1) full name and street address (if required by law) of the patient;
   (2) name, address, and, if required by law or rules of the Board, DEA registration number of the prescribing Practitioner;
   (3) date of issuance;
   (4) name, strength, dosage form, and quantity of Drug prescribed;
   (5) directions for use;
   (6) refills authorized, if any;
   (7) if a written Prescription Drug Order, prescribing Practitioner's signature;
   (8) if an electronically transmitted Prescription Drug Order, prescribing Practitioner's electronic or digital signature;

2. A Prescription Drug Order must be communicated directly to a Pharmacist, or when recorded, in such a way that the Pharmacist may review the Prescription Drug Order as transmitted. A prescription/order may be accepted by a pharmacist in written form, orally, or electronically unless the order is for a Schedule II controlled substance (refer to ARTICLE XIX) of these regulations. If transmitted orally or electronically, the prescription drug order shall be filed and maintained on paper of permanent quality by the pharmacist in accordance with ARTICLE XIII of these regulations. Electronically transmitted prescription drug orders shall meet the following requirements:
   A. Electronically transmitted prescription drug orders shall meet the following criteria:
      (1) be transmitted only to the pharmacy of the patients choice; and
      (2) be transmitted by an authorized Practitioner or his or her designated agent provided that the identity of the transmitting agent is included in the order; and
   B. Prescription drug orders transmitted by facsimile or computer shall include:
      (1) The complete name, address, and DEA Registration Number of the practitioner if required;
      (2) The transmitters telephone number or any other suitable means to contact the transmitter for verbal and/or written confirmation;
      (3) The name, address, and age of the patient;
      (4) The time and date of the transmission; and,
      (5) The full name of the person transmitting the order; and
      (6) The identity of the Pharmacy intended to receive the transmission, as well as any other information required by federal or state law.
   C. An electronically transmitted drug order which meets the requirements of this

ARTICLE shall be deemed the original order.

D. The pharmacist shall exercise professional judgment regarding the accuracy, validity, and authenticity of the transmitted prescription drug order consistent with federal or state laws and rules and regulations adopted pursuant to the same.

E. An electronically transmitted prescription/order from a prescriber to a pharmacist shall be considered a highly confidential transaction and the said transmission shall not be compromised by interventions, control, change, altering or manipulation by any other person or parties in any manner whatsoever.

F. Any pharmacist that transmits, receives or maintains any prescription or prescription refill either orally, in writing or electronically shall ensure the security, integrity and confidentiality of the prescription and any information contained therein.

G. To maintain the confidentiality of patient and prescriber records, a computer system shall have security and system safeguards designed to prevent and detect unauthorized access, modification or manipulation of patient records. Once the drug has been dispensed, any alterations in prescription drug order data shall be documented to include the identification of the individual responsible for the alteration.

H. Electronic transmission of prescription orders for controlled substances must comply with DEA Regulations.

3. Pharmacists must maintain complete and accurate records of all prescription drugs received, disposed of, or dispensed at a permitted facility.

4. A prescription may not be refilled without authorization. When refills are dispensed pursuant to authorization contained on the original prescription or when no refills are authorized on the original prescription but refills are subsequently authorized by the prescriber, the refill authorization shall be recorded on the original prescription document and the record of any refill made shall be maintained on the back of the original prescription document or on some other uniformly maintained record and the dispensing pharmacist shall record the date of the refill, the quantity of the drug dispensed and his/her initials; however, an original prescription for a controlled substance which contains no refill information may not be authorized to be refilled more than five (5) times or after six (6) months from the date of issuance. Authorization for any additional refill of a controlled substance prescription in excess of those refills originally authorized or after six (6) months from the date of issuance of the prescription shall be treated as a new prescription.

5. When filling a prescription or refilling a prescription which may be refilled, the pharmacist shall exercise professional judgment in the matter. No prescription shall be filled or refilled with greater frequency than the approximate interval of time that the dosage regimen ordered by the prescriber would indicate, unless extenuating circumstances are documented which would justify a shorter interval of time before the filling or refilling of the prescription.

6. The pharmacist who fills or refills a prescription shall record the date of the dispensing and indicate his/her identity as the dispensing pharmacist on the prescription document or some other appropriate and uniformly maintained record. If this record is maintained on the original prescription document, the original dispensing and any refills must be recorded on the back of the prescription.

7. A prescription shall not be refilled after twelve (12) months from the date of issuance.

8. A prescription becomes invalid thirty (30) days after the prescriber/patient relationship is terminated. When the patient is no longer able to seek personal consultation or treatment from the prescriber the prescriber/patient relationship is terminated.

9. A written prescription document prepared by the prescriber or his agent must bear an original signature of the prescriber, facsimile stamps are not acceptable. When an oral prescription or the oral authorization for the refilling of a prescription is received which is transmitted by someone other than the prescriber, the name of the transmitter and the date of the transmission must be recorded on the original prescription document by the pharmacist receiving the transmission.

10. A pharmacist licensed by the Mississippi Board of Pharmacy may dispense a one-time emergency dispensing of a prescription of up to a seventy-two (72) hour supply of a prescribed medication in the event the pharmacist is unable to contact the prescriber to obtain refill authorization, provided that;
    A. The prescription is not for a controlled substance;
    B. In the pharmacist's professional judgment, the interruption of therapy might reasonably produce undesirable health consequences or may cause physical or mental discomfort;
    C. The dispensing pharmacist notifies the prescriber or his agent of the emergency dispensing within seven (7) working days after the one-time emergency dispensing;
    D. The pharmacist properly records the dispensing as a separate non-refillable prescription. Said document shall be filed as is required of all other prescription records. This document shall be serially numbered and contain all information required of other prescriptions. In addition it shall contain the number of the prescription from which it was refilled; and
    E. The pharmacist shall record on the new document the circumstances which warrant this emergency dispensing.

    This emergency dispensing shall be done only in the permitted facility which contains the non-refillable prescription.

ARTICLE XIII PRESCRIPTIONS TO BE FILED

1. All prescriptions shall be filed in one of the following ways:
   A. Three separate files may be maintained; a file for Schedule II prescriptions dispensed; a file for Schedule III, IV and V prescriptions dispensed; and a file for all other prescriptions dispensed.
   B. Two files may be maintained; a file for all Schedule II prescriptions dispensed and another file for all other prescriptions dispensed, including those in Schedule III, IV and V.

2. A hard copy of original prescriptions, whether records are maintained manually or in a data processing system, shall be assigned a serial number and maintained by the pharmacy in numerical and chronological order. All prescriptions shall be maintained for at least six (6) years from the date of original dispensing.

3. If a pharmacy utilizes a data processing system for record keeping, all computer generated labels should be affixed to the prescription document in such a manner as not to obscure information on the face of the document.

ARTICLE XIV LABELING REQUIREMENTS

1. Before a dispensed drug for an outpatient is released from the dispensing area, it shall bear a label containing the name and address of the pharmacy, a prescription number, the name of the prescriber, the name of the patient, directions for taking the medication, the date of the filling or refilling of the prescription, the initials or identifying code of the dispensing pharmacist and any other information which is necessary or required.

2. The pharmacist who fills a prescription shall indicate his or her identity as the dispensing pharmacist on the label of the dispensed medication. Identification may be made by placing initials on the label of the dispensed medication. The label shall be affixed to the outside of the container of the dispensed medication by means of adhesive or tape or any other means which will assure that the label remains attached to the container.

ARTICLE XV ISSUANCE AND RECEIPT OF PRESCRIPTION COPIES

1. Prescriptions for drugs which are controlled substances as defined by the Mississippi Uniform Controlled Substances Law shall not be transferred. Prescriptions for non-controlled drugs may be transferred orally by telephone or electronically by pharmacists between pharmacies for the purpose of refill dispensing provided:
   A. That in pharmacies with a manual record keeping system the transferor pharmacist invalidates the prescription on file as of the date the copy is given by writing "Void" on its face; and records on the back of the invalidated prescription order that a copy has been issued, to whom, the date of issuance of such copy and the initials of the pharmacist issuing the transferred prescription.
   B. That in pharmacies with a computerized record keeping system the transferor pharmacist records in the system a cancellation of the prescription. This cancellation shall record that a copy of the prescription has been issued, to whom it was issued, the date of issuance of such copy and the initials of the pharmacist issuing the copy. This required information must be immediately retrievable (via CRT display or hard copy printout).
   C. The transferee pharmacist, upon receiving such prescription directly from another pharmacist, records the following and enters into the data processing system:
      (1) The name and address of the pharmacy from which the prescription was transferred and the original prescription number used by that pharmacy;
      (2) The name of the transferor pharmacist;
      (3) All information constituting a prescription order, including the following:
         (a)Patient's name.
         (b)Date of issuance of original prescription and date of original dispensing.
         (c)Original number of refills authorized on original prescription;
         (d)Number of valid refills remaining.
   D. The receiving pharmacist informs the patient that the original prescription has been canceled at the pharmacy from which it was obtained.

2. Computerized systems must satisfy all requirements of paragraph 1. of this ARTICLE.

3. Presentation of a written prescription copy or label from dispensed medication shall be for information purposes only and has no legal status as a valid prescription order. The recipient pharmacist of such copy or prescription label shall contact the prescribing practitioner for authorization to dispense the prescription, which is the same as obtaining an original prescription order, or transfer the prescription in accordance with the provisions of paragraph 1. of this ARTICLE.

ARTICLE XVI REGISTRATION WITH THE BOARD TO HANDLE CONTROLLED SUBSTANCES

1. Every facility/business under the jurisdiction of the Board of Pharmacy where controlled substances are manufactured, distributed, sold, bought, dispensed, or maintained within this state or that distributes or dispenses any controlled substance into this state from an out-of-state location, or who proposes to engage in the manufacture, distribution or dispensing of any controlled substance within this state or the distribution or dispensing of any controlled substance into this state from an out-of-state location, except those persons exempted by law, shall obtain and maintain a Controlled Substance Registration issued to that facility/business by the Mississippi Board of Pharmacy. Every pharmacist or pharmacy extern/intern who dispenses controlled substances in the usual and lawful course of business within this state shall obtain and maintain a controlled substance registration issued by the Board.

2. These registrations shall be renewed annually and shall be valid for the following period of time: If the registration is issued before or during the first half of the registration period, the registration shall expire at the end of the registration period and if the registration is issued in the second half of the registration period, the registration shall expire at the end of the succeeding registration period. A fee of fifty dollars ($50.00) shall be charged for this registration or the renewal of this registration.

   Extern or intern registrations shall be valid for a period of four (4) years or until six months after graduation.

   Any controlled substance renewal application postmarked after December 31 of the renewal period shall be returned and a fifty dollar ($50.00) late renewal fee shall be assessed prior to renewal.

3. Application for issuance or renewal of a Controlled Substance Registration shall be made on a form prescribed by the Board which specifies the activities to be engaged in and the Schedules of Controlled Substances which may be manufactured, distributed, dispensed, sold, purchased, or maintained by the registrant. A registrant shall not manufacture, distribute, dispense, sell, purchase, or maintain a controlled substance not authorized by his registration.

4. The application for the issuance or the renewal of a Controlled Substance Registration for a pharmacy shall be signed by a pharmacist. If the services of a pharmacist are not required at the facility the application for the Controlled Substance Registration shall be signed by the individual who will be responsible for conducting the business activities of the facility.

5. Persons who handle controlled substances or who maintain controlled substances on the premises must be registered. This includes all facilities which do not maintain dispensing areas containing controlled substance drugs, but which do maintain controlled substances

for inpatient use at nursing stations or in emergency medication supplies.

6. The administrator or the consultant pharmacist of the nursing home may sign the application for a controlled substance registration issued by the Board. The nursing home shall have policies and procedures for the security, control, and disposal of any controlled substances at the facility. A pharmacist shall not serve as a consultant to a nursing home which does not have a Controlled Substance Registration with the Mississippi Board of Pharmacy.

7. When requested by an agent of the Board of Pharmacy, evidence of a Controlled Substance Registration issued by the Board, all controlled substances, all areas where controlled substances are maintained, and all required controlled substance records shall be made available for inspection.

ARTICLE XVII REQUIREMENTS OF CONTROLLED SUBSTANCES PRESCRIPTIONS

Before they may be dispensed by a pharmacist, all prescriptions for controlled substances shall be dated and signed on the day when issued and shall bear the name and address of the patient and the name, address and registration number of the prescriber. The prescription must bear an original signature of the prescriber, facsimile stamps are not acceptable. The signature requirement does not apply to Schedule III, IV or V prescriptions which are transmitted orally or electronically by the prescriber or his authorized agent to the pharmacist. Electronically transmitted orders for controlled substances must comply with DEA regulations.

ARTICLE XVIII DISPENSING OF CONTROLLED SUBSTANCES

1. A controlled substance in Schedule II, III, IV or V, which is a prescription drug, shall not be dispensed without a valid prescription or a valid order.

2. A controlled substance in Schedule V which is not a prescription drug may be dispensed pursuant to a valid prescription or it may be dispensed without a prescription provided that:
   A. The substance is dispensed by a pharmacist. The pharmacist shall be responsible for the record keeping of the dispensing.
   B. No more than 120cc (4 ounces) is dispensed to the same purchaser or for the same person in any given 72 hour period.
   C. No more than two (2) sales in any seven (7) day period and no more than three (3) sales in any thirty (30) day period of any non-prescription controlled substance is made to the same purchaser or made for the same person. Additional sales shall be by prescription only.
   D. The substance is dispensed bearing a label which contains the expiration date and any other information needed by the consumer for the safe and effective use of the substance.
   E. The substance is dispensed for a bona fide medical need and the purchaser furnishes information to the pharmacist which establishes a bona fide need for the controlled substance.
   F. The purchaser furnishes to the pharmacist identification which shall include the purchaser's name, address and date of birth. The purchaser must be at least eighteen (18) years of age.
   G. A bound record book is maintained which contains the name and address of the purchaser, name and quantity of controlled substances sold, date of each sale, initials of the dispensing pharmacist, and the legible signature of the purchaser. This book shall be maintained for a period of two (2) years form the date of the last transaction and must be made available for inspection and copying by agents of the Mississippi Board of Pharmacy.
3. A prescription for an anorectic and/or central nervous system stimulant classified in Schedule II which is written for the treatment of obesity is not a valid prescription.

ARTICLE XIX DISPENSING OF SCHEDULE II CONTROLLED SUBSTANCES

1. A pharmacist may dispense a Schedule II controlled substance only pursuant to a valid written prescription/order signed by the prescribing practitioner except as described as follows:
   A. When a Schedule II controlled substance is needed in a situation in which a written prescription cannot reasonably be obtained it may be considered an emergency situation and a pharmacist may dispense a Schedule II controlled substance pursuant to an oral prescription of a practitioner. A Schedule II controlled substance prescription given in this manner shall be reduced to writing by the pharmacist and shall be for a quantity of medication sufficient for the emergency period, not to exceed 48 hours. Within seven (7) days of the receipt of an oral prescription for a Schedule II controlled substance, the pharmacist shall obtain a prescription signed by the prescribing practitioner for the medication dispensed. This prescription shall be attached to the copy of the prescription prepared by the pharmacist pursuant to the prescriber's oral order.
   B. A prescription for a controlled substance in Schedule II may be transmitted from the prescribing practitioner to a pharmacy via facsimile provided the original signed prescription is presented to the pharmacist for review prior to dispensing of the controlled substance. The original prescription shall be maintained in accordance with ARTICLE XIII of these regulations.
   C. A prescription/order written for a Schedule II controlled substance to be compounded for direct administration to the patient by parenteral, intravenous, subcutaneous or intraspinal infusion may be transmitted directly from the prescribing practitioner to a pharmacy by facsimile. The facsimile serves as the original prescription for purposes of this ARTICLE and it shall be maintained in accordance with ARTICLE XIII of these regulations.
   D. A prescription/order written for a Schedule II controlled substance for a resident of a long term care facility or for a patient in a hospice certified by Medicare under Title XVIII or licensed by the state may be transmitted directly from the prescribing practitioner to a pharmacy by facsimile. The facsimile serves as the original prescription for purposes of this ARTICLE and should be filed in accordance with ARTICLE XIII of these regulations.

2. A prescription for a controlled substance in Schedule II may not be refilled. In accordance with current DEA requirements, a pharmacist may dispense up to a ninety (90) day supply of a Schedule II controlled substance pursuant to multiple prescriptions signed on the date of issuance which indicate a “DO NOT FILL BEFORE” date listed elsewhere on the prescription document. Schedule II controlled substances shall not be dispensed for a patient with greater frequency than the approximate interval of time that the dosage regimen ordered by the prescriber would indicate unless circumstances are documented which would justify a shorter interval of time. Schedule II prescriptions shall not be filled after six (6) months from the date of issuance.

ARTICLE XX PARTIAL FILLING OF SCHEDULE II PRESCRIPTIONS

1. Partial filling of Schedule II prescriptions shall be as follows:
   A. The partial filling of a Schedule II controlled substance prescription is permissible if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription. He/she may supply a part of the quantity prescribed provided he/she makes a notation of the quantity supplied on the face of the written prescription (or written record of the emergency oral prescription). The remaining quantity may be supplied within 72 hours of the first dispensing; however, if the remaining quantity is not or cannot be supplied within the 72 hour period, the pharmacist must notify the prescribing practitioner. No further quantity may be supplied on the partially filled prescription beyond the 72 hours unless:
      (1) The prescription is for a nursing home patient or for a patient who is receiving long term therapy as a home health patient or a patient who is terminally ill as defined by the Federal Health Care Financing Administration (42 CFR 418.3). If such a prescription is partially filled, the pharmacist must record on the back of the prescription or on another appropriate uniformly maintained record the date of each partial filling, the quantity dispensed, the remaining quantity authorized to be dispensed, the remaining quantity authorized to be dispensed and the identity of the dispensing pharmacist. All partial filling of the prescription must be completed within 50 days of the date of issuance of the prescription.

ARTICLE XXI SCHEDULE III, IV AND V PRESCRIPTIONS NOT TO BE FILLED AFTER SIX MONTHS

A prescription for a controlled substance in Schedules III, IV and V may not be filled or refilled after six (6) months from the date of issuance of the prescription or be refilled more than five (5) times for the full amount prescribed.

ARTICLE XXII RECORDING REFILLS AND PARTIAL FILLING OF SCHEDULE III, IV, AND V PRESCRIPTIONS

1. Partial filling or refilling of prescriptions for controlled substances in Schedules III, IV, or V is permitted provided the pharmacist filling or refilling the prescription sets forth the quantity dispensed, the date and his/her initials or identifying code as the dispensing pharmacist on the prescription or on some other uniformly maintained record system. If a manual record is maintained on the original prescription document, the original dispensing and any refill must be recorded on the back of the prescription. The total quantity of dosage units authorized on the prescription may be dispensed by partial filling or refilling of the prescription provided the dispensing is done within six (6) months of the date the prescription was issued.

2. If the pharmacist records the refill without specifying the quantity of drug dispensed, he/she shall be deemed to have dispensed a refill for the full face amount of the prescription.

ARTICLE XXIII RECORD KEEPING ON CONTROLLED SUBSTANCES

1. Every facility permitted by the Board of Pharmacy shall keep complete and accurate records of the acquisition and disposition of all controlled substances. Records of acquisition must be maintained for a period of two (2) years. Records of disposition must be maintained for a period of six (6) years.

   These records shall include:
   A. A current dated and signed inventory of all controlled substances on hand on the inventory date;
   B. Complete and accurate records of receipt of all controlled substances;
   C. Complete and accurate records of ~~disposal~~ disposition of all controlled substances.

   These records shall be kept in such a manner that an audit will show the beginning inventory and record of acquisition of controlled substances to balance with the controlled substances on hand and the record of disposition of controlled substances.

2. Unless authorized by the Federal Drug Enforcement Administration to maintain records of controlled substances at a location other than the location permitted by the Mississippi Board of Pharmacy, these records shall be maintained at the permitted location. All records pertaining to controlled substances shall be made available for inspection and copying by agents of the Mississippi Board of Pharmacy. A pharmacy may use a data processing system or a manual record keeping system for the storage and retrieval of all prescription order information. A hard copy of original prescriptions, whether records are maintained manually or in a data processing system, shall be maintained and filed in accordance with the provisions of ARTICLE XIII of these regulations.

   All records of controlled substances in Schedule II shall be maintained separately from all other records of the registrant. All records of controlled substances in Schedule III, IV and V, whether maintained manually or in a data processing system, shall be maintained separately or in such a manner that they are readily retrievable from the other business records. Invoices for controlled substances shall be dated and initialed by the person receiving the order.

3. If a pharmacy utilizes a data processing system it must provide immediate retrieval of original prescription order information for those prescription orders which are currently authorized for refilling and of the refill history for the past six months for controlled substances prescription orders. The data processing system must have the capability of producing a hard copy printout of this information. The data processing system must also have the capability of producing a hard copy printout of all dispensing information required to be kept by the pharmacy, including an audit trail for any specified strength and dosage form of any controlled substance either by brand name or generic name or both for any time period in the prior two (2) years. The audit trail specified by this Article must be produced on verbal or written request of any Compliance Agent of the Board. Failure to

produce and provide this audit trail within twenty-four (24), constitutes prima facie evidence of failure to keep and maintain records as defined in paragraph 1., C., of this ARTICLE.

The records of controlled substances in Schedules II, III, IV and V, which are maintained in a data processing system shall be maintained as follows:

A. The following information pertaining to the initial dispensing of the prescription shall be entered into the data processing system:
   (1) Prescription number;
   (2) Date of initial dispensing;
   (3) Name and address of patient;
   (4) Prescribing practitioner's name and DEA registration number;
   (5) The name, strength, dosage form and quantity of the controlled substance ordered and dispensed;
   (6) Total number of refills authorized; and,
   (7) The initials or identifying code of the dispensing pharmacist.

B. Additionally, the following information pertaining to the refilling of the prescription shall be maintained by the data processing system:
   (1) The date of the refill dispensing, and the total number of refills dispensed to date, or the total number of refills remaining for that prescription order; and,
   (2) The initials or identifying code of the dispensing pharmacist;

4. A permanent record of the dispensing of all controlled substances shall be made and maintained as follows:

A. Each time a prescription is filled or refilled a record of such filling shall be entered into the data processing system. A hard-copy printout containing only the dispensing record of original filling of Schedule II controlled substance prescriptions and the record of original filling and the refill history for Schedule III, IV or V controlled substance prescription orders shall be produced daily, or at regular intervals, not to exceed seven (7) days. These hard-copy printouts shall be filed chronologically and stored in an orderly manner in a separate file at the pharmacy and be maintained for a two-year period from the date of the last dispensing. The hard-copy printout shall include:
   (1) Prescription number;
   (2) Name of the patient;
   (3) The prescribing practitioner's name;
   (4) The name, strength, dosage form and quantity of the controlled substance dispensed;
   (5) Number of refills originally authorized;
   (6) Date of initial dispensing if an original prescription or if a refill, the date of refilling and the date of initial dispensing, and the total number of refills dispensed to date or the total number of refills remaining for that prescription order; and,
   (7) The initials or identifying code of the dispensing pharmacist.

(8) Hard copy printouts shall only contain information regarding prescriptions dispensed.

B. The hard copy printout containing the information required by this paragraph shall be signed and dated by the pharmacist who produces the printout. The signature of the pharmacist on the printout shall serve as verification by that pharmacist that the information contained on the printout is complete.

5. A record of all controlled substance dispensing information shall be transmitted to the Prescription Monitoring Program on a time basis determined by the program by all pharmacies dispensing controlled substances (greater than a 48 hours supply) on an out-patient basis for the purpose of tracking the dispensing of Schedules II, III, IV and V controlled substances by the Prescription Monitoring Program. Dispensers will be required to collect and transmit the following information:

(A) The recipient's name.
(B) The recipient's or the recipient representative's identification number.
(C) The recipient's date of birth.
(D) The national drug code (NDC) number of the controlled substance dispensed.
(E) The date the controlled substance is dispensed.
(F) The quantity of the controlled substance dispensed.
(G) The number of days supply dispensed.
(H) The dispenser's NABP or NCPDP registration number.
(I) The prescriber's U. S. DEA registration number.
(J) The method of payment of the prescription purchase.

6. Records of controlled substances in Schedule III, IV and V which are maintained manually shall be maintained as follows:

A. A pharmacist, who fills or refills a prescription for a controlled substance in Schedule III, IV or V, must enter on that prescription or some other uniformly maintained record system, his/her initials or identifying code as the dispensing pharmacist, the date the prescription was filled or refilled and the quantity of the controlled substance dispensed if different from the original quantity prescribed.

If this record is maintained on the original prescription document, the original dispensing must be recorded on the face of the prescription and any refills must be recorded on the back of the prescription.

B. Original prescription documents shall be filed and maintained in accordance with the provisions of ARTICLE XII of these regulations.

For purposes of this ARTICLE, "hard-copy" means a physical document that is readable without the use of a special device (i.e., cathode ray tube, microfiche reader, etc.).

ARTICLE XXIV SECURITY OF CONTROLLED SUBSTANCES

1. In all places where controlled substances are maintained, they shall be maintained in a manner to deter loss by theft or burglary. When a person who has a controlled substances registration with the Board of Pharmacy has a loss of controlled substances, the Board may issue an order to that person to appear before the Board to present a plan to the Board designed to prevent further loss of controlled substances or he/she may be ordered by the Board to implement any other reasonable measure to improve security on controlled substances deemed necessary by the Board to prevent further loss of controlled substances.

2. Storage of controlled substances shall be as follows:
   A. In a pharmacy, storage of controlled substances in any schedule may be made in a securely locked, substantially constructed container or area; or they may be dispersed throughout the stock of non-controlled substances in such a manner as to obstruct the theft or diversion of the controlled substances; or they may be stored by a combination of these methods.

      When an institutional pharmacy dispensing area is closed and the permitted location is accessible to non-pharmacist personnel all controlled substances must be stored in a securely locked, substantially constructed container or area. Only the pharmacist or person authorized by the pharmacist shall have access to this storage area. Authorization for access to this controlled substances storage area may be granted by the pharmacist in accordance with written policy of the pharmacy department of the facility.
   B. In a nursing home or other institution which does not maintain a pharmacy, a securely locked, substantially constructed area shall be provided for storage of all controlled substances. Controlled substances left by the death or discharge of a patient shall be maintained in the drug storage area of the institution until proper disposition of such controlled substances is made. Controlled substances thus maintained in the drug storage area shall be kept in a locked cabinet, drawer, or other suitable locked container and only the consultant pharmacist or a person designated by the consultant pharmacist shall have access to the container.
   C. Expired medication must be secured.

ARTICLE XXV INVENTORY REQUIREMENTS FOR CONTROLLED SUBSTANCES

1. If a facility has a loss of controlled substances, a complete inventory of all remaining controlled substances shall be made within forty-eight (48) hours of discovery of the loss of controlled substances. This inventory shall be dated and signed by the pharmacist conducting the inventory. Any loss or suspected loss of controlled substances shall be reported directly to the Mississippi Board of Pharmacy immediately upon discovery and a written report made to the Mississippi Board of Pharmacy within fifteen (15) days; this written report shall include a copy of the inventory required by this ARTICLE.

2. When a facility has a change in ownership or a change in pharmacist-in-charge, or is permanently closed, a complete inventory shall be made of all controlled substances at the time of the change. A copy of this inventory shall be kept with other records of controlled substances in the facility and a copy shall be sent to the office of the Board of Pharmacy. When a facility is permanently closed, the pharmacist-in-charge shall notify the Board in writing within fifteen (15) days by what means and as to whom controlled substances were transferred or disposed of.

3. Every facility permitted by the Mississippi Board of Pharmacy shall take an annual inventory of all controlled substances on hand on or about May 1 but no later than May 15 ~~on May 1~~, or at such a time as to be in compliance with the inventory requirements of the Federal Drug Enforcement Administration. This inventory shall be maintained with the other controlled substance records of the facility.

ARTICLE XXVI DISPOSAL OF CONTROLLED SUBSTANCES

1. Any registrant of the Board authorized to possess controlled substances in the course of their professional practice or the course of their business may dispose of any expired, excess or unwanted controlled substances by contacting and utilizing the services of a reverse distributor as defined by the Federal Drug Enforcement Administration. Any such reverse distributor must hold a valid Certificate of Registration Number issued by the Federal Drug Enforcement Administration and the Mississippi Board of Pharmacy. All records of the disposal of controlled substances shall be maintained for a period of two (2) years.

2. An institution permitted or registered by the Mississippi Board of Pharmacy in which controlled substances are administered to patients, may make on-premises destruction of controlled substances provided:
   A. The controlled substance is the remainder of a prepackaged single dosage unit or unit of use.
   B. At least part of the unit dose or unit of use was administered.
   C. The destruction is recorded showing:
      (1) The name of the drug;
      (2) The amount of the drug which was administered and the amount of the drug which was destroyed;
      (3) The time and the date of destruction;
      (4) The name of the patient;
      (5) The room number of the patient;
      (6) The name of the person administering the drug;
      (7) The signature of the person (pharmacist or nurse) making the destruction;
      (8) The signature of a second person who witnessed the destruction.
   D. The record of the destruction is maintained by the facility.
   E. A single dosage unit or any unit of use of a controlled substance which (1) is broken, (2) becomes contaminated, (3) or for any reason cannot be used, must be returned to the control of the pharmacy for proper disposal. When it is not possible to return a broken or contaminated or unwanted dosage unit or unit of use to the pharmacy, documentation of the loss may be substituted. Broken or contaminated single dosage units or units of use returned to the pharmacy for destruction may be destroyed on premise provided the destruction is documented.

3. If for any reason a registrant is unable to dispose of excess or undesired stock of controlled substances under other provisions of this ARTICLE, the registrant may contact the Board of Pharmacy and the disposal shall be made as follows:

   An agent of the Pharmacy Board shall obtain an inventory of the controlled substances to be disposed of and make two (2) copies of this inventory. The first copy of this inventory shall be retained by the Pharmacy Board; the second copy shall be given to the registrant. After complying with this inventory requirement, the agent of the Pharmacy Board shall

take possession of the controlled substances. The controlled substances thus taken by the Pharmacy Board Agent shall be placed in a sealed container and labeled with the date and the name and address of the registrant and stored by the Board of Pharmacy until such time as they are disposed.

4. Except as provided for in this ARTICLE, no controlled substance may be destroyed or disposed of by a registrant without written permission of the Regional Director of the Federal Drug Enforcement Administration.

ARTICLE XXVII NUCLEAR/RADIOLOGIC PHARMACY

In addition to all other applicable sections of the Mississippi Code of 1972, ARTICLE XXVII of the Mississippi Board of Pharmacy Regulation pertains specifically to nuclear pharmacy and radiopharmaceuticals.

1. DEFINITIONS

   A. Authentication of product history means, but is not limited to, identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical;
   B. A nuclear pharmacy is a pharmacy providing the services of storing, compounding, dispensing, labeling or distributing radiopharmaceuticals;
   C. Practice of Nuclear Pharmacy means a patient-orient service that embodies the scientific knowledge and professional judgment required to improve and promote health through the assurance of the safe and efficacious use of radiopharmaceuticals and other related drugs.
   D. A qualified licensed professional means an individual (such as a physician, nurse, or technologist) who possesses a current state license if applicable, and who has sufficient training and experience to safely handle radiopharmaceuticals as defined by the Mississippi State Department of Health, Division of Radiological Health;
   E. A qualified nuclear pharmacist means a currently licensed pharmacist in the state of Mississippi who is certified by the Mississippi State Department of Health, Division of Radiological Health, or who meets the following standards:
      (1) Minimum standards of training for "authorized user status" of radioactive materials as defined by Mississippi State Department of Health, Division of Radiological Health;
      (2) Completed a minimum of two hundred (200) contact hours of instruction in nuclear pharmacy and the safe handling and the use of radioactive materials from a program approved by the Mississippi Board of Pharmacy, and United States Nuclear Regulatory Commission or Agreement State Agency, with emphasis in the following areas:
         (a)Radiation Physics and Instrumentation;
         (b)Radiation Protection;
         (c)Mathematics of Radioactivity;
         (d)Radiation Biology;
         (e)Radiopharmaceutical Chemistry.
      (3) Attain a minimum of five hundred (500) hours of clinical nuclear pharmacy training under the supervision of a qualified nuclear pharmacist.
   F. Nuclear pharmacy technician means a person who works under the supervision of a qualified nuclear pharmacist and who is currently registered with the Mississippi Board of Pharmacy. The duties and responsibilities of these personnel must be consistent with their training and experience.

G. Radiopharmaceutical is any substance defined as a drug in Section 201(g) (1) of the Federal Food, Drug and Cosmetic Act which also contains unstable nuclei which undergo spontaneous disintegration with the emission of nuclear radiation. Radiopharmaceuticals also include any non-radioactive reagent kit or radionuclide generator which is intended to be used in the preparation of radiopharmaceutical doses.

H. Radiopharmaceutical Service means, but shall not be limited to the procurement, storage, handling, compounding, quality control testing, dispensing, delivery, recordkeeping, and disposal of radiopharmaceutical and other drugs as well as quality control procedure, radiological health activities, any consulting activities associated with the use of radiopharmaceuticals, health physics and any other activities required for provision of pharmaceutical care.

I. Radiopharmaceutical Compounding means the preparation, mixing assembling, packaging, or labeling of a reagent kit or biological substance with radioactivity.

J. Radiopharmaceutical quality control means, but is not limited to, the performance of appropriate chemical, biological and physical tests on potential and prepared radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans or animals.
Assurance that variances in the processes are clearly identified, assessed and improved upon if necessary is required for adequate quality control. All quality control procedures must be a set of planned, defined and systematic activities to provide adequate confidence that the product optimally fulfils professional expectations and requirements.

K. The restricted area of a Nuclear Pharmacy is an area with limited access for the purpose of protecting individuals against the undue risks from exposure to radiation and radioactive materials. Generally, the restricted area(s) consists of the compounding/dispensing area, radioactive material storage area and radioactive dose return or breakdown area.

2. NUCLEAR PHARMACY STANDARDS AND EQUIPMENT

Written procedures and policy showing proof of adequate space and equipment for all operations involving radioactive material must be submitted to the Mississippi Board of Pharmacy along with a certified copy of the RADIOACTIVE MATERIAL LICENSE issued by the Mississippi State Department of Health, Division of Radiological Health, before a permit to operate as a Nuclear Pharmacy is issued.
Compliance with applicable radiation protection regulations of the Mississippi State Department of Health, Division of Radiological Health, is further required. Violation of rules and regulations established by the Mississippi State Department of Health, Division of Radiological Health, that directly affects public health and safety, shall serve as prima facie evidence of violation of this ARTICLE.

The restricted area of a nuclear pharmacy shall have at least the following supplies and equipment:

A. Radiation detection and measuring instruments capable of accurately measuring quantities of radioactivity and radiation; and
B. Refrigerator, microscope and a hemacytometer; and
C. Radiochemical fume hood and filter system with suitable air sampling equipment if storing or dispensing volatile substances; and
D. Laminar air flow hood and appropriate supplies to ensure sterile practices for parental solutions; and
E. Syringes, vials, filters and other necessary supplies needed to compound and dispense any oral or sterile parenteral drug product; and
F. Adequate shielding for syringes vials drawing stations and returned dose storage area: and
G Materials needed for decontamination; and
H. All supplies needed to perform quality control ~~assurance~~ testing; and
I. Appropriate shielding for the transportation of D. O. T. approved outer transport containers; and
J. Required labels and other supplies for proper shipment of radioactive material.

A pharmacy exclusively handling radiopharmaceuticals may be exempt from the general requirements of conventional pharmacies as regards to equipment and inventory.

3. OPERATION OF A NUCLEAR PHARMACY

A. Nuclear Pharmacy License. A license to operate a pharmacy providing radiopharmaceutical services shall only be issued to a qualified nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radioactive drugs shall be under the direct supervision of a qualified nuclear pharmacist. A qualified nuclear pharmacist shall be responsible for all operations of the pharmacy.
B. Nuclear pharmacies shall have adequate space and equipment, commensurate with the scope of services required and provided.
C. The nuclear pharmacy restricted area shall be secured from unobserved entry and/or unauthorized personnel.
D. Nuclear pharmacies shall maintain complete and accurate records of acquisition, inventory, and disposition of all radioactive drugs and other radioactive materials, in accordance with guidelines established by the Mississippi State Department of Health, Division of Radiological Health.
E. All pharmacies handling radiopharmaceuticals shall provide a radioactive storage and product decay area in accordance with guidelines established by the Mississippi State Department of Health, Division of Radiological Health.
F. Radiopharmaceuticals are to be dispensed only upon receipt of a prescription drug order, from a licensed practitioner or his agent. Validation that he is authorized to possess, use or administer radiopharmaceuticals is required.
G. Nuclear pharmacies shall, in addition to this ARTICLE XXVII and the Mississippi State Department of Health, Division of Radiological Health's applicable regulations, comply with any applicable requirements of other governing agencies regarding its

daily operations and the disposal of any biohazardous medical waste.

4. DISPENSING OF RADIOPHARMACEUTICALS

Radiopharmaceuticals shall be dispensed/transferred only to a licensed practitioner authorized by the Nuclear Regulatory Commission and/or the Mississippi State Department of Health, Division of Radiological Health to possess, use and administer such drug. A radiopharmaceutical shall be dispensed for medical use only upon receipt of a prescription or medication order from such authorized practitioner. Otherwise, a radiopharmaceutical may be transferred to a person who is authorized by federal or state law to possess and use such drug for non-medical applications. All prescriptions/orders shall be readily retrievable if requested by any governing agency.

A nuclear pharmacy, upon receiving an oral prescription order for a radiopharmaceutical, shall have the prescription order reduced to writing or recorded in a data processing system, which the written or electronic record shall contain at least the following:

A. The name of the institution and prescriber or if applicable the prescriber's agent;
B. The date of dispensing and the calibration time of the radiopharmaceutical;
C. The name of the procedure;
D. The name of the radiopharmaceutical;
E. The activity of the dose or quantity of the radiopharmaceutical;
F. The serial number assigned to the order for the radiopharmaceutical;
G. Any specific instructions; and
H. The initials of the pharmacist who dispensed the order.

Whenever an order is for a therapeutic or blood-product radiopharmaceutical, the patient's name must be obtained and recorded prior to dispensing.

The immediate outer container transportation shield of a radiopharmaceutical to be dispensed shall be labeled with:

A. The name and address of the pharmacy and prescriber;
B. Activity dispensed, expiration date and time, calibration time, serial number and date of dispensing;
C. The standard radiation symbol and the words "Caution Radioactive Material";
D. The name of the procedure and the radiopharmaceutical, including pharmacy oot number associated with dose;
E. If a liquid, the volume, if a gas, the number of ampules or vials and if a solid, the number of items or weight;
F. Molybdenum 99 content to USP limits (<0.15 mCi Mo-99 per 1.0 mCi Tc 99m at time of administration or expiration); and
G. The name of the patient or the words "per physician order" in the absence of a patients name.

When the prescription is for a therapeutic or blood product radiopharmaceutical, the

patient's name shall appear on the label. The requirements of this subsection shall be met when the name of the patient is readily retrievable from the physician upon demand.

The immediate inner container label of a radiopharmaceutical to be dispensed shall be labeled with:

A. Identity of the radiopharmaceutical and the serial number;
B. The standard radiation symbol and the words "Caution Radioactive Material";
C. The chemical form; and
D. The name of the procedure and date dispensed.

For a radiopharmaceutical intended for a specific patient, the immediate inner container shall be labeled with:

A. The standard radiation symbol and the words, "Caution - Radioactive Material";
B. The prescription number and name of patient;
C. Identity and activity or quantity, of the radiopharmaceutical.

When a radiopharmaceutical is dispensed under the authority of an Investigational New Drug Application (IND) the nuclear pharmacy records shall include an investigator's protocol for the preparation of the radiopharmaceutical, a copy of the Institutional Review Board approval form or letter, and a letter from the manufacturer (sponsor) indicating that the physician requesting the radiopharmaceutical is a qualified investigator.

ARTICLE XXVIII REGULATIONS FOR PREPARATION OF STERILE PHARMACEUTICALS

Every facility under the jurisdiction of the Mississippi Board of Pharmacy shall comply with the following regulations relating to the preparation, labeling, and distribution of sterile pharmaceuticals.

1. POLICY AND PROCEDURE MANUAL

Each facility shall develop and maintain a policy and procedure manual. This manual shall be reviewed and revised on an annual basis and be available for inspection by an agent of the Board of Pharmacy. This manual shall include policies and procedures as necessary for:

A. Clinical services;
B. Cytotoxics handling, storage, disposal and spills;
C. Disposal of unused supplies and medications;
D. Drug destruction and returns;
E. Drug dispensing;
F. Drug labeling-relabeling;
G. Drug storage;
H. Duties and qualifications for professional and non-professional staff;
I. Equipment;
J. Handling of infectious wastes;
K. Infusion devices and drug delivery systems;
L. Investigational drugs;
M. Obtaining a protocol on investigational drugs from the principal investigator;
N. Public safety;
O. Quality assurance procedures to include:
    (1) Recall procedures;
    (2) Storage and dating;
    (3) Educational procedures for professional staff, non-professional staff and patient;
    (4) Sterile procedures to include a record of the routine maintenance and report of hood certification;
    (5) Sterility testing.
P. Record keeping;
Q. Reference materials;
R. Sanitation;
S. Security;
T. Sterile product preparation procedures;
U. Transportation.

In facilities permitted by the Mississippi Board of Pharmacy the Policy and Procedure Manual shall, except in emergency situations, require that all sterile pharmaceuticals be prepared using the appropriate hood. Such hood shall be inspected and certified at least annually by a qualified technician.

2. PHYSICAL REQUIREMENTS

A. Space:
The facility shall have a designated area with entry restricted to designated personnel for preparing compounded sterile products. This area shall be designed to avoid unnecessary traffic and airflow disturbances from activity within the facility. This designated area shall be used only for the preparation of these specialty products. It shall be of sufficient size to accommodate a laminar airflow hood and to provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation, and security.

B. Equipment:
The facility shall have:
(1) Appropriate environmental control devices capable of maintaining at least Class 100 conditions in the work space where critical objects are exposed and critical activities are performed; furthermore, these devices are capable of maintaining Class 100 conditions during normal activity. Examples of appropriate devices include laminar airflow hoods and zonal laminar flow of HEPA - filtered air;
(2) Sink with hot and cold running water which is convenient to the compounding area for the purpose of hand scrubs prior to compounding;
(3) Appropriate disposal containers for used needles, syringes, etc., and if applicable for cytotoxic waste from the preparation of chemotherapy agents, and infectious wastes;
(4) When cytotoxic drug products are prepared, appropriate environmental control also includes appropriate biohazard cabinetry;
(5) Refrigerator/Freezer with a thermometer;
(6) Appropriate delivery container including temperature controlled container when needed;
(7) Infusion devices, if appropriate.

C. Supplies:
The facility shall maintain:
(1) Disposable needles, syringes, and other supplies needed for aseptic admixture;
(2) Disinfectant cleaning solutions;
(3) Hand washing agent with germicidal action;
(4) Disposable, lint free towels or wipes;
(5) Appropriate filters and filtration equipment;
(6) Disposable masks, caps, gown, and sterile disposable gloves if applicable.

D. Security:
The facility shall provide adequate security for all drugs and shall comply with requirements of other ARTICLES of these regulations relative to security on controlled substances.

E. Reference Library:
The facility shall have adequate reference materials related to the preparation, labeling, and distribution of sterile products. Some suggested sources include;

Handbook on Injectable Drugs (ASHP)
King's Guide to Parenteral Admixtures
USP/NF
American Hospital Formulary Service
Procedures for Handling Cytotoxic Drugs (ASHP)

The pharmacy shall have copies of applicable state and federal laws and OSHA requirements.

3. PERSONNEL

A. Pharmacist In Charge: Each facility shall be supervised by a pharmacist who is licensed to practice pharmacy in this state and who is knowledgeable in the specialized functions of preparing and dispensing compounded, sterile pharmaceuticals, including the principles of aseptic technique and quality assurance. This knowledge may be obtained through residency training programs, continuing education programs, or experience in an IV admixture facility. The pharmacist-in-charge shall be responsible for the purchasing, storage, compounding, repackaging, dispensing, and distribution of all drugs and pharmaceuticals. He/she shall also be responsible for the development and continuing review of all policies and procedures, training manuals, and the quality assurance programs, as well as participation in those aspects of the facility's patient care evaluation program relating to pharmaceutical material utilization and effectiveness. The pharmacist-in-charge may be assisted by additional pharmacists adequately trained in this area of practice.

B. Pharmacy Technicians: The pharmacist-in-charge may be assisted by pharmacy technicians. The duties and responsibilities of these personnel must be consistent with their training and experience.

C. Staffing: A pharmacist shall be accessible at all times at each facility to respond to patients and other health professionals questions and needs.

4. DRUG DISTRIBUTION AND CONTROL

A. Drug Orders: The pharmacist must receive a written, electronic or verbal order from an authorized prescriber before dispensing any compounded, sterile products.
If the drug order is for an inpatient in an institutional facility, a copy of the patient's

medication order may serve as an order for the preparation and dispensing of the sterile product. This and the record of administration as recorded on the medication administration record may be maintained as the permanent record in medical records at the facility. Sterile products prepared for inpatient administration shall be labeled, stored and delivered in accordance with written policy and procedure which comply with all requirements of The Joint Commission on Accreditation of Health Care Organizations or the Mississippi State Department of Health.

If the drug order is for an outpatient, the order must be in the form of a prescription document or a patient medication order sheet which contains, at a minimum, the following:

(1) Patient name;
(2) Patient address;
(3) Name of IV medication and strength and amount of additives;
(4) Directions for use;
(5) Date;
(6) Prescriber's name;
(7) Physician's address and Drug Enforcement Administration registration number, if applicable;
(8) Refill instructions.

B. Records required to be maintained: Prescriptions for sterile products shall be filed in accordance with the provisions of ARTICLE XII of these regulations. Patients medication order sheets used as authorization for the dispensing of drugs shall be filed in an easily retrievable manner.

Additionally, a facility which dispenses outpatient prescriptions for sterile products shall produce and maintain a patient profile or medication record system which is separate from the prescription file and/or file of patient medication order sheets. The patient profile or medication record system shall be maintained for a period of two (2) years from the date of the last dispensing. The patient profile or medication record system shall contain, at a minimum:

(1) Patient's name;
(2) Date of birth or age;
(3) Weight;
(4) Sex;
(5) Sterile products dispensed;
(6) Date dispensed;
(7) Drug content and quantity;
(8) Patient directions;
(9) Identifying number;
(10) Identification of dispensing pharmacist;
(11) Complete record of other drugs patient is receiving;
(12) Known drug sensitivities and allergies to drugs and foods;
(13) Primary diagnosis, chronic conditions.

It shall be the responsibility of the pharmacist-in-charge to ensure that the patient profile or medication record is monitored in accordance with provisions of ARTICLE VIII of these regulations.

C. Labeling: Each sterile pharmaceutical dispensed for an outpatient shall bear a label with the following information:
   (1) Name and address of the facility;
   (2) Date and identifying number;
   (3) Patient's name;
   (4) Name of medication and strength, and amount of additives;
   (5) Directions for use, including infusion rate;
   (6) Prescriber's name;
   (7) Date of compounding;
   (8) Expiration date and time;
   (9) Identity of pharmacist responsible for compounding and dispensing;
   (10) Storage requirements;
   (11) Auxiliary labels, where applicable.

D. Storage and Delivery: The pharmacist-in-charge shall be responsible for the proper storage in the pharmacy of all sterile pharmaceuticals after they are compounded. It shall be the responsibility of the pharmacist-in-charge to assure that all sterile pharmaceuticals dispensed as outpatient prescriptions are shipped or delivered to the patient in appropriate temperature controlled (as defined by USP Standards) delivery containers and stored appropriately in the patient's home. The pharmacist-in-charge shall also be responsible for security on controlled substance prescriptions until delivered to the patient's home.

E. Disposal of Infectious Wastes: The pharmacist-in-charge is responsible for assuring that there are written policies and procedures for safe collection and disposal of any medical or infectious waste resulting from the dispensing of sterile products. These policies and procedures shall extend to any location where sterile products are administered.

5. CYTOTOXIC MEDICATION

A. Additional Requirements: To insure the protection of personnel involved, the pharmacist-in-charge shall assure that the following requirements are met in facilities that prepare cytotoxic medications;
   (1) All cytotoxic medications should be compounded in a vertical flow, Class II, biological safety cabinet;
   (2) Disposal of cytotoxic waste shall comply with all applicable local, state and federal requirements;
   (3) Prepared doses of cytotoxic medications must be dispensed, labeled with proper precautions inside and outside, and shipped in a manner to minimize the risk of accidental rupture of the primary container.

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) 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 (2) 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 XXX INSTITUTIONAL/LONG TERM CARE FACILITIES (LTCF)

A. CONSULTING PHARMACISTS TO INSTITUTIONAL (LTC) FACILITIES

1. Unless specifically authorized by the Board to do so, no person shall serve as a consultant pharmacist or act or purport to act in this capacity to any institutional facility unless he/she possesses the following qualifications:
   A. Have and maintain a license to practice pharmacy within the State of Mississippi;
   B. Have attended within the last two years a training course of not less than eight (8) hours in institutional pharmacy services that has been approved by the Board of Pharmacy;
   C. In order to be approved by the Board of Pharmacy, the training course for a consultant pharmacist to an institutional facility shall provide instruction in the areas of clinical pharmacy services, drug distribution systems and state and federal pharmacy regulations governing the practice of institutional pharmacy.

2. For purposes of this ARTICLE a Consultant Pharmacist shall mean a Mississippi licensed pharmacist who is responsible for developing, coordinating and supervising pharmaceutical services on a regularly scheduled basis in an institutional facility as well as the following responsibilities.

   A. Reviewing policies and procedures regarding the distribution and storage of medications within the facility and as necessary making recommendations to the facility and provider pharmacist;
   B. Monitoring utilization and therapeutic response of medications prescribed for and administered to residents of the facility as well as providing consultation on matters related to medications;
   C. Serving as a resource for pharmacy related educational services within the facility;
   D. Communication and discussion with the provider pharmacist regarding areas of concern and resolution thereof;
   E. Serving on appropriate committees;
   F. Supervising and assisting in the disposal of all discontinued, expired or otherwise un-needed controlled substance medications;
   G. Reviewing records of the destruction of all medications and verification of the reasons for destruction;
   H. Ensuring that complete and accurate records of the acquisition and disposition of controlled substance medications which have been dispensed for residents of the institutional facility are maintained;
   I. Attending, within the last two (2) years, a consultant pharmacist seminar which has been approved by the Board;
   J. Maintain consultant pharmacist eligibility as described in Section 1.

3. A Long Term Care Facility which is permitted by the Board and where the services of a consultant pharmacist are required shall have the following responsibilities:

A. Policy Manual. The institution shall develop policies and procedures regarding pharmacy services which includes, but is not limited to proper labeling of patient medications and emergency drugs, security of patient medications and emergency drugs, administration and controlled substances record-keeping and accountability. This procedural manual shall be the responsibility of the institution and is to be promulgated with the concurrence of the consultant pharmacist, nursing home administrator and the directors of medical and nursing services.

B. Reference. Reference materials shall be located in the nursing stations(s) and contain current editions of appropriate reference materials as may be deemed necessary by the consultant pharmacist and the medical and nursing directors.

C. Reporting. The institution shall establish policies and procedures which assures that all medication errors and adverse drug reactions are reported immediately to the patient's physician and the consultant pharmacist and an entry made in the patient's record. These procedures should assure that corrective measures are implemented. The consultant pharmacist should be notified within twenty-four (24) hours of discovery of any discrepancy in counts or of a loss of any controlled substances. The consultant pharmacist should notify the Board immediately upon his/her notification with a plan to investigate the loss.

D. Emergency Medication Kits. The institution shall establish policies and procedures which assure that the institution is in compliance with ARTICLE XXXV INSTITUTIONAL EMERGENCY MEDICATION KIT PERMITS of these Pharmacy Practice Regulations.

E. Disposal of Patient Medication. The Long Term Care Facility, with the assistance of the consultant pharmacist shall establish policies and procedures which assures the proper disposal of any discontinued, expired, or otherwise unwanted patient medications. Policies and procedures should ensure that any medication, removed subject to destruction, does not have a current valid order for the medication on the patient's medication profile. Policies and Procedures for disposal of these medications should include as follows:

(1) All unwanted patient medications should remain in a secured location at the institution until proper disposal is made; and

(2) Documentation of any disposal of patient medications should include a paper trail from the time the medication was logged into the discontinued ~~patient~~ drug storage area until destruction is made. This paper trail shall include a log containing the patient name, medication and strength, and quantity to be destroyed as well as the initials of the person logging in the medication for destruction. This documentation should be stored at the institution and be readily retrievable for inspection by Board Agents for a period of two (2) years; and

(3) Discontinued and unwanted patient medications should be destroyed on a timely basis not to exceed ninety (90) days from the date that the medication was discontinued. Any such destruction should be performed by two licensed personnel and documented for their signatures.

4. A consultant pharmacist shall document communication of the findings of his/her reviews to the attending physician and director of nursing along with their response and maintain these records for a period of two (2) years. A copy of these reviews must be maintained at the facility and available for inspection.

B. UNIT DOSE DISPENSING SYSTEMS FOR (LTCF)

Definitions: For the purpose of this ARTICLE XXX, the following definitions apply:

A. "Provider pharmacist, means a pharmacist licensed to practice pharmacy by the Board who is responsible for supervising the accurate dispensing and proper delivery of medications to a (LTCF) located within this state. These services shall include, at a minimum, proper medication labeling, storage, transport, record keeping and prospective drug utilization review in compliance with all federal, state and local laws and regulations.

B. "Provider Pharmacy" means any pharmacy permitted by the Board where medications are dispensed to residents of a long term care facility located in this state.

C. "Single unit dose package" is a package, which contains one discrete pharmaceutical medication dosage form.

D. "Unit dose dispensing systems" are those drug medication distribution systems determined by the Board, which involve single unit, unit dose or unit of issue packaging in a manner which helps reduce or remove traditional drug stocks from patient care areas and enables the selection and distribution of medications to be provider pharmacy based and controlled. A unit dose dispensing system shall preserve the identity and the integrity of the medication until the time of administration.

E. "Unit dose package" is a package, which contains that particular dose of a medication ordered for the patient for one administration time. A unit dose package is not always a single unit dose package.

F, "Unit of issue package" is a medication package issued by a provider pharmacy, which provides multiple units/dosages of medications attached to each other but separated in a card or a specifically designed container;

1. Packaging for all non-sterile medications stored and dispensed in single unit dose, unit dose or unit of issue packages for use in (LTCF) other than hospitals shall:

A. Preserve and protect the identity and integrity of the drug medication from the point of packaging to the point of patient administration;

B. When packaged by the manufacturer or distributor, be in compliance with Federal Food and Drug Administration guidelines;

C. Shall be in containers clean and free of extraneous matter when the dosage unit(s) are placed into the package;

D. Utilize containers, which are classified according to USP Standard 671 as being Class A or Class B for oral solid dosage forms or is a tight container for liquid dosage forms.

2. Labeling for single unit dose or unit dose packaging shall comply with the following;

A. Single unit doses or unit doses packaged by the manufacturer or distributor shall be

properly labeled according to Federal Food and Drug Administration requirements;
B. Single unit doses or unit doses packaged by the provider pharmacy shall be properly labeled according to ARTICLE XXIX paragraph 7.;

3. Labeling for unit of issue packages shall contain the following information:
A. Name and room or bed number of patient, name of prescribing practitioner, name and strength of drug, directions for use, and the name and address of the provider pharmacy when a unit of issue package is utilized for patients in an (LTCF) setting.

4. If a pharmacist selects a generically equivalent drug product for a brand name drug product prescribed by a practitioner, labeling must comply with ARTICLE X of the Pharmacy Practice Regulations of the Board.

5. Expiration dating for non-sterile medications dispensed and packaged into single unit doses, unit doses and unit of issue packages shall meet the following conditions:
A. Not exceed the manufacturer's original expiration date;
B. Have an expiration date assigned based on the unit dose container manufacturer's recommendations;
C. May exceed Ninety (90) days from date of repackaging provided that the container is classified according to USP Standard 671 as being Class A or Class B for oral solid dose forms or is a tight container for liquid dosage forms, the container is light resistant when the manufacturer has labeled the drug product "sensitive to light" and the expiration date is not greater than twelve (12) months;
D. Drugs or dosage forms having known stability problems are assigned an expiration date of less than ninety (90) days or are not repackaged as determined by policies developed by the provider pharmacy.
The shortest time span of any of the listed conditions shall be the expiration date assigned to the medication.

C. RETURN OF MEDICATIONS FROM AN INSTITUTIONAL FACILITY TO THE PROVIDER PHARMACY

1. Medication that has been dispensed for a patient residing in an institutional facility may be returned to the provider pharmacy provided that the medication has an approved reason for return as follows:
A. Medication was discontinued prior to delivery;
B. Patient expired prior to medication being delivered;
C. Patient in the hospital (discharge status) at time of delivery;
D. Medication dosage changed prior to delivery;
E. Patient has excessive medications remaining from previous cycle (requires written explanation by the Director of Nurses).
F. Medication is considered to be dispensed when it leaves the dispensing pharmacy and is delivered to the institutional facility.
Any such medication subject to return must be intact with no doses removed from

blister package (unit dose). Medications, which have been dispensed and placed in bulk packages and accepted by a responsible person at the LTCF, shall not be returned to the dispensing pharmacy for any reason. All medication subject to return, must be returned to the provider pharmacy by pharmacy personnel within five (5) days. No controlled substances may be returned.

The provider pharmacy must implement approved procedures, which ensure that any returned medication has been properly stored, has not been tampered with, and the integrity of the medication remains intact. Paper trails tracking these procedures must be maintained by the provider pharmacy for a period of two (2) years and be readily retrievable for inspection by agents of the Board.

ARTICLE XXXI COMPOUNDING GUIDELINES

GOOD COMPOUNDING GUIDELINES

The following Good Compounding Practices (GCP's) are meant to apply only to the compounding of medication by pharmacies licensed in the State of Mississippi. Applicable portions of the Pharmacy Practice Act formed the basis for the development of these rules and regulations.

1. GENERAL PROVISIONS

   A. These rules and regulations are considered to be the minimum current good compounding practices for the preparation of medications by pharmacists licensed in the State of Mississippi for dispensing and/or administration to humans or animals.
   B. Pharmacists engaged in the compounding of drugs shall operate in conformance with applicable law regulating the practice of pharmacy.
   C. Based on the existence of a pharmacist/patient/practitioner relationship and the presentation of a valid prescription, or in anticipation of prescription medication orders based on routine, regularly observed prescribing patterns, pharmacists may compound, for an individual patient, medications that are not commercially available in the marketplace. No compounding and manufacturing shall take place at the same location.
   D. Pharmacists shall receive, store, or use drug substances for compounding that meet official compendia requirements, or of a chemical grade in one of the following categories: Chemically Pure (CP), Analytical Reagent (AR), American Chemical Society (ACS), or, if other than this, drug substances which in the professional judgment of the pharmacist are obtained from acceptable and reliable alternatives.
   E. Pharmacists may compound drugs prior to receiving a valid prescription based on a history of receiving valid prescriptions that have been generated solely within an established pharmacist/patient/practitioner relationship, and provided that they maintain the prescriptions on file for all such products compounded at the pharmacy as required by the Mississippi Board of Pharmacy.
   F. Pharmacists shall not offer compounded medications to other pharmacies for resale; however, practitioners may obtain compounded medications to administer to patients. Compounding pharmacies/pharmacists may advertise or otherwise promote the fact that they provide prescription compounding services (e.g., chemicals, devices and information when requested); however, they shall not solicit business by promoting to compound specific drug products (e.g., like a manufacturer).
   G. The compounding of inordinate amounts of drugs in anticipation of receiving prescriptions without any historical basis or the distribution of inordinate amounts of compounded products without a patient/practitioner/pharmacist relationship is considered manufacturing.

2. ORGANIZATION AND PERSONNEL

A. Pharmacists engaging in compounding shall maintain proficiency through current awareness and training. Continuing education should include training in the art and science of compounding and the rules and regulations of compounding.
B. Pharmacy technicians may assist the pharmacist in compounding. It is the responsibility of the pharmacist to train and monitor the pharmacy technician. Their duties shall be consistent with the training received.
C. Personnel engaged in the compounding of medications shall wear clean clothing appropriate to the operation being performed. Protective apparel, such as coats/jackets, aprons, gowns, hand or arm coverings, or masks shall be worn as necessary to protect personnel from chemical exposure and medication or chemical contamination.
D. Only personnel authorized by the responsible pharmacist shall be in the immediate vicinity of the drug compounding operation. Any person shown at any time (either by medical examination or pharmacist determination) to have an apparent illness or open lesions that may adversely affect the safety or quality of a drug product being compounded shall be excluded from direct contact with components, medication containers, closures, in-process materials, and medication products until the condition is corrected or determined by competent medical personnel not to jeopardize the safety or quality of the product(s) being compounded. All personnel who assist the pharmacist in compounding procedures shall be instructed to report to the pharmacist any health conditions that may have an adverse effect on drug products.

3. DRUG COMPOUNDING FACILITIES

A. Pharmacies engaging in compounding shall have a specifically designated and adequate area (space) for the orderly compounding of prescriptions that is maintained in a good state of repair and for the placement of materials and equipment. Sterile compounding shall be performed in a separate area in compliance with ARTICLE XXVIII of these regulations.
B. Bulk medications and other chemicals or materials used in the compounding of medications must be stored in adequately labeled containers in a clean, dry, and temperature controlled area or, if required, under proper refrigeration.
C. Adequate lighting and ventilation shall be provided in all drug compounding areas. Potable water shall be supplied under continuous positive pressure in a plumbing system free of defects that could contribute contamination to any compounded drug product. Adequate washing facilities, easily accessible to the compounding area(s) of the pharmacy, shall be provided. These facilities shall include, but not be limited to, hot and cold water, soap or detergent, and air-driers or single use towels.
D. The area(s) used for the compounding of drugs shall be maintained in a clean and sanitary condition. It shall be free of infestation by insects, rodents, and other vermin. Trash shall be held and disposed of in a timely and sanitary manner. Sewage and other refuse in and from the pharmacy and immediate medication compounding

area(s) shall be disposed of in a safe and sanitary manner.

E. If sterile products are being compounded, the pharmacist shall follow ARTICLE XXVIII, (2), (3), (4) AND (5), of these regulations as applicable to the procedure.

F. If radiopharmaceuticals are being compounded, the pharmacist shall follow ARTICLE XXVII and ARTICLE XXVIII (2), (3), (4) and (5) of these regulations as applicable to the procedure.

G. If drug products with special precautions for contamination, such as penicillin, are involved in a compounding procedure, appropriate measures, including either the dedication of equipment or meticulous cleaning of contaminated equipment prior to its use for the preparation of other drugs, must be utilized in order to prevent cross-contamination.

4. EQUIPMENT

A. Equipment and utensils used for compounding shall be of appropriate design and appropriate capacity and stored in a manner to protect from contamination. In addition, all equipment and utensils shall be cleaned and sanitized prior to use to prevent contamination that would alter the safety or quality of the drug product beyond that desired. The pharmacist is responsible for determining suitability for use. In the case of sterile compounding, follow ARTICLE XXVIII of these regulations as applicable to equipment and utensils.

B. Automatic, mechanical, electronic or other equipment used in compounding shall be routinely inspected, calibrated (if necessary) or checked to ensure proper performance.

C. It shall be the responsibility of the pharmacist to ensure that the proper container is selected to dispense the finished compounded prescription, whether sterile or non-sterile.

5. MEDICATION COMPOUNDING CONTROLS

A. The pharmacist shall ensure that there are formulas and logs maintained either electronically or manually. Formulas shall be comprehensive to include: ingredients, amounts, methodology and equipment, if needed and special information regarding sterile compounding.

B. The pharmacist shall ensure that components used in compounding are accurately weighed, measured, or subdivided as appropriate at each stage of the compounding procedure to conform to the formula being prepared. Any chemical transferred to a container from the original container shall be labeled with the same information as on the original container and the date of transfer placed on the label.

C. The pharmacist shall establish and conduct procedures so as to monitor the output of compounded prescriptions, i.e., capsule weight variation, adequacy of mixing, clarity and pH of solutions and where appropriate procedures to prevent microbial contamination of medications purported to be sterile (refer to ARTICLE XXVIII of these regulations as applicable).

6. LABELING CONTROL OF EXCESS PRODUCTS

A. The pharmacist shall label any excess compounded product so as to reference it to the formula used and the assigned control number and estimated beyond use date based on the pharmacist's professional judgment, appropriate testing or published data. The product shall be stored appropriately.
B. At the completion of compounding the prescription, the pharmacist shall examine the prescription for correct labeling.

7. RECORDS AND REPORTS

The pharmacist shall keep records of all compounded products for a period of time as other prescriptions as required by the Mississippi Board of Pharmacy. Such records shall be readily available for authorized inspection during the retention period at the establishment. These records shall be subject to duplication by photocopying or other means of reproduction as part of any such inspection.

ARTICLE XXXII WHOLESALER/MANUFACTURER PERMITS

1. Every facility/business that shall engage in the wholesale distribution of prescription drugs, to include without limitation, manufacturing in this state, distribution into this state, or selling or offering to sell in this state, or distribution from or within this state, shall register biennially with the Mississippi Board of Pharmacy by applying for a permit on a form supplied by the Board and accompanied by a fee not to exceed five-hundred dollars ($500.00). Every facility/business that shall engage in distribution of prescription drugs into this state to an affiliated or related company under common ownership and control of a corporate entity must register biennially with the Board. The Board shall determine criteria and classification of permits as required.

   Permits issued to any wholesaler/manufacturer facility become null and void sixty (60) days from the date of issuance if inspection reveals a lack of legitimate business activity.

2. To obtain a permit or renew a permit for a drug wholesaler the applicant shall:
   A. Submit a written application on a form prescribed by the Board which provides at a minimum the following information:
      (1) Name of the business, including all trade or business names used by the business;
      (2) Address of the business;
      (3) Ownership of the business;
      (4) Information identifying the type of activities to be conducted by the business;
      (5) Signature, telephone number and complete address of the individual applying for the permit;
      (6) Complete name, telephone number and address of all officers and directors and the name of the state of incorporation, if a corporation;
      (7) Complete name, telephone number and address of all partners if a partnership;
      (8) If a sole proprietorship, the complete name, telephone number and address of the sole proprietor and the business entity.
   B. Submit the required fees as follows:
      A fee not to exceed five hundred ($500.00) dollars for the registration period January 1, 2012 through December 31, 2013, and each biennial registration period thereafter.
   C. Wholesaler permits shall not be issued for the same location occupied by a Pharmacy Permit after January 1, 2012.

3. Each Mississippi wholesaler that maintains or distributes controlled substances shall apply for and obtain a controlled substance registration issued by the Board. To obtain a controlled substance registration or renew a controlled substance registration the applicant shall:
   A. Submit a written application on a form prescribed by the Board;
   B. Submit the required fees as follows:
      Fifty dollars ($50.00) for the registration period January 1, 2012, through December

31, 2012, and each annual registration period thereafter.

Any loss or suspected loss of controlled substances shall be reported directly to the Mississippi Board of Pharmacy immediately upon discovery and a written report made to the Mississippi Board of Pharmacy within fifteen (15) days.

4. The Mississippi Board of Pharmacy will consider the following factors in determining eligibility for issuing or renewing a permit for persons who engage in the wholesale distribution of prescription drugs:

   A. Any convictions of the applicant under any federal, state, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;
   B. Any felony convictions of the applicant under federal, state or local laws;
   C. The applicant's past experience in the distribution of prescription drugs, including controlled substances;
   D. The furnishing by the applicant of false or fraudulent information in any application made in connection with drug distribution;
   E. Suspension or revocation by federal, state, or local government of any permit currently or previously held by the applicant for the distribution of any drugs, including controlled substances;
   F. Compliance with requirements under previously granted permits or registrations, if any;
   G. Compliance with the requirements to maintain and/or make available to state and federal regulatory authorities those records required to be maintained by wholesale drug distributors; and
   H. Any other factors or qualifications the Mississippi Board of Pharmacy considers relevant to and consistent with the public health and safety.

   The Mississippi Board of Pharmacy reserves the right to deny a permit or a registration to an applicant if it determines that the granting of such a permit or registration would not be in the public interest.

5. Every business issued a wholesaler permit by the Board shall renew this permit biennially. Newly issued permits which do not coincide with the registration period shall be valid for the following periods of time: If the permit is issued in the first half of the registration period, it must be renewed at the end of the registration period, or if the permit is issued in the second half of the registration period, it must be renewed at the end of the next registration period.

6. The operations manager shall sign the application for a wholesaler permit or the renewal of a wholesaler permit and shall be the operations manager for that facility and shall be responsible for all activities in the permitted facility which are subject to regulation by the Board. Once issued, a permit cannot be amended, transferred or assigned to another person. Failure to comply with this paragraph invalidates the permit.

7. If the employment of a permit holder is terminated, or if for any other reason he/she wished to be relieved of the responsibilities of the permit holder, he/she must return the wholesaler permit to the Mississippi Board of Pharmacy with written notice that he/she is no longer the permit holder for that facility. When a permit is thus returned, application for a new permit for that facility must be made to the Mississippi Board of Pharmacy within ten (10) days.

8. If a permitted facility is permanently closed or has a change of ownership, the permit holder for that facility shall give notice to the Board of the effective date of closure or change in ownership at least ten (10) days prior to the closure or change in ownership.

9. If a permitted facility has a change in name or location, a new permit must be obtained. Application for this new permit must be made to the Board at least ten (10) days prior to the change.

10. All drug wholesalers permitted by the Mississippi Board of Pharmacy shall comply with the following:
    A. Storage Conditions;
        (1) Each facility where legend drugs or devices are repackaged, wholesaled, manufactured, distributed, stored, held, sold or offered for sale, shall provide storage areas that assure proper lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions. All legend drugs or chemicals shall be stored at appropriate temperatures and under appropriate condition per label requirements or official compendium requirements to assure that the identity, strength, quality, and purity of the products are not affected. If no storage requirements are established for a prescription drug they may be stored at controlled room temperature as defined in an official compendium such as the United States Pharmacopeia/Nation Formulary. Appropriate manual, electro-mechanical or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of prescription drugs. This data shall be recorded daily.
        (2) A separate storage section shall be provided for legend drugs that are deteriorated, outdated, misbranded, or otherwise adulterated.
    B. Facilities:
        (1) All buildings in which legend drugs or devices are wholesaled, repackaged, manufactured, distributed, stored, held, sold, or offered for sale, shall be of suitable size, construction, and location to facilitate cleaning, maintenance, and proper operations. Buildings shall meet all applicable federal, state, and local standards and shall be maintained in a clean and orderly condition and be free from infestation by insects, rodents, birds or vermin of any kind.
        (2) Each facility shall have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that

are in immediate or sealed outer or sealed secondary container that have been opened.

(3) A facility may not be located in a residence.

C. Security:

(1) All facilities shall be equipped with an electronic security system that will provide suitable protection against theft and diversion.
When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(2) Drug wholesalers shall ensure that access from outside their premises is reduced to a minimum and be well controlled. This includes, but is not limited to, the installation of adequate lighting at the outside perimeter of the premises. Entry into areas where prescription drugs are stored or held shall be limited to authorized personnel.

(3) Drug wholesalers shall maintain written internal security policies which provide protection against theft and diversion by personnel. These policies shall provide protection against computer theft and crimes.

D. Recordkeeping:

(1) Drug wholesalers shall establish and maintain inventories and other records of all transactions regarding the receipt, distribution and disposition of legend drugs including the name and principle address of the seller or transferor and the address of the location from which the drugs were shipped. These records shall be maintained for a period of two (2) years following disposition of the drugs. These records shall be made available for inspection and copying by agents of the Mississippi Board of Pharmacy or other authorized federal, state, or local law enforcement agency officials. These records shall contain source of supply (items received, quantity, and date) and distribution (items distributed, quantity, and date).

(2) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by an agent of the Mississippi Board of Pharmacy or other authorized federal, state, or local law enforcement agency officials.

(3) Upon request by the Board, drug wholesalers that are permitted by the Board and who distribute prescription drugs to persons within this state shall make available to the Board the following:

(a)A complete Mississippi customer roster;

(b)Distribution and sales records for any period during the past two (2) years listing all sales or distribution of prescription drugs to authorized persons located in this state upon request by the Board. This request shall be made in writing and may be signed by a compliance agent of

the Board. This data shall be supplied to the Board within five (5) working days and shall consist of the following:

(i) Identity of the purchaser;
(ii) Identity of the distributor;
(iii) Drug name, strength, dosage form and quantity distributed;
(iv) The invoice number;
(v) Date distributed;
(vi) All records of returns or credits.

E. Written Policies and Procedures:

Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories.

(1) There shall be written policies and procedures to assure that the drug wholesaler prepares for, protects against, and handles crisis situations that affect the security or operation of the facility. Such crises may include fires, floods, or other natural disasters, and situations of local, state, or national emergency.

(2) A procedure whereby the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate.

(3) There shall be written policies and procedures to assure that any outdated stock, or any stock with an expiration date that does not allow sufficient time for repacking or resale shall be segregated from other stock and shall be prepared for return to the manufacturer or otherwise appropriately destroyed. This procedure shall provide for written documentation of the disposition of out dated prescription drugs. This documentation shall be maintained for a period of two (2) years after the disposition of the outdated drugs.

(4) There shall be written policies and procedures by which the drug wholesaler exercises control over the shipping and receiving of all stock within the operation.

(a) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(b) Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

(c) The recordkeeping requirements in paragraph (D.) of this section shall be followed for all incoming and outgoing prescription drugs.

F. Returned, Damaged and Outdated Prescription Drugs:

(1) Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier.

(2) Any prescription drug whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.

(3) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed, or returned to the supplier, unless examination, testing or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, the wholesale drug distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton or labeling, as a result of storage or shipping.

(4) The recordkeeping requirements in paragraph D. of this section shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs. Written policies and procedures shall be maintained at the permitted facility to implement the above requirements.

G. Handling Recalls:

(1) A wholesale operation must maintain and follow written policies and procedures for handling recalls and withdrawals of products. Such a policy should cover all recalls and withdrawals of drug products due to:

(a) Any voluntary action on the part of the manufacturer;

(b) The direction of the Food and Drug Administration, or any other federal, state, or local government agency; and

(c) Replacement of existing merchandise with an improved product or new package design.

H. Compliance with Local, State and Federal Law; Inspections, Violations and Penalties:

(1) Each drug wholesaler shall comply with all applicable local, state and federal laws and regulations.

(2) The Board may conduct inspections upon all premises purporting or appearing to be used by persons permitted under this ARTICLE. The Board in its discretion may accept a satisfactory inspection by the Federal Food and Drug Administration or a state agency of another state which the Board determines to be comparable to that made by the Federal Food and Drug Administration or the Board. The permit holder of the permitted location, upon request, shall furnish to the Board a copy of any and all reports of inspections conducted by the Federal Food an Drug Administration or the state agency of another state.

(3) Mississippi wholesalers that deal in controlled substances shall obtain a controlled substance registration from the MS Board of Pharmacy and a

registration number from the Federal Drug Enforcement Administration and shall comply with all applicable state and federal DEA regulations.

(4) The Board or it's representatives may enter to inspect, during reasonable hours, a wholesaler's facility which has obtained or applied for a permit with the Board relative to the following:
(a)Drug storage and security;
(b)Equipment;
(c)Sanitary conditions;
(d)Records, reports or other documents required to be kept by the Board.

(5) The Board shall have the authority to suspend, revoke or restrict any permit or registration issued under this ARTICLE upon conviction of violations of this ARTICLE or other federal, state or local drug laws or regulations.

(6) The Board may impose monetary penalties of not less than ($100.00) and not more than ($25,000.00) for each violation.

(7) Before any wholesaler permit may be suspended, restricted or revoked or monetary penalties imposed, a wholesaler shall have the right to prior notice and a hearing pursuant to Section 73-21-99, Mississippi Code of 1972.

I. Personnel

(1) Each drug wholesaler shall employ adequate personnel with the education and experience necessary to safely and lawfully engage in the wholesale distribution of prescription drugs.

(2) Each wholesaler shall maintain a list of all personnel who have access to controlled substances and shall make available to the Board proof of background searches on any such employee. No person who has access to controlled substances shall have been convicted in any federal or state court of any drug related crime.

(3) Wholesale drug distributors shall establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

J. Salvaging and Reprocessing:

(1) Wholesale drug distributors shall be subject to the provisions of any applicable federal, state, or local laws or regulations that relate to prescription drug product salvaging or reprocessing, including Chapter 21, parts 207, 210d, 211 of the Code of Federal Regulations.

K. Repackaging:

(1) Every wholesaler permitted by the Board that repackages prescription drugs for distribution shall register with the Federal Food and Drug Administration and shall be in compliance with all laws, rules, and regulations regarding such registration. Written notification furnished by the Federal Food and Drug Administration citing violations of federal laws, rules, and regulations shall be prima facie evidence of violation of this ARTICLE.

(2) In wholesaler facilities permitted by the Board where prescription drugs are repackaged for distribution, all drug products shall be maintained in the

manufacturer's original container except as allowed by federal laws, rules, and regulations regarding prescription drug repackaging. Once distributed, repackaged prescription drug products which are returned to the repackager shall be immediately quarantined and either destroyed or returned to the original manufacturer.

(3) In addition every wholesaler that repackages prescription drugs shall comply with the following:

(a) Maintain and provide documentation showing that solid oral dosage form drug products are repackaged into a container/closure system that is equivalent to the manufacturer's container closure system if the manufacturer's expiration date is placed on the repackaged container. In the absence of stability testing, the repackager shall obtain and maintain certification from the container/closure manufacturer, supporting the expiration date placed on the label of the repackaged drug product;

(b) Maintain and provide documentation of stability testing to support any expiration date placed on containers wherein liquid oral dosage forms have been repackaged;

(c) Maintain written specifications for labeling repackaged products and written procedures that assure only correct labels are used. Documentation should be maintained showing that labeling placed on the repackaged containers is examined for correctness before and after the drug is repackaged;

(d) The label placed on a repackaged product shall indicate at a minimum:

(i) All active ingredients, dosage form and strength;

(ii) Name and address of the repackager;

(iii) Name and address of the manufacturer;

(iv) Storage requirements; and

(v) Control lot number and expiration date.

(e) Assures that penicillin drug products or penicillin synthetics shall not be repackaged in the same room, on the same equipment, and using the same air handling system, where other drug products are repackaged;

(f) Maintain documentation that cleaning procedures are followed when equipment and other surfaces are cleaned to assure that no drug residue remains on or near repackaging equipment; and

(g) Assures that drug products that are known to have stability problems such as, but not limited to nitroglycerin sublingual tablets or other drug products that interact with packaging materials not be repackaged in the absence of specific test data demonstrating the stability of the repackaged drug product and the actual container/closure system used.

11. A facility, located in this state, and permitted by the Mississippi Board of Pharmacy as a wholesaler shall not sell or distribute a prescription drug to any individual or business unless the individual or business is licensed or permitted to prescribe, dispense, or possess

prescription drugs by an agency of the state in which the individual or business is located.

A facility permitted by the Board as a wholesaler shall not distribute prescription drugs to persons in this state unless such person is either a licensed physician, osteopath, or podiatrist, licensed by the Mississippi Board of Medical Licensure, a licensed dentist, licensed by the Mississippi Board of Dental Examiners, a licensed veterinarian, licensed by the Mississippi Board of Veterinary Medicine, pharmacies and wholesalers permitted by the Board. An optometrist licensed by the Mississippi State Board of Optometry, may purchase prescription drugs as authorized by said Board of Optometry.

12. For purposes of these regulations the following definitions shall apply:
    - A. "Blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.
    - B. "Blood Component" means that part of blood separated by physical or mechanical means.
    - C. "Drug Sample" means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.
    - D. "Manufacturer" means a person engaged in the manufacturing preparing, propagating, compounding, processing, packaging, repackaging, distributing or labeling of a prescription drug.
    - E. "Prescription Drug" means any human drug including, but not limited to medical oxygen, which is required by federal law or regulation to be dispensed only by a prescription, and drugs which are required under federal law to be labeled with either of the following statements prior to being dispensed or delivered:
        - (1) "Caution: Federal law prohibits dispensing without prescription," or
        - (2) "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian"; or a drug which is required by any applicable federal or state law or regulation to be dispensed on prescription only or is restricted to use by practitioners only.
    - F. "Wholesale Distribution" means distribution of prescription drugs to a person other than a consumer or patient, but does not include:
        - (1) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons; for purposes of these regulations "emergency medical reasons" includes transfers of prescription drugs from one permitted facility to another permitted facility to alleviate a temporary shortage;
        - (2) The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription;
        - (3) The lawful distribution of drug samples by manufacturers' representatives or distributors' representatives;
        - (4) The sale, purchase, or trade of blood and blood components intended for transfusion;
        - (5) The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for its own

use from the group purchasing organization or from other hospitals or health care entities that are members of such organizations;

(6) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals that are under common control; for purposes of these regulations, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, by contract or otherwise;

(7) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in section 501© (3) of the U.S. Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(8) Any entity that distributes prescription drugs or controlled substances into the state must hold a wholesaler permit issued by the Mississippi Board of Pharmacy.

(9) The sale/purchase of a prescription drug by a retail pharmacy to other retail pharmacies or to a licensed practitioner for office use, if the total annual dollar volume of these sales/purchases does not exceed five percent (5%) of that pharmacy's total annual prescription drug sales.

G. "Wholesaler" means a person who buys or otherwise acquires prescription drugs or prescription devices for resale or distribution or for repackaging for resale or distribution to persons other than consumers.

H. "Wholesale Distributor" means any person engaged in wholesale distribution of prescription drugs or prescription devices, including but not limited to, manufacturers; repackagers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions.

I. "Deliver" or "Delivery" means the actual constructive or attempted transfer of a drug or device from one person to another, whether or not for a consideration.

J. "Distribute" means the delivery of a drug or device other than by administering or dispensing to persons other than the ultimate consumer.

K. "Repackager" means a person registered by the Federal Food and Drug Administration as a repackager who removes a prescription drug product from its marketed container and places it into another, usually of smaller size, to be distributed to persons other than the consumer.

L. "Board of Pharmacy", "Pharmacy Board", "Board", or "MSBP" shall mean the Mississippi Board of Pharmacy.

M. "Person" shall mean an individual, corporation, partnership, association, or any other legal entity.

ARTICLE XXXIII HOME HEALTH/HOSPICE PERMITS

1. Every home health agency, hospice organization or business/location in this state subject to regulation by the Mississippi Board of Pharmacy where certain prescription drugs as approved by the Board are bought, maintained, administered or provided directly to consumers, without the services of a pharmacist being required, shall obtain a permit as a home health/hospice from the Mississippi Board of Pharmacy.

2. To obtain a permit or renew a permit for a home health/hospice, the applicant shall:
   A. Submit a written application on a form prescribed by the Board;
   B. Submit the required fees as follows:
      Fifty dollars ($50.00) for the registration period January 1, 2012, through December 31, 2013, and each biennial registration period thereafter.

   Any home health/hospice permit renewal application postmarked after December 31 of the renewal period shall be returned and a fifty dollar ($50.00) late renewal fee shall be assessed prior to renewal.

3. Every business issued a home health/hospice permit by the Board shall renew this permit biennially. Newly issued permits which do not coincide with the registration period shall be valid for the following periods of time: If the permit is issued in the first half of the registration period, it must be renewed at the end of the registration period. If the permit is issued in the second half of the registration period, it must be renewed at the end of the next registration period.

4. The person who signs the application for a home health/hospice permit or the renewal of a home health/hospice permit shall be the permit holder for that facility and shall be responsible for all activities in the permitted facility which are subject to regulation by the Board. Once issued, a permit cannot be amended, transferred or assigned to another person.

5. If the employment of a permit holder is terminated or if for any other reason he/she wishes to be relieved of the responsibilities of the permit holder, he/she must return the home health/hospice permit to the Mississippi Board of Pharmacy with written notice that he/she is no longer the permit holder for that facility. When a permit is thus returned, application for a new permit for that facility must be made to the Mississippi Board of Pharmacy within ten (10) days.

6. If a permitted facility is permanently closed or has a change of ownership, the permit holder for that facility shall give notice to the Board of the effective date of closure or change in ownership at least ten (10) days prior to the closure or change of ownership.

7. If a permitted facility has a change in name or location, a new permit must be obtained.

Application for this new permit must be made to the Board at least ten (10) days prior to the change.

8. All home health/hospices permitted by the Mississippi Board of Pharmacy shall comply with the following:

   A. Prescription drugs that are bought or maintained, in a home health/hospice or provided to a consumer from a home health/hospice shall be limited to those items authorized by the Board. A list of the authorized prescription drugs shall be published by the Board at least annually.
   Items may be added to or deleted from the list by the Board at any regularly called meeting. At any time a change in the list of authorized drugs is made, the Board shall provide the changed list to all persons registered with a home health/hospice permit.
   B. A home health/hospice shall not buy, maintain or provide to a consumer any prescription drug not authorized by the Board of Pharmacy unless such prescription drug was obtained pursuant to the valid prescription or order of a practitioner.
   C. Delivery of any prescription drug to a consumer shall be pursuant to a valid order of a practitioner who is authorized to prescribe the drug. These orders shall be maintained for a period of six (6) years.
   D. A facility permitted with a home health/hospice permit shall not sell or distribute a prescription drug to any person who is not permitted or otherwise authorized to purchase prescription drugs except that a facility permitted by the Board of Pharmacy with a home health/hospice permit may supply these items to other facilities under common control or ownership.
   E. Complete and accurate records of acquisition and disposition of all prescription drugs which are bought or maintained by a home health/hospice shall be maintained for a period of six (6) years. These records shall be readily retrievable and available for inspection by agents of the Mississippi Board of Pharmacy.
   F. Any prescription drug maintained in a home health/hospice or provided to a consumer from a home health/hospice shall be labeled so as to be in compliance with the labeling requirements of the Federal Food and Drug Administration and any additional labeling necessary for the safe and effective use of the product by the consumer.
   G. Each home health/hospice where prescription drugs are bought or maintained shall provide storage areas that ensure proper lighting, ventilation, temperature, sanitation, humidity, space and equipment. All prescription drugs shall be stored at appropriate temperatures per label requirements or official United States Pharmacopeia (USP) compendium requirements to ensure that the identity, strength, quality, and purity of the products are not affected. If no temperature requirements are listed, prescription drugs may be stored at room temperature as defined in the USP. A separate storage area shall be provided for prescription drugs that are deteriorated, outdated, misbranded, or otherwise adulterated.
   H. Each home health/hospice shall employ adequate personnel with the education and experience necessary to safely and lawfully engage in the preparation, administration

or delivery of prescription drugs

I. Home health/hospices shall be maintained in an orderly and sanitary fashion.

J. A permit shall not be issued for a home health/hospice located in a residence.

K. The Board of Pharmacy may refuse to issue or renew, or may suspend, revoke or restrict the permit of any home health/hospice under the applicable provisions of ARTICLE IX of these regulations.

9. For purposes of these regulations the following definitions shall apply:

A. "Home health/hospice" shall mean a business, which does not require the services of a pharmacist, where certain prescription drugs are bought, maintained or provided to consumers.

B. "Home Health Agency" shall mean a public or privately owned agency or organization or a subdivision of such agency or organization, properly authorized to conduct business in Mississippi, which is primarily engaged in providing to individuals, at the written direction of a licensed physician, in the individual's place of resident, skilled nursing services provided by or under the supervision of a registered nurse licensed to practice in Mississippi.

C. "Hospice" shall mean an autonomous, centrally administered, ~~nonprofit,~~ medically directed, nurse coordinated program providing palliative and supportive care to meet the special needs arising out of the physical, emotional, spiritual, social and economic stresses which are experienced during the final stages of illness and during dying and bereavement. This care is available twenty-four (24) hours a day, seven (7) days a week, and is provided on the basis of need regardless of inability to pay.

D. "Prescription Drug" or "Legend Drug" shall mean a drug which is required under federal law to be labeled with either of the following statements prior to being dispensed or delivered:

(1) "Caution: Federal law prohibits dispensing without prescription," or

(2) "Rx Only", or

(3) "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian"; or a drug which is required by any applicable federal or state law or regulation to be dispensed on prescription only or is restricted to use by practitioners only.

ARTICLE XXXIV PHARMACY EXTERN/INTERN REGISTRATION

1. Every person enrolled in the professional curriculum of a school of pharmacy and pursuing either a Bachelor of Science in pharmacy degree or a Doctor of Pharmacy degree must obtain an extern/intern registration from the Mississippi Board of Pharmacy prior to enrolling and participating in externship or clerkship rotations or obtaining practical experience in a pharmacy permitted by the Board. The Pharmacy extern/intern shall in no manner falsely assume, directly or by inference, to be a Pharmacist. To obtain an extern/intern registration, the applicant shall:
   A. Have submitted a written application on a form prescribed by the Board;
   B. Be of good moral character as evidenced by having undergone and successfully passed a criminal background check conducted by the Board;
   C. Show proof to the Board the applicant is enrolled in a school of pharmacy approved by the Board;
   D. Have paid fees as specified by the Board.

2. A pharmacy extern/intern registration which has been issued by the Board shall expire when:
   A. The extern/intern is expelled, suspended, withdraws or is dismissed from a school of pharmacy;
   B. The extern/intern fails to become licensed as a registered pharmacist within six (6) months of graduation from a school of pharmacy;
   C. Upon the expiration of a pharmacy extern/intern registration, the registrant may petition the Board for re-registration.

   All pharmacy interns/externs shall notify the Board immediately upon change of employment and residence address.

   When a Pharmacy Intern desires to obtain credit for training received in a state other than this State, he/she shall abide by all the provisions of the internship rules in that state, and shall provide evidence from that state's Board of Pharmacy of the number of clock hours of experience actually participated in by the Pharmacy Intern.

3. The Board may refuse to issue or renew or may suspend, revoke or restrict the registration of any extern/intern upon one or more of the following grounds:
   A. Unprofessional conduct as defined in ARTICLE V, paragraph G., Pharmacy Practice Regulations of the Mississippi Board of Pharmacy;
   B. Violation of any regulation(s) of the Board;
   C. Violation of any provisions of the Mississippi Pharmacy Practice Act or the Mississippi Uniform Controlled Substances Act;
   D. Violation of pharmacy or drug laws of this state or any other state or rules and regulations pertaining thereto;
   E. Fraud or intentional misrepresentation by a extern/intern in securing the issuance of a pharmacy extern/intern registration or failing to report to the Board any adverse

action taken by another licensing jurisdiction, government agency, law enforcement agency, or court that would constitute grounds for action;

F. Addiction to or dependence on alcohol, controlled substances or other habit forming legend drugs or the unauthorized use, possession, or theft of controlled substances or other habit forming legend drugs;

G. Physical or mental incapacity that prevents the intern/extern from practicing pharmacy with reasonable skill and safety to the public.

H. Divulging or revealing patient confidential or protected health information to any person other than as authorized by Board regulations.

I. Failure to comply with any lawful order of the Board;

J. Obtaining practical experience in a pharmacy permitted by the Board without the direct supervision and presence of a pharmacist licensed by the Board;

K. Failure to notify the Board of expulsion, suspension, dismissal or withdrawal from a school of pharmacy;

L. Violation of any university, college or school of pharmacy policies, rules or regulations thereof.

M. Failure to report directly to the Board, losses or suspected losses of controlled substances or prescription drugs.

N. Theft from a permitted facility.

O. Theft or embezzlement of prescription drugs, controlled substances or medical devices from a permitted facility.

P. Jeopardizing, compromising, interfering or failing to cooperate with any lawful investigation conducted by the Board or any state or federal regulatory or law enforcement agency.

Q. 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.

R. 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.

S. Failing to pay costs assessed in a disciplinary hearing.

T. The unlawful disclosure of information from the Prescription Monitoring Program.

U. Using information obtained from the Prescription Monitoring Program for unlawful or unethical purposes.

4. For purposes of this ARTICLE "obtaining practical experience" shall include, but not be limited to the compounding, dispensing and labeling of drugs, interpreting and evaluating prescriptions, maintaining prescription records and any other activity included in the practice of pharmacy under the direct supervision of a pharmacist.

ARTICLE XXXV INSTITUTIONAL EMERGENCY MEDICATION KIT PERMITS

1. Institutions, under the jurisdiction of the Board, that maintain prescription drugs on the premises for emergency use by patients, shall comply with the following:
   A. Permit. Every institutional facility, except a hospital, that desires to maintain a stock of prescription drugs for emergency use by patients who are confined to the institution, shall obtain an Institutional Emergency Medication Kit (IEMK) permit from the Mississippi Board of Pharmacy. Application for the IEMK shall be on a form supplied by the Board and accompanied by a fee not to exceed fifty dollars ($50.00). A separate permit shall be required for each provider pharmacy and shall be renewed a biennially. The Administrator (if a nursing home or other long term care facility) or business manager of the institution shall make application for the (IEMK) permit. In the event of the departure of the administrator or business manager, a new permit must be obtained.

   Any IEMK permit renewal application postmarked after December 31 of the renewal period shall be returned and a twenty-five ($25.00) dollar late renewal fee shall be assessed prior to renewal.

   B. Emergency Drug Kit Inventory and Accountability. Prescription drugs selected from a drug formulary specified by the Board, may be maintained by institutions for emergency use provided that:
      (1) The contents of the IEMK (up to 42 items) are supplied by any pharmacy permitted by the Board)controlled Substance Class II narcotics are not allowed); and
      (2) The contents of the IEMK are jointly determined by the consultant pharmacist, medical director, director of nurses and the pharmacist supplying the IEMK; and
      (3) A copy of the inventory of the IEMK is signed by administrator, the medical director, director of nurses and the pharmacist supplying the IEMK and placed on file in the institution and at the provider pharmacy; and
      (4) Only limited quantities (not to exceed twelve (12) dosage units) of prepackaged medications are available from the IEMK; and
      (5) Each prepackaged drug maintained in the IEMK is assigned a "par value" and each addition to or withdrawal from the IEMK is properly documented; and
      (6) An IEMK withdrawal log is maintained at the institution and all withdrawals of medications from the IEMK are documented as follows:
         (a) name and room number of resident/patient; and
         (b) drug name, quantity and strength; and
         (c) date and time of withdrawal and/or administration; and
         (d) name of person withdrawing and/or administering the medication.

(7) The provider pharmacy is furnished a copy of the IEMK medication withdrawal log on a timely basis in order for proper replacement of medications which have been utilized by the institution; and

(8) Any additions to the Board's drug formulary must be requested by the institution and approved by the Board.

2. Use. Emergency kit medications shall be administered to patients only for emergencies and pursuant to a valid medication order or prescription. Institutional emergency medication kit drug supplies are not to be used when medications are readily available from a community or hospital pharmacy.

3. Pharmacy Records. The pharmacist provider of the IEMK shall maintain complete and accurate records regarding the date, name, strength and quantity of medications supplied to each IEMK. These records shall be maintained separately for each IEMK and be readily retrievable at the provider pharmacy.

4. Storage and Security. The IEMK shall, at all times, be maintained in a securely locked room or cabinet at the institution. Access to the IEMK and it's contents shall be limited to only those persons as designated by the director of nurses and the provider pharmacist.

5. Controlled Substances. Controlled substance drugs may be maintained in an IEMK provided that:

   A. All requirements as outlined above are met; and

   B. The institution has applied for and been issued a controlled substance registration by the Mississippi Board of Pharmacy; and

   C. Controlled substances are stored in a separate locked container; and

   D. A copy of the medication order for those drugs listed in Schedule III, IV and V is delivered to the provider pharmacist within seventy-two (72) hours; and

   E. Use of Schedule II drugs shall comply with ARTICLE XIX of these Regulations of the Board. No Schedule II drugs may be maintained in the IEMK.

ARTICLE XXXVI PHARMACEUTICAL HEALTH CARE/INITIATION AND/OR MODIFICATION OF DRUG THERAPY UNDER PROTOCOL

1. Pharmacists may provide pharmaceutical health care to patients by initiating and/or modifying prescription drug therapy after a written protocol, indicating approval by a licensed practitioner who is authorized to prescribe prescription drugs, has been placed on file at the

office of the Board. Any such protocol must define the agreement by which the practitioner delegates this authority and any such authority granted must be within the scope of the

practitioner's prescribing authority and current practice. Any modification of the agreement must be treated as a new protocol.

For purposes of this ARTICLE "written protocol" shall mean an agreement in which any practitioner authorized to prescribe drugs delegates to a pharmacist authority to conduct specific initiation and/or modification of drug therapy functions in an institutional setting. In a community pharmacy out-patient setting, a specific protocol agreement shall be signed on each patient for whom a practitioner delegates any authority to initiate or modify drug therapy.

2. Unless specifically authorized by the Board, no person shall initiate or modify drug therapy under a protocol agreement unless he/she is certified and possesses the following qualifications: and
   A. Have and maintain a license to practice pharmacy issued by the Mississippi Board of Pharmacy; and
   B. Have attended and successfully completed at least sixteen (16) hours of continuing education consisting of basic pharmaceutical care, development of patient care plans and the clinical practice of pharmacy which has been approved by the Board; and in addition
   C. Have attended and successfully completed a Board pre-approved study course consisting of not less than sixteen (16) hours of continuing education focusing on a specific disease state, patient care plans and protocol management.

   Pharmacists shall, on a biennial basis, obtain re-certification in each disease state by successfully completing a continuing education program consisting of not less than six (6) hours focusing on nationally recognized updates.

   Pharmacists who have successfully completed any study course(s) focusing on disease state management and protocols or re-certification, shall send to the Board office copies of any documents certifying such on request.

3. Protocol agreements shall meet the following requirements:
   A. Identification of the practitioner who agrees to supervise the pharmacist and the scope of the practitioner's active practice; and

B. Describe the specific responsibilities authorized by the supervising practitioner; and
C. Describe the method the pharmacist shall use to document decisions or recommendations the pharmacist makes to the supervising practitioner; and
D. Describe the patient activities the supervising practitioner requires the pharmacist to monitor; and
E. Describe the types of reports the supervising practitioner requires the pharmacist to report and the schedule by which the pharmacist is to submit these reports; and
F. Include a statement of the medication categories and the type of initiation and modification of drug therapy that the supervising practitioner authorizes the pharmacist to perform; and
G. Describe the procedures or plan that the pharmacist shall follow if the pharmacist exercises initiation and modification of drug therapy; and
H. Indicate the date the supervising practitioner's supervision ends. The duration of the protocol agreement shall not exceed one (1) year; and
I. Be dated and signed by the pharmacist(s) and the supervising practitioner, if more than one practitioner agrees to supervise the pharmacist(s), each practitioner and pharmacist(s) shall sign and date the protocol; and
J. Include a statement that stipulates that the patient has been notified by the pharmacist(s) and the supervising practitioner that a protocol agreement exists.

ARTICLE XXXVII DUTIES AND RESPONSIBILITIES OF EXECUTIVE DIRECTOR

Pursuant to Section 6. Section 73-21-79, paragraph (3), Mississippi Code of 1972, Annotated, the duties and responsibilities of the Executive Director of the Mississippi Board of Pharmacy shall be defined by rules and regulations prescribed by the Board as follows:

The Executive Director (Director) is the executive officer in charge of the office of the Mississippi Board of Pharmacy and he/she shall be appointed by the Board. The Director shall serve as the budget officer and shall make, keep and be in charge of all records, record books and any files required to be maintained by the Board. The Director shall attend to the correspondence required by the office, and shall perform such other duties as the Board may require in keeping with the office. The Director shall be provided with, supervise, and have the aid of clerical, investigative and other office staff as necessary for the fulfillment of said duties and responsibilities.

1. GENERAL DUTIES AND RESPONSIBILITIES: The Executive Director shall have, but not be limited to, the following responsibilities:
   A. Issuance of all licenses, registrations and permits to all pharmacists, businesses, facilities, pharmacies or other persons as authorized by statutes, rules or regulations;
   B. Maintaining, preserving, and releasing of any public records which are required to be kept by the Board;
   C. Administration of any examinations or tests required under statutes or regulations;
   D. Serve as the representative of the Board on any committees, boards or other organizations as necessary to carry out the Board's responsibilities;
   E. Act as the Board's agent and cause to be issued and cause to be served, all subpoenas, Orders of the Board, and any Notice of Hearing and Complaint issued to any pharmacist, permit holder, business/facility, registrant or other person under the jurisdiction of the Board and execute the foregoing for and on behalf of the Board;
   F. Provide initiative, leadership and input into any proposed legislation or regulations pertaining to the practice of pharmacy, the distribution of prescription drugs, pharmacy technicians and pharmacy externs/interns;
   G. Set the agenda for all meetings of the Board, act as recording secretary and be responsible for the preparation of the Minutes of all meetings of the Board;
   H. Serve as the Board's representative in the approval of all continuing education as required by Regulations of the Board;
   I. Serve as the Board's representative when interacting and/or cooperating with other state or federal agencies or law enforcement entities.

ARTICLE XXXVIII MEDICAL EQUIPMENT SUPPLIERS PERMIT

1. Permit required:

Pursuant to Mississippi Pharmacy Practice Act Section 73-21-108 no person, business or entity subject to this chapter shall sell, rent or provide or offer to sell, rent or provide directly or indirectly to consumers in this state any home medical equipment, legend devices, and/or medical gas unless such person, business or entity first obtains a Medical Equipment Suppliers Permit from the Mississippi Board of Pharmacy. Permitting procedures are as follows:

A. The permitting requirements of this section will apply to all companies, agencies and other business entities that are in the business of supplying home medical equipment to patients in residential settings and which bill the patient or the patient's insurance, Medicare, Medicaid or other third party payor for the rent or sale of that equipment.
B. The application for a permit shall be on a form supplied by the Board and accompanied by a fee of $150.00. Once issued, every permit must be renewed annually. The renewal fee shall not exceed $150.00.
C. The Board shall require a separate permit for each facility location directly or indirectly owned or operated in this state. Permits shall not be issued for facilities located in a residence.
D. The Board shall require that all facilities issued a Non-Resident Durable Medical Equipment Supplier permit obtain a permit for a facility located within the State of Mississippi.
E. All permits issued under this section shall expire annually on June 30, of each year. Application and payment for renewal must be postmarked on or before June 30 and must be accompanied by the fee as prescribed by this section. A penalty of $50.00 shall be added to all late renewals postmarked after June 30, of each renewal period. The Permit shall become null and void if the renewal application~~,~~ and renewal fee are not received by July 1 of each year.
F. The person who signs the application for a medical equipment suppliers permit or the renewal of a medical equipment suppliers permit shall be the permit holder for that facility and shall be responsible for all activities in the permitted facility which are subject to regulation by the Board. Once issued, a permit cannot be amended, transferred or assigned to another person.
G. If the employment of a permit holder is terminated or if for any other reason he/she wishes to be relieved of the responsibilities of the permit holder, he/she must return the medical equipment suppliers permit to the Mississippi Board of Pharmacy with written notice that he/she is no longer the permit holder for that facility. When a permit is thus returned, application for a new permit for that facility must be made to the Mississippi Board of Pharmacy within ten (10) days.
H. If a permitted facility is permanently closed or has a change of ownership, the permit holder for that facility shall give notice to the Board of the effective date of closure or change in ownership at least ten (10) days prior to the closure or change of

ownership.

I. If a permitted facility has a change in name or location, a new permit must be obtained. Application for this new permit must be made to the Board at least ten (10) days prior to the change.

J. The Board shall not issue any original or annual renewal medical equipment permit until the Board is satisfied that:

(1) Adequate qualified personnel have been secured by management of the facility to properly render medical equipment services in the manner prescribed by law; and

(2) Such personnel shall be maintained during the period for which the permit is issued; and

(3) Suitable facilities shall be maintained to house inventory, to allow for equipment maintenance work space and the storage and retrieval of all records required to be kept; and

(4) Each non-resident medical equipment supplier holds a permit for a medical equipment supplier facility physically located within the State of Mississippi; and

(5) A copy of these regulations shall be present in the facility at all times; and

(6) The facility is kept in a clean, orderly and sanitary condition at all times ; and

(7) The applicant's services are accessible to its customer base; and

(8) The applicant complies with all USP, FDA, DOT and OSHA requirements regarding the storage, packaging, labeling and shipping of medical equipment including medical gases; and

(9) The applicant's services are available twenty-four (24) hours, seven (7) days per week when essential to the maintenance of life or when lack of services might reasonably cause harm; and

(10) The applicant implements and maintains a written procedure at each location for handling complaints and problems, which includes a complaint file documenting complaints and problems and resolution of the complaints and problems; and

(11) The applicant complies with all local/state fire and building laws; and

(12) The facility is equipped with a functioning lavatory where hot and cold running water or hand washing appliances or waterless hand cleaner are available; and

Exemptions are as follows:

A. The permitting requirements of this section do not apply to the following unless the following have a separate business entity, company, corporation or division that is in the business of providing home medical equipment to patients at their home: home health agencies; hospitals; wholesalers and/or manufacturers; medical doctors, physical therapists, respiratory therapists, occupational therapists, speech

pathologists, optometrists, chiropractors and podiatrists who use home medical equipment and/or legend devices in their individual practices; pharmacies; hospice programs; nursing homes and or long term care facilities; veterinarians; dentists; and emergency medical services.

B. Community pharmacies, long term care facilities and hospitals although excluded from permitting requirements of this section, will be subject to the same regulations for the sale or rental of home medical equipment covered by this section.

C. It is also recognized that oxygen, liquid oxygen and/or legend devices may be used in emergencies by trained individuals.

D. Nothing in this section shall prohibit the pre-hospital emergency administration of oxygen by licensed health care providers, emergency medical technicians, first responders, fire fighters, law enforcement officers and other emergency personnel trained in the proper use of emergency oxygen.

2. Medical Equipment Advisory Committee (MEAC) to the Board:

A. A MEAC committee, composed of three (3) members selected by the Mississippi Association of Medical Equipment Suppliers and approved by the Board, shall review and make recommendations to the Board on the merit of all regulations dealing with home medical equipment, legend devices and medical gases, which are proposed by the Board and before they are adopted by the Board.
Newly appointed MEAC members shall be assigned to Post 1., Post 2. or Post 3. Subsequent terms of MEAC members shall be for a period of five (5) years and no member shall serve two consecutive terms.

B. All MEAC members shall have been actively involved in the home medical equipment business for a minimum of five (5) years and shall hold and maintain, in good standing, a permit issued by the Board pursuant to this section.

C. The MEAC members shall meet at least quarterly and review all home medical equipment suppliers' inspection reports. All complaints and reports of investigations of violation of law or regulations shall first be reviewed by the MEAC. After review, the MEAC may make recommendations to the Board's Investigations Review Committee as to further administrative action by the Board.

D. The MEAC shall keep and maintain minutes of all meetings of the MEAC and shall provide copies of said minutes to the Board on a quarterly basis.

E. The Mississippi Board of Pharmacy may remove any or all MEAC members on proof of unprofessional conduct, continued absence from the state, being found guilty of any provisions of these regulations or other regulations of the state or federal government or failure to perform the duties of his/her office. Any MEAC member who shall not attend two (2) consecutive regular meetings of the MEAC for any reason other than illness shall be subject to removal by the Mississippi Board of Pharmacy.

3. Order Required:

Home Medical Equipment Suppliers shall not provide any legend device or medical gas to

a patient without a valid order from an authorized practitioner all orders must be readily retrievable and must be produced on request by a compliance agent. All legend items, including oxygen, require a new prescription order on a yearly basis.

4. Medical gas, oxygen and respiratory equipment suppliers shall:

   A. Comply with all applicable home medical equipment laws and regulations of Mississippi; and
   B. If transporting oxygen and other medical gases in cylinder or liquid form, comply with all current Department of Transportation rules and regulations; and
   C. If transfilling medical oxygen systems, comply with Food and Drug Administration (FDA) and all state agency requirements regarding transfilling and repackaging; and
   D. Demonstrate that oxygen and other medical gases provided in cylinder or liquid form meets minimum purity standards for medical grade oxygen and medical gases; and
   E. Meet the following safety inspection requirements:
      (1) Demonstrate that each piece of oxygen/respiratory equipment has been checked, is free of defects and operates within the manufacturer's specifications; and
      (2) Refrain from modifying equipment to the extent that the modification might reasonably cause harm; and
      (3) Maintain all electrical components so that they do not present fire or shock hazard; and
      (4) Ensure that all appropriate warning labels or labeling, including tags, are present on the equipment provided.

   I. Medical gas, oxygen and respiratory related equipment suppliers shall comply with the following recall procedures:
      A. Ensure that lot numbers and expiration dates are affixed to each cylinder delivered; and
      B. Maintain a tracking system for all medical oxygen and gas delivered; and
      C. Document all equipment serial numbers and model numbers to ensure that equipment can be retrieved if a recall is initiated; and
      D. Maintain records for equipment that requires FDA tracking.

   II. Medical gas, oxygen and respiratory related equipment suppliers shall comply with the following maintenance and cleaning requirements:
      A. Maintain documentation demonstrating that a function and safety check of equipment was performed prior to set up; and
      B. Maintain an established protocol for cleaning and disinfecting equipment which addresses both aerobic and anaerobic pathogens; and
      C. Maintain a Material Safety Data Sheet (MSDS) on file for solutions and products used in cleaning and disinfecting procedures; and
      D. Maintain segregated areas on the premises and in delivery vehicles for clean, dirty, and contaminated equipment; and

E. Clean and disinfect equipment according to manufacturers' specifications; and
F. Instruct the patient on proper cleaning techniques as specified by the manufacturer; and
G. Ensure that all medical gas, oxygen and respiratory related equipment is properly identified by a tag or label as to it's current status of use, i.e. out of order or ready for use.

III. Medical gas, oxygen and respiratory related equipment suppliers shall implement a comprehensive preventative maintenance program which includes the following:
A. Procedures for problem reporting, tracking, recall, and resolution; and
B. Performance of service as specified by the manufacturer and the documentation of such performance in the service records; and
C. Routine inspection, service, and maintenance of equipment located in the patient's/customer's home according to manufacturers' specifications.

IV. Medical gas, oxygen and respiratory related equipment suppliers shall maintain repair logs to document repair and maintenance of equipment, including, but not limited to, oxygen concentrators, infant monitors, and mechanical ventilators. The following information shall be documented in the repair log:
A. type of equipment; and
B. manufacturer; and
C. model; and
D. serial number; and
E. date of repair; and
F. specific repair made; and
G. name of person or company performing the repair.

V. Medical gas, oxygen and respiratory related equipment suppliers shall maintain testing equipment to ensure accurate calibration. Testing equipment shall be appropriate for the level of service offered. Scales used to weigh liquid oxygen reservoirs shall be properly maintained to ensure accuracy.

VI. Medical gas, oxygen and respiratory related equipment suppliers shall implement a written procedure at each location for handling complaints and problems, which includes a complaint file documenting complaints and problems and resolutions of the complaints or problems.

VII. Medical gas, oxygen and respiratory related equipment suppliers shall comply with the following counseling requirements:
A. Utilize orientation checklists to review:
(1) Instructions for use of the equipment; and
(2) Safety precautions; and
(3) Cleaning procedures; and
(4) Maintenance procedures; and

(5) Return demonstrations on back up oxygen systems delivered; and

B. Instruct the patient about emergency and routine contact procedures; and

C. Deliver and review written instruction materials to ensure that the patient receives adequate information in order to properly operate the equipment.

A written plan of service shall be developed, implemented, and documented in the patient record. The plan of service shall include, but is not limited to, an assessment of the safety of the home environment, the care giver or patient ability to comply with the order, and the care giver or patient ability to operate and clean the equipment as instructed.

5. Other Medical Equipment

Persons that shall sell, rent and/or provide other medical equipment or legend devices, as defined in these regulations, shall also comply with the following:

A. Provide proper training of personnel for the safe delivery and use of any medical equipment or legend device; and

B. Ensure that all manufacturer's recommended assembly and maintenance procedures are followed; and

C. Meet the following safety inspection requirements:

(1) Demonstrate that each piece of medical equipment or legend device has been checked, is free of defect and operates within the manufacturer's specifications; and

(2) Refrain from modifying equipment to the extent that the modification might reasonably cause harm; and

(3) Maintain all electrical components so that they do not present fire or shock hazard; and

(4) Ensure that all appropriate warning labels or labeling, including tags, are present on the equipment provided.

6. Revocation, Suspension or Restriction, Penalties of Permit shall be as follows:

A. The Board may revoke, suspend, restrict, refuse to issue or renew or impose a monetary penalty, in accordance with Section 73-21-103. Mississippi Code of 1972, Annotated, if the business or holder of a permit or applicant for a permit, issued under this section, has committed or is found guilty by the Board of any of the following:

(1) Violation of any Federal, State or local law or regulation relating to medical equipment, legend devices or medical gases.

(2) Violation of any of the provisions of these regulations.

(3) Commission of an act or engaging in a course of conduct which constitutes a clear and present danger to the public health and safety.

(4) Filing a claim or assisting in the filing of a claim for reimbursement for medical equipment, medical gases, legend devices or professional services which were not provided or which were not authorized to be provided.

(5) Failure to comply with any lawful order of the Board.

(6) Conviction of a felony.

(7) Entering into any written agreements or other activities which interferes with or otherwise denies a patient the freedom to choose any willing provider of medical equipment or services.

B. Disciplinary action by the Board against a business or any person holding a permit pursuant to this section shall be in accordance with Section 73-21-99 of the Mississippi Code of 1972, Annotated.

Definitions:

For purposes of these regulations:

A. "Home Medical Equipment" means technologically sophisticated medical equipment and devices usable in a home care setting including, but not limited to:

(1) Oxygen for human consumption, oxygen concentrators, and/or oxygen delivery systems and equipment;

(2) Ventilators;

(3) Respiratory disease management devices;

(4) Electronic and computer driven wheelchairs and seating systems;

(5) Apnea monitors;

(6) Transcutaneous electrical nerve stimulator (TENS) units;

(7) Low air loss cutaneous pressure management devices;

(8) Sequential compression devices;

(9) Neonatal home phototherapy devices;

(10) Feeding pumps;

(11) And other similar equipment as defined in any regulations established

B. "Home Medical Services" means the delivery, installation, maintenance, replacement, and/or instruction in the use of home medical equipment, used by a sick or disabled individual, to allow the individual to be cared for and maintained in a home or non-institutional environment.

C. "Medical gas" means those gases and liquid oxygen intended for human consumption.

D. "Order" means an order issued by a licensed medical practitioner legally authorized to order medical gases, legend devices and/or home medical equipment.

E. The term "Home Medical Equipment" does not mean medical equipment used in the normal course of treating patients by hospitals, hospices, long term care facilities or home health agencies or medical equipment used or dispensed by health care professionals licensed by the State of Mississippi---provided that the professional is practicing within the scope of his/her professional practice. Further, that items such as upper and lower extremity prosthetics, canes, crutches, walkers, bathtub grab bars, standard wheelchairs, commode chairs and bath benches are not considered to be home medical equipment.

F. "Pharmacy Board, State Board of Pharmacy or Board" shall mean the Mississippi Board of Pharmacy.

G. The term "Legend Device" shall mean any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including any component part or accessory which is required under federal or state law to be prescribed or ordered by a physician and/or practitioner.

ARTICLE XXXIX AUTOMATED PHARMACY SYSTEMS

1. Automated pharmacy systems include, but are not limited to, mechanical systems that perform operations or activities relative to the storage, packaging, delivery, or distribution of medications, and which collects, controls and maintains all transaction information. Every pharmacy that utilizes any such automated medication delivery system shall comply with the following.

2. PERSONNEL

   The pharmacist-in-charge shall have the following responsibilities:
   - A. Assuring that the automated pharmacy system is in good working order and accurately delivers the correct strength, dosage form and quantity of the medication prescribed while maintaining appropriate record-keeping and security safeguards; and
   - B. Implementing an ongoing quality assurance program that monitors performance of the automated pharmacy system, which is evidenced by written policies and procedures developed by the pharmacy; and
   - C. Providing the Board with prior written notice of the installation or removal of any automated pharmacy system. Such notice must include the name and address of the pharmacy, the location of the automated equipment and the identification of the responsible pharmacist.

3. PHARMACY PRACTICE

   Automated pharmacy systems can be utilized in permitted pharmacies, remote locations wherein patients are receiving pharmaceutical care by the pharmacist and/or pharmacy responsible for the automated pharmacy system, and other health care facilities, provided they are under the jurisdiction of the Board. The pharmacist-in-charge shall be responsible

   for the following:
   - A. Documentation as to type of equipment, serial numbers, content, policies and procedures and location shall be maintained onsite in the pharmacy for review by the Board. Such documentation may include, but is not limited to:
     - (1) Name and address of the pharmacy and/or licensed health care facility where the automated pharmacy system(s) is being used; and
     - (2) Manufacturer's name and model; and
     - (3) Description of how the device is used; and
     - (4) Quality assurance procedures to determine continued appropriate use of the automated device; and
     - (5) Policies and procedures for system operation, safety, security, accuracy, patient confidentiality, access and malfunction.
   - B. Automated pharmacy systems should be used only in settings where there is a program of pharmaceutical care which provides that medication orders are reviewed by a pharmacist in accordance with established policies and procedures. The delivery

of a “first dose” or an “emergency dose” may take place without prior order review by a pharmacist, provided appropriate security and patient medication management controls are in place.

C. All policies and procedures must be maintained in the pharmacy responsible for the system. If the system is not within the facility where the pharmacy is located, policies and procedures must be maintained at the location where the system is being used.

D. Automated pharmacy systems shall have adequate security systems and procedures, evidenced by written polices and procedures, to:
   (1) Prevent unauthorized access and to comply with federal and state regulations; and
   (2) Maintain patient confidentiality.

E. Records and/or electronic data kept by automated pharmacy systems shall meet the following requirements:
   (1) All events involving the contents of the automated pharmacy system must be recorded electronically; and
   (2) Records must be maintained by the pharmacy and must be readily available to the Board. Such records shall include:
      (a) Identity of system accessed; and
      (b) Identification of the individual accessing the system; and
      (c) Type of transaction; and
      (d) Name, strength, dosage form and quantity of the drug accessed and/or removed; and
      (e) Name of the patient for whom the drug was ordered and a record in the automated pharmacy system or other readily retrievable system of the name of the prescriber; and
      (f) Such additional information as the pharmacist-in-charge may deem necessary.

F. Access to, and limits on access (e.g. security levels) to the automated pharmacy system must be defined by policy and procedures and must comply with state and federal regulations.

G. The pharmacist-in-charge shall be responsible for:
   (1) Assigning, discontinuing or changing access to the system; and
   (2) Ensuring that access to the medications comply with state and federal regulations; and
   (3) Ensuring that the automated pharmacy system is filled/stocked/replenished accurately and in accordance with established written policies and procedures.

H. The filling/stocking/replenishing of all medications in the automated pharmacy system shall be accomplished by qualified personnel under the supervision of a pharmacist licensed by the Board.

I. A record of the medications filled/stocked/replenished in an automated pharmacy system shall be maintained for a period of two (2) years and shall include identification of the persons filling/stocking/replenishing and checking for accuracy.

J. All containers of medications stored in an automated pharmacy system shall be packaged and labeled in accordance with federal and state laws and regulations.

K. The automated pharmacy system must have the capability to produce a hard copy printout of the utilization of controlled substances maintained in each automated pharmacy system. All aspects of handling controlled substances shall meet the requirements of all state and federal laws and regulations.

L. The automated pharmacy systems shall provide a mechanism for securing and accounting for medications removed from and subsequently returning to the equipment, all in accordance with existing state and federal law.

M. The automated pharmacy system shall provide a mechanism for securing and accounting for wastage of medications or discarded medications in accordance with state and federal law and/or regulations.

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 serve~~s~~ 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) 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 XLI MEDICAL GAS WHOLESALERS PERMIT

1. Every person, business or other entity where medical gas(es) are maintained, bought, sold or distributed within this state shall obtain a permit as a medical gas wholesaler from the Mississippi Board of Pharmacy.

2. To obtain a permit or renew a permit for a medical gas wholesalers permit, the applicant shall:
   A. Submit a written application on a form prescribed by the Board;
   B. Submit the required fees as follows:
      Fifty dollars ($50.00) for the registration period January 1, 2012, through December 31, 2013, and each biennial registration period thereafter.

      A penalty of $50.00 shall be added to all late renewals postmarked after January 1, of each renewal period.

3. Every business issued a medical gas wholesalers permit shall renew this permit biennially. Newly issued permits which do not coincide with the registration period shall be valid for the following periods of time: If the permit is issued in the first half of the registration period, it must be renewed at the end of the registration period. If the permit is issued in the second half of the registration period, it must be renewed at the end of the next registration period.

4. The person who signs the application for a medical gas wholesalers permit or its renewal shall be the permit holder for that facility and shall be responsible for all activities in the permitted facility which are subject to regulation by the Board. Once issued, a permit cannot be amended, transferred or assigned to another person.

5. If the employment of a permit holder is terminated or if for any other reason he/she wishes to be relieved of the responsibilities of the permit holder, he/she must return the medical gas distributors permit to the Mississippi Board of Pharmacy with written notice that he/she is no longer the permit holder for that facility. When a permit is thus returned, application for a new permit for that facility must be made to the Mississippi Board of Pharmacy within ten (10) days.

6. If a permitted facility is permanently closed or has a change of ownership, the permit holder for that facility shall give notice to the Board of the effective date of closure or change in ownership at least ten (10) days prior to the closure or change of ownership.

7. If a permitted facility has a change in name or location, a new permit must be obtained. Application for this new permit must be made to the Board at least ten (10) days prior to the change.
8. All medical gas wholesalers permitted by the Mississippi Board of Pharmacy shall comply with the following:

A. A medical gas wholesaler shall distribute medical gases only to those persons authorized by state law to purchase, maintain, administer or use these products.
B. A medical gas wholesaler shall not distribute medical gases directly to a patient.
C. A medical gas wholesaler must maintain records of all acquisition and sales of medical gases for a period of two (2) years. Normal business records are sufficient.
D. A medical gas wholesaler who wishes to transfill medical gases shall register with the Food and Drug Administration and shall comply with all regulations and standards as required by such registration. All copies of any inspections conducted by the Food and Drug Administration shall be maintained and produced for review by any agent of the Mississippi Board of Pharmacy. A copy of the transfilling registration must be maintained on file.
E. A medical gas wholesaler shall properly store and transport any medical gas in compliance with all federal, state and local laws and regulations.
F. The Board of Pharmacy may refuse to issue or renew, or may suspend, revoke or restrict the permit of any medical gas wholesaler under the applicable provisions of ARTICLE IX of these regulations.

9. For purposes of these regulations “medical gas” means a liquid or gaseous substance used for medical purposes and that is required by federal law to bear the following statement: “Caution: Federal law prohibits dispensing without a prescription.” Medical gases may include, but not be limited to liquid oxygen, compressed oxygen and nitrous oxide.

ARTICLE XLII ADMINISTRATIVE PROCEDURE RULES

1. SCOPE

The following Rules of Procedure as contained in this ARTICLE shall apply to all pharmacists licensed by the Mississippi Board of Pharmacy and all other persons under the jurisdiction of said Board. The purpose of this ARTICLE is to implement and enforce the standards of pharmacy and pharmacy practice and conduct of all other persons under the jurisdiction of the Mississippi Board of Pharmacy as provided for in all state & federal drug laws, the Mississippi Pharmacy Practice Act and the Pharmacy Practice Regulations of the Mississippi Board of Pharmacy.

2. DEFINITIONS

For purposes of this ARTICLE the following definitions shall apply:

A. The word "Board" shall mean the Mississippi Board of Pharmacy.

B. The term “Investigative Staff” shall mean duly sworn Mississippi Board of Pharmacy Compliance Agents.

C. The term “Investigations Review Committee” shall mean a committee composed of two (2) members as designated by the Board to serve on a rotating, no longer than three-consecutive-month basis along with the Board’s Executive Director and counsel for the Board.

D. The word "Respondent" shall mean a pharmacist or other person against whom a disciplinary action and proceeding has been initiated by the Mississippi Board of Pharmacy.

E. Masculine terms, when used in the following Rules of Procedure, shall also be deemed to include the feminine.

F. The term “Mississippi Pharmacy Practice Act” shall mean Sections 73-21-71, et. seq. of the Mississippi Code of 1972, Annotated.

3. COMPLAINTS/INVESTIGATIONS

An investigation of alleged violation(s) of the Mississippi Pharmacy Practice Act may be initiated by the investigative staff of the Board either:

A. In response to a written complaint or adverse information received by the Board; or

B. Based on information independently developed by the investigative staff of the Board.

Upon receipt of information indicating possible violation of the Pharmacy Practice Act, the investigative staff, with advice and consultation of members of the Investigations Review Committee, shall make an initial determination as to whether the information justifies further investigation. A case may be dismissed without further investigation based on a determination of either:

A. Lack of jurisdiction; or

B. No violation of the Mississippi Pharmacy Practice Act.

4. INITIATION OF DISCIPLINARY ACTION

Upon conclusion of an investigation, the investigative staff shall present the results of the investigation to the Investigations Review Committee for review and action. Disciplinary action by the Board shall require the following:

A. A sworn affidavit filed with the Board charging a licensee, registrant or pharmacist-in-charge with an act which is grounds for discipline as provided for in Section 73-21-97, Mississippi Code of 1972, Annotated; and

B. An order of the investigations Review Committee which shall cause the Executive Director of the Board to fix a time and place for Hearing by the Board. Such Notice of Hearing and Complaint may be served by mailing a copy thereof by certified mail, postage prepaid, to the last known residence or business address of the licensee, registrant or pharmacist-in-charge.

5. ADMINISTRATIVE HEARINGS

Policies for the granting of a continuance are as follows:

A. Hearings shall be held before the Board at the time and place designated in the "Notice of Hearing and Complaint", unless a continuance is granted for just good cause by the Board. A motion for a continuance must be filed with the Board at least fifteen (15) days prior to the scheduled hearing, or upon a showing of good cause, at any time prior to the hearing; and

B. It must be recognized that the Board consists of seven (7) practicing pharmacists representing various regions of the State. Unlike the judiciary, the Board members are not in the business of conducting hearings, therefore hearings will be held only during regularly scheduled meetings or other dates established by the Board. Attorneys representing pharmacists should take this fact into consideration. A scheduled hearing may be continued if the Respondent shows substantial, legitimate grounds for continuing the hearing, based on the balance of:

   (1) The right of Respondent to a reasonable opportunity to prepare and present a defense; and

   (2) The Board's responsibility to protect the public health, safety and welfare.

C. Where the counsel for Respondent has a scheduling conflict on the initial hearing date, continuances will be liberally granted. However, Respondent's Counsel must submit written proof of the scheduling conflict fifteen (15) days prior to the scheduled hearing date. Thereafter, no further continuances will be granted based solely on scheduling conflicts; and

D. So that counsel for the Respondent and Complaint Counsel shall be able to adequately prepare for hearing, any motion for a continuance filed within the time limitations as specified in Subsection A above, will be immediately considered by the Board's President, who shall have the authority to grant or deny said motion. If granted, the Director of Compliance of the Board shall reschedule hearing at the earliest open date on the Board's calendar; and

E. It is the responsibility of the Respondent to make a prompt decision as to whether to appear before the Board without counsel or to retain counsel for this purpose.

Unless due to extraordinary circumstances, the Respondent's last minute decision to retain counsel will not be considered valid grounds for continuance of the matter.

6. SUBPOENAS

Policies for the issuance of subpoenas are as follows:

A. For the purpose of disciplinary hearings, the Board acting by and through its Executive Director, may subpoena persons and papers on its own behalf and on behalf of a Respondent.

B. Prior to the Board issuing any subpoena on behalf of a Respondent, the Respondent shall:

(1) File with the Board a written request for the issuance of said subpoenas, identifying with certainty the identity and address of all individuals to be subpoenaed, along with a concise description of the records to be subpoenaed with the identity and address of the custodian of said records; and

(2) All subpoenas issued by the Board on behalf of Respondent shall be hand delivered or effected by registered mail; and

(3) All requests for issuance of subpoenas shall be filed with the Board sufficiently distant in time to allow for the preparation and mailing of said subpoenas at least ten (10) working days before the scheduled hearing date. The Board shall not be responsible for the timely receipt of subpoenas issued after the aforementioned deadline.

C. The Board shall charge a Respondent a reasonable fee, not to exceed $25.00 per subpoena, for preparation and mailing of subpoenas.

7. INFORMAL SETTLEMENT, PRE-HEARING, STIPULATIONS, CONSENT ORDERS

Policies for informal settlements and consent orders are as follows:

A. All disciplinary proceedings initiated by the Board shall be brought to a final resolution through one of three means:

(1) Disciplinary hearings before the Board; or

(2) Acceptance by the Board of a mutually agreeable Consent Order in lieu of a hearing; or

(3) Dismissal of the case.

B. As to disciplinary proceedings wherein the Respondent has been duly served with a Notice of Hearing and Complaint, said Respondent and/or Respondent's Counsel may agree that an Informal Settlement Conference be held for the purpose of possible resolution of the matter or for purposes of simplifying the issues for hearing or promoting stipulations as to facts and proposed evidentiary offerings which will not be disputed at hearing.

C. The Informal Settlement Conference shall be conducted by Respondent and/or his counsel and Board Counsel. Other parties who may attend include Compliance Agents for the Board and Board members who served on the Investigations Review Committee (IRC) that authorized that a Notice of Hearing and Complaint

be issued in the matter. Other Board members may not attend or have knowledge or input into any activities of the Conference.

D. Discovery or exchange of information may be accomplished during the Informal Settlement Conference.

E. The Informal Settlement Conference may result in:

(1) Preparation of a proposed Consent Order as a resolution of the matter;

(2) Proceeding with the scheduled hearing.

F. Any action which the Board may take following a full disciplinary hearing may be taken in lieu thereof by Consent Order, Duly executed by the Respondent. Because of the lengthy dockets before the Board, informal Settlement Conferences must be held in sufficient time to allow consummation of negotiations of a Consent Order, at least ten (10) working days prior to the scheduled hearing date. After the terms of the Consent Order have been prepared and mutually accepted by Board Counsel, the investigating Compliance Agent and the two (2) IRC Board members that originally heard the matter, all terms of the Consent Order shall be binding on the Board. Said terms of the Consent Order are not effective until Board approval. Notwithstanding, it is still the responsibility of the Respondent to personally appear before the Board on the scheduled hearing date to answer any questions which the Board may have prior to Board approval.

G. Failure of the Board to approve and/or ratify any Consent Order shall result in an administrative hearing before the Board as originally scheduled in order to resolve all matters as outlined in the Notice of Hearing and Complaint.

H. Hearings for matters in which Consent Orders are considered by the Board, shall be conducted according to the Board's Rules of Procedures for Administrative Hearings.

8. DISCOVERY

Policies for discovery are as follows:

A. Upon written request by a Respondent or his counsel, Complaint Counsel of the Board shall disclose and permit Respondent or his counsel to inspect, copy or photograph the following information and material, which is in the possession, custody, or control of the Board, or the existence of which is known to the Complaint Counsel:

(1) Names and addresses of all witnesses proposed to be called in Complaint Counsel's case in chief, together with a copy of the contents of any statement, written, recorded, or otherwise preserved, of each such witness.

(2) Copies of any written or recorded statement of Respondent and the substance of any oral statement made by the Respondent.

(3) Copies of any criminal records of a Respondent, if proposed to be used.

(4) Any written reports or statements of experts, if proposed to be offered as evidence in connection with the particular case.

(5) All records, documents, physical evidence or photographs which may be offered as evidence.

(6) Any exculpatory material concerning the Respondent. The Board shall charge a Respondent a reasonable fee, not to exceed fifty cents per copy, payable in advance of delivery of copied documents.

B. The Board may deny disclosure authorized by subsection A if it finds that there is a substantial risk to any person of physical harm, intimidation, bribery, economic reprisals, or unnecessary embarrassment, resulting from such disclosure, which outweighs any usefulness of the disclosure to Respondent or his counsel.

C. If Respondent requests discovery under this rule, Respondent shall, promptly disclose to Complaint Counsel and permit him to inspect, copy or photograph, the following information and material which is in the possession, custody, or control of Respondent of his counsel, or the existence of which is known to Respondent or his counsel:

(1) Names and addresses of all witnesses proposed to be called in Respondent's defense together with a copy of the contents of any statement, written, recorded, or otherwise preserved, of each such witness.

(2) All records, documents, physical evidence or photographs which may be offered as evidence in Respondent's defense.

(3) Any written reports or statements of the experts, if proposed to be offered as evidence in connection with the particular case.

D. No depositions shall be taken in preparation for matters to be heard before the Board.

9. POLICIES FOR ADMINISTRATIVE HEARINGS

Procedures for administrative hearings are as follows:

A. Procedures are designed to give the accused the right to be heard in a fair and impartial hearing.

B. The President or Vice-President or Senior Member of the Board present shall act as the presiding officer and shall rule on all objections and motions. All such rulings are subject to the full Board's approval.

C. The Board is not bound by strict rules of evidence but all determinations must be based upon sufficient evidence.

D. All hearings are open to the public, however, public members shall not participate nor be present during any Executive Session of the Board.

E. The Executive Director, with the advice of the Board Counsel, will subpoena all witnesses for the Board or the defendant when requested to do so.

F. All charges shall be based upon affidavits sufficiently definite to constitute an allegation or specific violation of any law or regulation that governs pharmacists and the practice of pharmacy or any other person under the jurisdiction of the Board.

G. The Respondent has the right to appear either personally, by counsel, or both; to produce witnesses, cross-examine witnesses and have subpoenas issued by the Board.

H. A definite time and place shall be set with proper notice being given and a quorum present for all proceedings.

I. Board members who served on the Investigations Review Committee and who reviewed the investigation of the complaint that led to the administrative hearing, shall recuse themselves and not participate in the disciplinary proceeding.

J. All Board decisions are made in Executive Session.

K. A copy of these Board Rules of Procedure for Administrative Hearings shall be supplied to the Respondent along with the Notice of Hearing and Complaint.

10. PROCEDURES FOR ADMINISTRATIVE HEARINGS

Procedures for the conduct of administrative hearings are as follows:

A. The Hearing is called to order by the President or presiding officer.

B. President requests that the Respondent/counsel be called.

C. When Respondent appears, introductions are made and oaths administered to the Respondent and others, as may be necessary for proper conduct of the hearing.

D. The Respondent is then asked to state his/her name, address and license number and is informed that the hearing is being recorded.

E. If Respondent is represented by counsel, counsel name and address is entered into the record.

F. The President then asks Board Counsel to present the charges and place said charges into the record as appropriate.

G. Before going into the merits of the cause, evidence should be placed into the record showing that the Respondent was properly notified of the charges.

H. The Respondent is then asked to respond to the charges.

I. The Board Counsel may have witnesses called for the Board and shall conduct the direct examination of same.

(1) At the conclusion of the examination, the Respondent or Respondent’s Counsel may cross-examine.

(2) At the conclusion of the cross-examination, the Board may question the witness.

(3) At the conclusion of the witness' testimony, the witness may be excused subject to recall.

J. The Respondent may call witnesses after the Board has rested it's case. The Respondent or Respondent’s Counsel will conduct the direct examination.

(1) Board Counsel may cross-examine Respondent witness.

(2) Board members may then question Respondent witness.

(3) The witness may be excused subject to recall.

K. The Board may then call rebuttal witnesses.

L. Respondent or Respondent’s Counsel may make closing arguments if desired.

M. After all response has been presented by both sides, the Board by majority vote, shall enter into Executive Session to consider all evidence presented and make a final decision or ruling.

N. The Board shall make findings of fact on each charge. The Board should adjudicate each charge as presented, based on the evidence submitted.

O. The Board then determines what disciplinary action, if any, should be taken in the matter.

P. Following the Executive Session, the Respondent may or may not be informed of the Board's action. However, within thirty (30) days the Board shall reduce its decision to writing and include the Proceedings, Conclusions of Law, Findings of Fact and the Final Order of the Board. The Board shall forward an attested true copy thereof to the last known residence or business address of such licensee or permit holder by way of United States first-class, certified mail, postage prepaid.

ARTICLE XLIII PRESCRIPTION MONITORING PROGRAM

1. The Board of Pharmacy shall establish and maintain, with the consultation of the Prescription Monitoring Advisory Board, an electronic system for monitoring and tracking prescriptions dispensed for controlled substances listed in Schedules II, III, IV or V that are dispensed by a pharmacy.
   The Prescription Monitoring Program shall provide information regarding the inappropriate use of controlled substances in Schedule II, III, IV and V to pharmacies, practitioners and appropriate state or federal agencies in order to prevent the improper or illegal use of such controlled substances. This program shall not infringe on the legal use of controlled substances for the management of severe or intractable pain.
   The Board of Pharmacy will report any activity it reasonably suspects may be fraudulent or illegal to the appropriate law enforcement or regulatory board and provide them with relevant information obtained for further investigation.

2. A record of all controlled substance dispensing information shall be transmitted to the Prescription Monitoring Program on a time basis determined by the program by all pharmacies dispensing controlled substances (greater than a 48 hours supply) on an out-patient basis for the purpose of tracking the dispensing of Schedules II, III, IV and V controlled substances by the Prescription Monitoring Program. Dispensers will be required to collect and transmit the following information:

   (A) The recipient's name.
   (B) The recipient's or the recipient representative's identification number.
   (C) The recipient's date of birth.
   (D) The national drug code (NDC) number of the controlled substance dispensed.
   (E) The date the controlled substance is dispensed.
   (F) The quantity of the controlled substance dispensed.
   (G) The number of days supply dispensed.
   (H) The dispenser's NABP or NCPDP registration number.
   (I) The prescriber's U. S. DEA registration number.
   (J) The method of payment of the prescription purchase.

3. Each dispenser shall submit the required information as required by the Prescription Monitoring Program.

4. (a) Except as indicated in paragraphs (b), (c), and (d) of this Section, Prescription Monitoring Information submitted to the program shall be considered Protected Health Information and not subject to public or open record laws.
   (b) The program shall review the Prescription Monitoring Information. If there is reasonable cause to believe a violation of law or of occupational standards may have occurred, the program shall notify the appropriate law enforcement and/or occupational licensing, certification, or regulatory agency or entity, and provide Prescription Monitoring

information required for an investigation.
(c) The program may provide Prescription Monitoring Information for public research, policy or education purposes, to the extent all information has been de-identified.
(d) The Board of Pharmacy and the Prescription Monitoring Program shall be immune from civil liability arising from inaccuracy of any of the information submitted to the program pursuant to this act.

5. Disciplinary action for failure to submit drug monitoring information or knowingly submitting incorrect information shall be in accordance with Section 73-21-103, paragraph (1), (d), (v) of the Pharmacy Practice Act.

ARTICLE XLIV SEVERABILITY PROVISION

If any ARTICLE, Section, Paragraph, Sentence, Clause, Phrase, or any part of the above and foregoing Rules and Regulations of the Mississippi Board of Pharmacy is declared to be unconstitutional or void or for any reason is declared to be invalid or of no effect, the remaining ARTICLES, Sections, Paragraphs, Sentences, Clauses, Phrases, shall be in no manner affected thereby but shall remain in full force and effect.

ARTICLE XLV PHARMACY BENEFIT MANAGER

In addition to all other applicable sections of the Mississippi Code of 1972, ARTICLE XXLV of the Mississippi Board of Pharmacy Regulation pertains specifically to Pharmacy Benefit Managers.

1. DEFINITIONS

A. "Board" means the State Board of Pharmacy.

B. "Commissioner" means the Mississippi Commissioner of Insurance.

C. "Day" means a calendar day, unless otherwise defined or limited.

D. "Electronic claim" means the transmission of data for purposes of payment of covered prescription drugs, other products and supplies, and pharmacist services in an electronic data format specified by a pharmacy benefit manager and approved by the department.

E. "Electronic adjudication" means the process of electronically receiving, reviewing and accepting or rejecting an electronic claim.

F. "Enrollee" means an individual who has been enrolled in a pharmacy benefit management plan.

G. "Health insurance plan" means benefits consisting of prescription drugs, other products and supplies, and pharmacist services provided directly, through insurance or reimbursement, or otherwise and including items and services paid for as prescription drugs, other products and supplies, and pharmacist services under any hospital or medical service policy or certificate, hospital or medical service plan contract, preferred provider organization agreement, or health maintenance organization contract offered by a health insurance issuer, unless preempted as an employee benefit plan under the Employee Retirement Income Security Act of 1974. However, "health insurance coverage" shall not include benefits due under the workers compensation laws of this or any other state.

H. "Pharmacy benefit manager" means a business that administers the prescription drug/device portion of pharmacy benefit management plans or health insurance plans on behalf of plan sponsors, insurance companies, unions and health maintenance organizations. For purposes of Sections 73-21-151 through 73-21-159, a "pharmacy benefit manager" shall not include an insurance company that provides an integrated health benefit plan and that does not separately contract for pharmacy benefit management services. The pharmacy benefit manager of the Mississippi State and School Employees Health Insurance Plan or the Mississippi Division of Medicaid or its contractors when performing services for the Division of Medicaid shall not be subject

to Sections 73-21-151 through 73-21-159 because of those activities, but, if they are conducting business as a pharmacy benefit manager other than with those agencies, they shall be subject to Sections 73-21-151 through 73-21-159 for those activities only.

I. "Pharmacy benefit management plan" means an arrangement for the delivery of pharmaceutical services in which a pharmacy benefit manager undertakes to administer the payment or reimbursement of any of the costs of pharmacist's services for an enrollee on a prepaid or insured basis which (i) contains one or more incentive arrangements intended to influence the cost or level of pharmaceutical services between the plan sponsor and one or more pharmacies with respect to the delivery of pharmacist's services; and (ii) requires or creates benefit payment differential incentives for enrollees to use under contract with the pharmacy benefit manager. A pharmacy benefit management plan does not mean any employee welfare benefit plan if preempted by the Employee Retirement Income Security Act of 1974, which is self-insured or self-funded, the Mississippi State and School Employees Health Insurance Plan or the programs operated by the Mississippi Division of Medicaid.

J. "Pharmacist", "pharmacist services" and "pharmacy" or "pharmacies" shall have the same definitions as provided in Section 73-21-73.

K. "Uniform claim form" means a form prescribed by rule by the State Board of Pharmacy, provided however that, for purposes of Sections 73-21-151 through 73-21-159, the board shall adopt the same definition or rule where the State Department of Insurance has adopted a rule covering the same type of claim. The board may modify the terminology of the rule and form when necessary to comply with the provisions of Sections 73-21-151 through 73-21-159.

L. "Plan sponsors" means the employers, insurance companies, unions and health maintenance organizations that contract with a pharmacy benefit manager for delivery of prescription services.

2. LICENSE REQUIRED BEFORE CONDUCTING BUSINESS AS PHARMACY BENEFIT MANAGER; PHARMACY BENEFIT MANAGERS TO FILE CERTAIN FINANCIAL STATEMENTS WITH STATE BOARD OF PHARMACY; TIME PERIOD FOR FILING STATEMENTS

A. Before beginning to do business as a pharmacy benefit manager, a pharmacy benefit manager shall obtain a license from the board. To obtain a license, the applicant shall submit an application to the board on a form prescribed by the board.

a. Contents of Application shall include:

i. The identity of the pharmacy benefits manager and any company or organization controlling the operation of the pharmacy benefits manager, including the name, business address, and contact person, for

the pharmacy benefit manager and the controlling entity.

ii. A "Certificate of Good Standing" from the Mississippi Secretary of State and, if applicable, a Mississippi "Certificate of Existence".

iii. In the case of pharmacy benefit managers domiciled out of the State of Mississippi, a certificate that the pharmacy benefits manager, company or organization is in good standing in the state of domicile or organization.

iv. A report of the details of any suspension, sanction, penalty or other disciplinary action relating to the pharmacy benefits manager, controlling company or organization, in the State of Mississippi or any other state, territory or country.

v. The pharmacy benefit manager shall report all previous and future data security breaches and HIPAA security breaches.

vi. The name and address of the agent of record or for services of process for the pharmacy benefit manager in Mississippi.

vii. A list of the pharmacy benefit manager's principal owners.

viii. The geographical services area of the pharmacy benefit manager.

ix. A list of all entities on whose behalf the pharmacy benefit manager has contracts or agreements to provide pharmacy benefit services.

x. The number of total enrollees or lives served under all of the pharmacy benefit manager's contracts or agreements in Mississippi and nationwide.

xi. A contingency plan describing how contracted pharmacy benefit services will be provided in the event of insolvency of the pharmacy benefit manager.

xii. The most recently concluded fiscal year-end financial statements for the pharmacy benefit manager and its controlling company or organization, which statements have been audited by an independent certified public accountant (CPA) under U.S. generally accepted accounting principles (GAAP).

xiii. The names and addresses of the public accounting firm and internal accountant(s) preparing or assisting in the preparation of such financial statements.

xiv. A certificate signed by the Chief Executive Officer of the pharmacy benefit manager attesting to the accuracy of the information contained in the filing.

xv. The Pharmacy Benefit Manager license shall be an annually renewable license expiring on January 1st of each calendar year.

xvi. A non-refundable license fee of $500.00 must accompany each application for the application to be considered complete.

xvii. 'Pro rata' pharmacy benefit manager licenses are not allowed by the Board.

xviii. A completed application for renewal of a Pharmacy Benefit Manager license must be received at the offices of the Board no later than

December 31st annually.

xix. In the event that a pharmacy benefit manager license renewal is received after December 31st, a $500.00 late fee will be assessed and payment must be received by the Board before a license will be issued.

xx. A monetary penalty of $1000.00 per day may be imposed upon any Pharmacy Benefit Manager that practices or conducts business in the State of Mississippi without a license.

B. The pharmacy benefit manager, including all contracted entities, shall operate to the best interest of the patient or citizen of Mississippi, including costs related to the patient or citizen.

C. Each pharmacy benefit manager providing pharmacy management benefit plans in this state shall file a statement with the board annually by March 1 or within sixty (60) days of the end of its fiscal year if not a calendar year. The statement shall be verified by at least two (2) principal officers and shall cover the preceding calendar year or the immediately preceding fiscal year of the pharmacy benefit manager.

D. The statement shall be on forms prescribed by the board and shall include:

a. A financial statement of the organization, including its balance sheet and income statement for the preceding year; and

b. Any other information relating to the operations of the pharmacy benefit manager required by the board under this section.

However, no pharmacy benefit manager shall be required to disclose proprietary information of any kind to the board.

E. If the pharmacy benefit manager is audited annually by an independent certified public accountant, a copy of the certified audit report shall be filed annually with the board by June 30 or within thirty (30) days of the report being final.

F. The board may extend the time prescribed for any pharmacy benefit manager for filing annual statements or other reports or exhibits of any kind for good cause shown. However, the board shall not extend the time for filing annual statements beyond sixty (60) days after the time prescribed by subsection (1) of this section. The board may waive the requirements for filing financial information for the pharmacy benefit manager if an affiliate of the pharmacy benefit manager is already required to file such information under current law with the Commissioner of Insurance and allow the pharmacy benefit manager to file a copy of documents containing such information with the board in lieu of the statement required by this section.

G. The expense of administering this section shall be assessed annually by the board

against all pharmacy benefit managers operating in this state.

3. FINANCIAL EXAMINATION OF PHARMACY BENFIT MANAGER

A. In lieu of or in addition to making its own financial examination of a pharmacy benefit manager, the board may accept the report of a financial examination of other persons responsible for the pharmacy benefit manager under the laws of another state certified by the applicable official of such other state.

B. The board shall coordinate financial examinations of a pharmacy benefit manager that provides pharmacy management benefit plans in this state to ensure an appropriate level of regulatory oversight and to avoid any undue duplication of effort or regulation. The pharmacy benefit manager being examined shall pay the cost of the examination. The cost of the examination shall be deposited in a special fund that shall provide all expenses for the licensing, supervision and examination of all pharmacy benefit managers subject to regulation under Sections 73-21-71 through 73-21-129 and Sections 73-21-151 through 73-21-159.

C. The board may provide a copy of the financial examination to the person or entity that provides or operates the health insurance plan or to a pharmacist or pharmacy.

D. The board is authorized to hire independent financial consultants to conduct financial examinations of a pharmacy benefit manager and to expend funds collected under this section to pay the costs of such examinations.

4. CLEAN CLAIM

Most current nationally recognized reference price to be used in calculation of reimbursement for prescription drugs and other products and supplies; updating of reference price; time period for payment of benefits; "clean claim" defined; compliance; penalties

A. Reimbursement under a contract to a pharmacist or pharmacy for prescription drugs and other products and supplies that is calculated according to a formula that uses a nationally recognized reference in the pricing calculation shall use the most current nationally recognized reference price or amount in the actual or constructive possession of the pharmacy benefit manager, its agent, or any other party responsible for reimbursement for prescription drugs and other products and supplies on the date of electronic adjudication or on the date of service shown on the nonelectronic claim.

B. Pharmacy benefit managers, their agents and other parties responsible for reimbursement for prescription drugs and other products and supplies shall be required to update the nationally recognized reference prices or amounts used for calculation of

reimbursement for prescription drugs and other products and supplies no less than every three (3) business days.

C. All benefits payable under a pharmacy benefit management plan shall be paid within fifteen (15) days after receipt of due written proof of a clean claim where claims are submitted electronically, and shall be paid within thirty-five (35) days after receipt of due written proof of a clean claim where claims are submitted in paper format. Benefits due under the plan and claims are overdue if not paid within fifteen (15) days or thirty-five (35) days, whichever is applicable, after the pharmacy benefit manager receives a clean claim containing necessary information essential for the pharmacy benefit manager to administer preexisting condition, coordination of benefits and subrogation provisions under the plan sponsor's health insurance plan. A "clean claim" means a claim received by any pharmacy benefit manager for adjudication and which requires no further information, adjustment or alteration by the pharmacist or pharmacies or the insured in order to be processed and paid by the pharmacy benefit manager. A claim is clean if it has no defect or impropriety, including any lack of substantiating documentation, or particular circumstance requiring special treatment that prevents timely payment from being made on the claim under this subsection. A clean claim includes resubmitted claims with previously identified deficiencies corrected.

I. A clean claim does not include any of the following:
   (a) A duplicate claim, which means an original claim and its duplicate when the duplicate is filed within thirty (30) days of the original claim;
   (b) Claims which are submitted fraudulently or that are based upon material misrepresentations;
   (c) Claims that require information essential for the pharmacy benefit manager to administer preexisting condition, coordination of benefits or subrogation provisions under the plan sponsor's health insurance plan; or
   (d) Claims submitted by a pharmacist or pharmacy more than thirty (30) days after the date of service; if the pharmacist or pharmacy does not submit the claim on behalf of the insured, then a claim is not clean when submitted more than thirty (30) days after the date of billing by the pharmacist or pharmacy to the insured.

II. Not later than fifteen (15) days after the date the pharmacy benefit manager actually receives an electronic claim, the pharmacy benefit manager shall pay the appropriate benefit in full, or any portion of the claim that is clean, and notify the pharmacist or pharmacy (where the claim is owed to the pharmacist or pharmacy) of the reasons why the claim or portion thereof is not clean and will not be paid and what substantiating documentation and information is required to adjudicate the claim as clean. Not later than thirty-five (35) days after the date the pharmacy benefit manager actually receives a paper claim, the pharmacy benefit manager shall pay the appropriate benefit in full, or any portion of the claim that is clean, and notify the pharmacist or pharmacy (where the claim is owed to the pharmacist

or pharmacy) of the reasons why the claim or portion thereof is not clean and will not be paid and what substantiating documentation and information is required to adjudicate the claim as clean. Any claim or portion thereof resubmitted with the supporting documentation and information requested by the pharmacy benefit manager shall be paid within twenty (20) days after receipt.

D. If the board finds that any pharmacy benefit manager, agent or other party responsible for reimbursement for prescription drugs and other products and supplies has not paid ninety-five percent (95%) of clean claims as defined in subsection (3) of this section received from all pharmacies in a calendar quarter, he shall be subject to administrative penalty of not more than Twenty-five Thousand Dollars ($ 25,000.00) to be assessed by the State Board of Pharmacy.

I. Examinations to determine compliance with this subsection may be conducted by the board. The board may contract with qualified impartial outside sources to assist in examinations to determine compliance. The expenses of any such examinations shall be paid by the pharmacy benefit manager examined.

II. Nothing in the provisions of this section shall require a pharmacy benefit manager to pay claims that are not covered under the terms of a contract or policy of accident and sickness insurance or prepaid coverage.

III. If the claim is not denied for valid and proper reasons by the end of the applicable time period prescribed in this provision, the pharmacy benefit manager must pay the pharmacy (where the claim is owed to the pharmacy) or the patient (where the claim is owed to a patient) interest on accrued benefits at the rate of one and one-half percent (1- 1/2%) per month accruing from the day after payment was due on the amount of the benefits that remain unpaid until the claim is finally settled or adjudicated. Whenever interest due pursuant to this provision is less than One Dollar ($ 1.00), such amount shall be credited to the account of the person or entity to whom such amount is owed.

IV. Any pharmacy benefit manager and a pharmacy may enter into an express written agreement containing timely claim payment provisions which differ from, but are at least as stringent as, the provisions set forth under subsection (3) of this section, and in such case, the provisions of the written agreement shall govern the timely payment of claims by the pharmacy benefit manager to the pharmacy. If the express written agreement is silent as to any interest penalty where claims are not paid in accordance with the agreement, the interest penalty provision of subsection (4)(c) of this section shall apply.

V. The State Board of Pharmacy may adopt rules and regulations necessary to ensure compliance with this subsection.

5. AUDIT

DEFINITIONS:

A. "Entity" means a pharmacy benefit manager, a managed care company, a health plan sponsor, an insurance company, a third-party payor, or any company, group or agent that represents or is engaged by those entities.

B. "Health insurance plan" means benefits consisting of prescription drugs, other products and supplies, and pharmacist services provided directly, through insurance or reimbursement, or otherwise and including items and services paid for as prescription drugs, other products and supplies, and pharmacist services under any hospital or medical service policy or certificate, hospital or medical service plan contract, preferred provider organization agreement, or health maintenance organization contract offered by a health insurance issuer.

C. "Individual prescription" means the original prescription for a drug signed by the prescriber, and excludes refills referenced on the prescription.

D. "Pharmacy benefit manager" means a business that administers the prescription drug/device portion of pharmacy benefit management plans or health insurance plans on behalf of plan sponsors, insurance companies, unions and health maintenance organizations. Pharmacy benefit managers may also provide some, all, but may not be limited to, the following services either directly or through outsourcing or contracts with other entities:

(i) Adjudicate drug claims or any portion of the transaction.
(ii) Contract with retail and mail pharmacy networks.
(iii) Establish payment levels for pharmacies.
(iv) Develop formulary or drug list of covered therapies.
(v) Provide benefit design consultation.
(vi) Manage cost and utilization trends.
(vii) Contract for manufacturer rebates.
(viii) Provide fee-based clinical services to improve member care.
(ix) Third-party administration.

E. "Pharmacy benefit management plan" means an arrangement for the delivery of pharmacist's services in which a pharmacy benefit manager undertakes to administer the payment or reimbursement of any of the costs of pharmacist's services for an enrollee on a prepaid or insured basis that (i) contains one or more incentive arrangements intended to influence the cost or level of pharmacist's services between the plan sponsor and one or more pharmacies with respect to the delivery of pharmacist's services; and (ii) requires or creates benefit payment differential incentives for enrollees to use under contract with the pharmacy benefit manager.

F. "Pharmacist," "pharmacist services" and "pharmacy" or "pharmacies" shall have the same definitions as provided in Section 73-21-73.

Sections 73-21-175 through 73-21-189 shall apply to any audit of the records of a pharmacy conducted by a managed care company, nonprofit hospital or medical service organization, insurance company, third-party payor, pharmacy benefit manager, a health program administered by a department of the state or any entity that represents those companies, groups, or department.

II. Audit procedures; written report; report requirements

A. The entity conducting an audit shall follow these procedures:

i. The pharmacy contract must identify and describe in detail the audit procedures;

ii. The entity conducting the on-site audit must give the pharmacy written notice at least two (2) weeks before conducting the initial on-site audit for each audit cycle, and the pharmacy shall have at least fourteen (14) days to respond to any desk audit requirements;

iii. The entity conducting the on-site or desk audit shall not interfere with the delivery of pharmacist services to a patient and shall utilize every effort to minimize inconvenience and disruption to pharmacy operations during the audit process;

iv. Any audit that involves clinical or professional judgment must be conducted by or in consultation with a pharmacist;

v. Any clerical or record-keeping error, such as a typographical error, scrivener's error, or computer error, regarding a required document or record shall not constitute fraud; however, those claims may be subject to recoupment. No such claim shall be subject to criminal penalties without proof of intent to commit fraud;

vi. A pharmacy may use the records of a hospital, physician, or other authorized practitioner of the healing arts for drugs or medicinal supplies written or transmitted by any means of communication for purposes of validating the pharmacy record with respect to orders or refills of a legend or narcotic drug;

vii. A finding of an overpayment or an underpayment may be a projection based on the number of patients served having a similar diagnosis or on the number of similar orders or refills for similar drugs, except that recoupment shall be based on the actual overpayment or underpayment;

viii. A finding of an overpayment shall not include the dispensing fee amount unless a prescription was not dispensed;

ix. Each pharmacy shall be audited under the same standards and parameters as other similarly situated pharmacies audited by the entity;

x. The period covered by an audit may not exceed two (2) years from the date the claim was submitted to or adjudicated by a managed care company, nonprofit hospital or medical service organization, insurance company, third-

party payor, pharmacy benefit manager, a health program administered by a department of the state or any entity that represents those companies, groups, or department;

xi. An audit may not be initiated or scheduled during the first five (5) calendar days of any month due to the high volume of prescriptions filled in the pharmacy during that time unless otherwise consented to by the pharmacy;

xii. Any prescription that complies with state law and rule requirements may be used to validate claims in connection with prescriptions, refills or changes in prescriptions;

xiii. An exit interview that provides a pharmacy with an opportunity to respond to questions and comment on and clarify findings must be conducted at the end of an audit. The time of the interview must be agreed to by the pharmacy;

xiv. Unless superseded by state or federal law, auditors shall only have access to previous audit reports on a particular pharmacy conducted by the auditing entity for the same pharmacy benefits manager, health plan or insurer. An auditing vendor contracting with multiple pharmacy benefits managers or health insurance plans shall not use audit reports or other information gained from an audit on a particular pharmacy to conduct another audit for a different pharmacy benefits manager or health insurance plan;

xv. The parameters of an audit must comply with consumer-oriented parameters based on manufacturer listings or recommendations for the following:

(a) The day supply for eyedrops must be calculated so that the consumer pays only one (1) thirty-day copayment if the bottle of eyedrops is intended by the manufacturer to be a thirty-day supply;

(b) The day supply for insulin must be calculated so that the highest dose prescribed is used to determine the day supply and consumer copayment;

xvi. The day supply for a topical product must be determined by the judgment of the pharmacist based upon the treated area;

xvii. (a) Where an audit is for a specifically identified problem that has been disclosed to the pharmacy, the audit shall be limited to claims that are identified by prescription number;

(b) For an audit other than described in subparagraph (a) of this paragraph , an audit shall be limited to one hundred (100) individual prescriptions that have been randomly selected;

(c) If an audit reveals the necessity for a review of additional claims, the audit shall be conducted on site;

(d) Except for audits initiated under paragraph (a) of this subsection, an entity shall not initiate an audit of a pharmacy more than one (1) time in any quarter;

xviii. A recoupment shall not be based on:

(a) Documentation requirements in addition to or exceeding requirements for creating or maintaining documentation prescribed by the State Board of Pharmacy; or

(b) A requirement that a pharmacy or pharmacist perform a professional duty in addition to or exceeding professional duties prescribed by the State

Board of Pharmacy;

xiv. Except for Medicare claims, approval of drug, prescriber or patient eligibility upon adjudication of a claim shall not be reversed unless the pharmacy or pharmacist obtained the adjudication by fraud or misrepresentation of claim elements; and

xv. A commission or other payment to an agent or employee of the entity conducting the audit is not based, directly or indirectly, on amounts recouped.

III. The entity must provide the pharmacy with a written report of the audit and comply with the following requirements:

A. The preliminary audit report must be delivered to the pharmacy within one hundred twenty (120) days after conclusion of the audit, with a reasonable extension to be granted upon request;

B. A pharmacy shall be allowed at least thirty (30) days following receipt of the preliminary audit report in which to produce documentation to address any discrepancy found during the audit, with a reasonable extension to be granted upon request;

C. A final audit report shall be delivered to the pharmacy within one hundred eighty (180) days after receipt of the preliminary audit report or final appeal, as provided for in Section 73-21-185, whichever is later;

D. The audit report must be signed by the auditor;

E. Recoupments of any disputed funds, or repayment of funds to the entity by the pharmacy if permitted pursuant to contractual agreement, shall occur after final internal disposition of the audit, including the appeals process as set forth in Section 73-21-185. If the identified discrepancy for an individual audit exceeds Twenty-five Thousand Dollars ($ 25,000.00), future payments in excess of that amount to the pharmacy may be withheld pending finalization of the audit;

F. Interest shall not accrue during the audit period; and

G. Each entity conducting an audit shall provide a copy of the final audit report, after completion of any review process, to the plan sponsor.

IV. Appeals; dismissal of audit report; mediation of unresolved issues

A. Each entity conducting an audit shall establish a written appeals process under which a pharmacy may appeal an unfavorable preliminary audit report to the entity.

B. If, following the appeal, the entity finds that an unfavorable audit report or

any portion thereof is unsubstantiated, the entity shall dismiss the audit report or that portion without the necessity of any further action.

C. If, following the appeal, any of the issues raised in the appeal are not resolved to the satisfaction of either party, that party may ask for mediation of those unresolved issues. A certified mediator shall be chosen by agreement of the parties from the Court Annexed Mediators List maintained by the Mississippi Supreme Court.

V. Use of extrapolation in calculating recoupments or penalties prohibited:

Notwithstanding any other provision in Sections 73-21-175 through 73-21-189, the entity conducting the audit shall not use the accounting practice of extrapolation in calculating recoupments or penalties for audits. An extrapolation audit means an audit of a sample of prescription drug benefit claims submitted by a pharmacy to the entity conducting the audit that is then used to estimate audit results for a larger batch or group of claims not reviewed by the auditor.

VI. Limitation of applicability of Sections 73-21-175 through 73-21-189

Sections 73-21-175 through 73-21-189 do not apply to any audit, review or investigation that involves alleged fraud, willful misrepresentation or abuse.

VII. Penalty for noncompliance:

A. The State Board of Pharmacy may impose a monetary penalty on pharmacy benefit managers for noncompliance with the provisions of the Pharmacy Audit Integrity Act, Sections 73-21-175 through 73-21-189, in amounts of not less than One Thousand Dollars ($ 1,000.00) per violation and not more than Twenty-five Thousand Dollars ($ 25,000.00) per violation. The board shall prepare a record entered upon its minutes which states the basic facts upon which the monetary penalty was imposed. Any penalty collected under this subsection (1) shall be deposited into the special fund of the board.

B. The board may assess a monetary penalty for those reasonable costs that are expended by the board in the investigation and conduct of a proceeding if the board imposes a monetary penalty under subsection (1) of this section. A monetary penalty assessed and levied under this section shall be paid to the board by the licensee, registrant or permit holder upon the expiration of the period allowed for appeal of those penalties under Section 73-21-101, or may be paid sooner if the licensee, registrant or permit holder elects. Money collected by the board under this subsection (2) shall be deposited to the credit of the special fund of the board.

C. When payment of a monetary penalty assessed and levied by the board against a

licensee, registrant or permit holder in accordance with this section is not paid by the licensee, registrant or permit holder when due under this section, the board shall have the power to institute and maintain proceedings in its name for enforcement of payment in the chancery court of the county and judicial district of residence of the licensee, registrant or permit holder, or if the licensee, registrant or permit holder is a nonresident of the State of Mississippi, in the Chancery Court of the First Judicial District of Hinds County, Mississippi. When those proceedings are instituted, the board shall certify the record of its proceedings, together with all documents and evidence, to the chancery court and the matter shall be heard in due course by the court, which shall review the record and make its determination thereon in accordance with the provisions of Section 73-21-101. The hearing on the matter may, in the discretion of the chancellor, be tried in vacation.

TITLE 30: PROFESSIONS AND OCCUPATIONS

PART 3002: ADMINISTRATIVE RULES

MISSISSIPPI BOARD OF PHARMACY
ADMINISTRATIVE RULES
AS REQUIRED BY MISSISSIPPI ADMINISTRATIVE PROCEDURES LAW

I. METHOD OF OPERATION

1.Structure and Enabling Statutes

SEC. 73-21-75. State board of pharmacy; number, qualifications, appointment and terms of members; filling of vacancies; removal of members.

(1) The State Board of Pharmacy created by former Section 73-21-9 is hereby continued and reconstituted as follows: The board shall consist of seven (7) appointed members. At least one (1) appointment shall be made from each congressional district. Each appointed member of the board shall be appointed by the Governor, with the advice and consent of the Senate, from a list of five (5) names submitted by the Mississippi State Pharmaceutical Association/Mississippi Pharmacists Association. Of the members appointed, one (1) shall, at the time of appointment, have had five (5) years' experience as a pharmacist at a facility holding an institutional permit, and one (1) shall, at the time of appointment, have had five (5) years' experience as a pharmacist at a facility holding a retail permit. Any person appointed to the board shall be limited to two (2) full terms of office during any fifteen-year period, including any member serving on May 14, 1992.

(2) The members of the board appointed and serving prior to July 1, 1983, whose terms have not expired by July 1, 1983, shall serve the balance of their terms as members of the reconstituted board, and they shall be considered to be from the same congressional districts from which they were originally appointed if they still reside therein, even if the district boundaries have changed subsequent to their original appointments. The Governor shall appoint the remaining members of the reconstituted board in the manner prescribed in subsection (1) of this section on July 1, 1983. The initial members of the reconstituted board shall serve terms of office as follows:

(a) The term of the member from the First Congressional District shall expire on July 1, 1984; and from and after July 1, 1996, this appointment shall be designated as Post 1.

(b) The term of the member from the Second Congressional District shall expire on July 1, 1988; and from and after July 1, 1996, this appointment

shall be designated as Post 2.

(c)The term of the member from the Third Congressional District shall expire on July 1, 1986; and from and after July 1, 1996, this appointment shall be designated as Post 3.

(d) The term of the member from the Fourth Congressional District shall expire on July 1, 1985; and from and after July 1, 1996, this appointment shall be designated as Post 4.

(e) The term of the member from the Fifth Congressional District shall expire on July 1, 1987; and from and after July 1, 1996, this appointment shall be designated as Post 5.

(f) The term of one (1) of the members from the state at large shall expire on July 1, 1985; and from and after July 1, 1996, this appointment shall be designated as Post 6.

(g) The term of the other member from the state at large shall expire on July 1, 1988; and from and after July 1, 1996, this appointment shall be designated as Post 7.

(3) At the expiration of a term, members of the board shall be appointed in the manner prescribed in subsection (1) of this section for terms of five (5) years from the expiration date of the previous terms. Any vacancy on the board prior to the expiration of a term for any reason, including resignation, removal, disqualification, death or disability, shall be filled by appointment of the Governor in the manner prescribed in subsection (1) of this section for the balance of the unexpired term. The Mississippi State Pharmaceutical Association/Mississippi Pharmacists Association shall submit a list of nominees no more than thirty (30) days after a vacancy occurs, and the Governor shall fill such vacancies within ninety (90) days after each such vacancy occurs.

(4) To be qualified to be a member of the board, a person shall:

(a) Be an adult citizen of Mississippi for a period of at least five (5) years preceding his appointment to the board;

(b) Be a pharmacist licensed and in good standing to practice pharmacy in the State of Mississippi;

(c) Have at least five (5) years' experience as a pharmacist; and

(d) Be actively engaged full time in the practice of pharmacy in Mississippi.

(5) The Governor may remove any or all members of the board on proof of unprofessional conduct, continued absence from the state, or for failure to perform the duties of his office. Any member who shall not attend two (2) consecutive meetings of the board for any reason other than illness of such member shall be subject to removal by the Governor. The president of the board shall notify the Governor in writing when any such member has failed to attend two (2) consecutive regular meetings. No removal shall be made without first giving the accused an opportunity to be heard in refutation of the charges made against him, and he shall be entitled to receive a copy

of the charges at the time of filing.

SOURCES: Laws, 1983, ch. 414, Sec. 3; 1991, ch. 527, Sec. 3; 1992, ch. 531 Sec. 1; reenacted, 1993, ch. 416, Sec. 4; 1995, ch. 513, Sec. 2, eff from and after July 1, 1995

SEC. 73-21-77. Organization of board; oath; meetings; compensation and expenses of members.

(1) Each person appointed as a member of the board shall qualify by taking the oath prescribed by the Constitution for the state officers, and shall file certificate thereof in the office of the Secretary of State within fifteen (15) days after his appointment.
(2) There shall be a president of the board and such other officers as deemed necessary by the board elected by and from its membership.
(3) The board shall meet at least once each quarter to transact business, and may meet at such additional times as it may deem necessary. Such additional meetings may be called by the president of the board or a majority of the members of the board.
(4) The place for each meeting shall be determined prior to giving notice of such meeting and shall not be changed after such notice is given without adequate subsequent notice.
(5) A majority of the members of the board shall constitute a quorum for the conduct of the meeting and all actions of the board shall be by a majority.
(6) Each member of the board shall receive a per diem as provided in Section 25-3-69, not to exceed thirty (30) days in any one (1) period of twelve (12) months, for each day actually engaged in meetings of the board, together with necessary traveling and other expenses as provided in Section 25-3-41.

SOURCES: Laws, 1983, ch. 414, Sec. 4; reenacted without change, 1991, ch. 527, Sec. 4; 1992, ch. 531 Sec. 2; reenacted, 1993, ch. 416, Sec. 5, eff from and after passage (approved March 18, 1993).

SEC. 73-21-79. Executive director; additional employees; legal counsel.

(1) The board shall employ an executive director of the board. The executive director shall be a citizen of Mississippi and a pharmacist licensed and in good standing to practice pharmacy in the State of Mississippi, who has had five (5) years' experience as a pharmacist.
(2) The executive director shall receive a salary to be set by the board,

subject to the approval of the State Personnel Board, and shall be entitled to necessary expenses incurred in the performance of his official duties. He shall devote full time to the duties of his office and shall not be interested directly or indirectly as defined in Section 73-21-73 in the operation of a pharmacy in Mississippi or any other facility permitted by the board or engaged in any other business that will interfere with the duties of his office.
(3) The duties and responsibilities of the executive director shall be defined by rules and regulations prescribed by the board.
(4) The board may, in its discretion, employ persons in addition to the executive director in such other positions or capacities as it deems necessary to the proper conduct of board business. Any pharmacist-investigator employed by the board may have other part-time employment, provided that he shall not accept any employment that would cause a conflict of interest in his pharmacist-investigator duties. The board may employ legal counsel to assist in the conduct of its business.

SOURCES: Laws, 1983, ch. 414, Sec. 5; reenacted without change, 1991, ch. 527, Sec. 5; 1992, ch. 531 Sec. 3; 1993, ch. 416, Sec. 6, eff from and after passage (approved March 18, 1993).

SEC. 73-21-81. General powers and duties of board; enforcement of chapter; rules and regulations.

The responsibility for the enforcement of the provisions of this chapter shall be vested in the board. The board shall have all of the duties, powers and authority specifically granted by and necessary to the enforcement of this chapter. The board may make, adopt, amend and repeal such rules and regulations as may be deemed necessary by the board from time to time for the proper administration and enforcement of this chapter, in accordance with the provisions of the Mississippi Administrative Procedures Law (sections 25-43-1 et seq.).

SOURCES: Laws, 1983, ch. 414, Sec. 6; reenacted without change, 1991, ch.

527, Sec. 6; reenacted without change, 1993, ch. 416, Sec. 7, eff from and after passage (approved March 18, 1993).

SEC. 73-21-83. Board to regulate practice of pharmacy; licensing of pharmacists; fees; persons holding license on July 1, 1991.

(1) The board shall be responsible for the control and regulation of the practice of pharmacy, to include the regulation of pharmacy externs or interns and pharmacist technicians in this state, the regulation of the

wholesaler distribution of drugs and devices as defined in Section 73-21-73, and the distribution of sample drugs or devices by manufacturer's distributors as defined in Section 73-21-73 by persons other than the original manufacturer or distributor in this state.
(2) A license for the practice of pharmacy shall be obtained by all persons prior to their engaging in the practice of pharmacy. However, the provisions of this chapter shall not apply to physicians, dentists, veterinarians, osteopaths or other practitioners of the healing arts who are licensed under the laws of the State of Mississippi and are authorized to dispense and administer prescription drugs in the course of their professional practice.
(3) The initial licensure fee shall be set by the board but shall not exceed Two Hundred Dollars ($200.00).
(4) All students actively enrolled in a professional school of pharmacy accredited by the American Council on Pharmaceutical Education who are making satisfactory progress toward graduation and who act as an extern or intern under the direct supervision of a pharmacist in a location permitted by the Board of Pharmacy must obtain a pharmacy student registration prior to engaging in said activity. The student registration fee shall be set by the board but shall not exceed One Hundred Dollars ($100.00).
(5) All persons licensed to practice pharmacy prior to July 1, 1991, by the State Board of Pharmacy under Section 73-21-89 shall continue to be licensed under the provisions of Section 73-21-91.

SOURCES: Laws, 1983, ch. 414, Sec. 7; 1991, ch. 527, Sec. 7; 1993, ch. 416, Sec. 8; 1994, ch. 513, Sec. 2, eff from and after July 1, 1994; 1997, ch. 441, Sec. 1, eff July 1, 1997.

2.Public Information. The public may obtain information regarding operations and responsibilities of the Mississippi Board of Pharmacy, the Pharmacy Practice Act and Board Regulations and other pertinent information by contacting the Board office at 204 Key Drive, Suite C, Madison, Mississippi 39110, 601-605-5388. Additional information is available on the Mississippi Board of Pharmacy Website at www.mbp.state.ms.us.

II. FORMAL AND INFORMAL PROCEEDINGS

MISSISSIPPI BOARD OF PHARMACY

RULES OF PROCEDURE

I. SCOPE

The following Rules of Procedure shall apply to all pharmacists licensed by the Mississippi Board of Pharmacy and all other persons under the jurisdiction of said Board.

II. PURPOSE

A. To implement and enforce the standards of pharmacy and pharmacy practice and conduct of all other persons under the jurisdiction of the Mississippi Board of Pharmacy as provided for in all state & federal drug laws, the Mississippi Pharmacy Practice Act and the Pharmacy Practice Regulations of the Mississippi Board of Pharmacy.

III. DEFINITIONS

A. The word "Board" shall mean the Mississippi Board of Pharmacy.

B. The word "Respondent" shall mean a pharmacist or other person against whom a disciplinary action and proceeding has been initiated by the Mississippi Board of Pharmacy.

C. Masculine terms, when used in the following Rules of Procedure, shall also be deemed to include the feminine.

IV. ADMINISTRATIVE HEARINGS

1. CONTINUANCES

A. Hearings shall be held before the Board at the time and place designated in the "Notice of Hearing and Complaint", unless a continuance is granted for just good cause by the Board. A motion for a continuance must be filed with the Board at least fifteen (15) days prior to the scheduled hearing, or upon a showing of good cause, at any time prior to the hearing.

B. It must be recognized that the Board consists of seven (7) practicing pharmacists representing various regions of the State. Unlike the judiciary, the Board members are not in the business of conducting hearings, therefore hearings will be held only during regularly scheduled meetings or other dates established by the Board. Attorneys representing pharmacists should take this fact into consideration. A scheduled hearing may be continued if the Respondent shows substantial, legitimate grounds for continuing the hearing, based on the balance of:

(1) The right of Respondent to a reasonable opportunity to prepare and present a defense; and

(2) The Board's responsibility to protect the public health, safety and welfare.

C. Where the counsel for Respondent has a scheduling conflict on the initial hearing date, continuances will be liberally granted. However, Respondent's counsel must submit written proof of the scheduling conflict fifteen (15) days prior to the scheduled hearing date. Thereafter, no further continuances will be granted based solely on scheduling conflicts.

D. So that counsel for the Respondent and Complaint Counsel shall be able to adequately prepare for hearing, any motion for a continuance filed within the time limitations as specified in Subsection A above, will be immediately considered by the Board's President, who shall have the authority to grant or deny said motion. If Granted the order will be presented to the Board at the scheduled hearing date at which time the order will be formally entered and the rescheduled hearing date set.

E. It is the responsibility of the Respondent to make a prompt decision as to whether to appear before the Board without counsel or to retain counsel for this purpose.

Unless due to extraordinary circumstances, the Board will not consider as a valid ground for continuance, the Respondent's last minute decision to retain counsel.

2. POLICIES FOR ADMINISTRATIVE HEARINGS

A. Procedures are designed to give the accused the right to be heard in a fair and impartial hearing.

B. The President or the Senior Member of the Board present is the presiding officer and he/she rules on all objections and motions, subject to the Board's approval.

C. The Board is not bound by strict rules of evidence but all determinations must be based upon sufficient evidence.

D. All hearings are open to the public, however, public members may not participate nor be present for Executive Sessions.

E. The Executive Director, with the advice of the Board Counsel, will subpoena all witnesses for the Board or the defendant when requested.

F. All charges shall be based upon affidavits sufficiently definite to constitute allegation or specific violation of the laws and regulations that govern pharmacists and the practice of pharmacy.

G. The respondent has the right to appear either personally, by counsel, or both; to produce witnesses, cross-examine witnesses and have subpoenas issued by the Board.

H. A definite time and place shall be set with proper notice being given and a quorum present for all proceedings.

I. Board members who served on the Investigations Review Committee and who reviewed the investigation of the complaint that led to the administrative hearing, shall recuse themselves and not participate in the disciplinary proceeding.

J. All Board decisions are made in Executive Session.

K. A copy of these Board Rules of Procedure for Administrative Hearings shall be supplied to the respondent along with the Notice of Hearing and Complaint.

3. PROCEDURES FOR ADMINISTRATIVE HEARINGS

A. The Hearing is called to order by the President or presiding officer.

B. President requests that the respondent/counsel be called.

C. When respondent appears, introductions are made and oaths administered to respondent and others as may be necessary for proper conduct of the hearing.

D. The respondent is then asked to state his/her name, address and license number. He/she is also informed that the hearing is being recorded.

E. If respondent is represented by counsel, counsel name and address is entered into the record.

F. The President then asks Board counsel to present the charges and place same into the record as appropriate.

G. Before going into the merits of the cause, evidence should be placed into the record showing that the respondent was properly notified of the charges.

H. The respondent is then asked to respond to the charges.

I. The Board counsel may have witnesses called for the Board and he/she shall conduct the direct examination of same.

(1) At the conclusion of the examination, the respondent or respondents counsel

may cross-examine.
(2) At the conclusion of the cross-examination, the Board may question the witness.
(3) At the conclusion of the witness' testimony, the witness may be excused subject to recall.

J. The respondent may call his/her witnesses after Board has rested its case. The respondent or respondent's counsel will conduct the direct examination.
(1) Board Counsel may cross-examine respondent witness.
(2) Board members may then question respondent witness.
(3) The witness may be excused subject to recall.

K. The Board may then call rebuttal witnesses.

L. Respondent/counsel may make closing argument if desired.

M. After all response has been presented by both sides, the Board goes into Executive Session to consider all evidence presented and make a final decision or ruling.

N. The Board shall make findings of fact on each charge. The Board should adjudicate each charge as presented, based on the evidence submitted.

O. The Board then determines what disciplinary action, if any, should be taken in the matter.

P. Following the Executive Session, the respondent may or may not be informed of the Board's action, however, the action is always reduced to writing and notification may include Proceedings, Conclusions of Law, Findings of Fact and the Order of the Board.

V. INFORMAL SETTLEMENT, PRE-HEARING, STIPULATIONS, CONSENT ORDERS

A. All disciplinary proceedings initiated by the Board shall be brought to a final resolution through one of three means:
1. Disciplinary hearings before the Board; or
2. Acceptance by the Board of a mutually agreeable Consent Order in lieu of a hearing; or
3. Dismissal of the case.

B. As to disciplinary proceedings duly served by a Notice of Hearing and Complaint, Respondent and/or Respondent's Counsel may agree that an Informal Settlement Conference be held for the purpose of possible resolution of the matter or for purposes of simplifying the issues for hearing or promoting stipulations as to facts and proposed evidentiary offerings which will not be disputed at hearing.

C. The Informal Settlement Conference shall be conducted by Respondent and/or his counsel and Board Counsel. Other parties who may attend include Compliance Agents for the Board and Board members who served on the Investigations Review Committee (IRC) that authorized that a Notice of Hearing and Complaint be issued in the matter. Other Board members may not attend or have knowledge or input into any activities of the Conference.

D. Discovery or exchange of information may be accomplished during the Informal Settlement Conference.

E. The Informal Settlement Conference may result in:
   1. Preparation of a proposed Consent Order as a resolution of the matter;
   2. Proceed with the scheduled hearing.

F. Any action which the Board may take following a full disciplinary hearing may be taken in lieu thereof by Consent Order, Duly executed by the Respondent. Because of the lengthy dockets before the Board, informal Settlement Conferences must be held in sufficient time to allow consummation of negotiations of a Consent Order, at least ten (10) working days prior to the scheduled hearing date. After the terms of the Consent Order have been prepared and mutually accepted by Board Counsel, the investigating Compliance Agent and the two (2) IRC Board members that originally heard the matter, it shall be binding on the Board, but not effective until Board approval. Notwithstanding, it is still the responsibility of the Respondent to personally appear before the Board on the scheduled hearing date to answer any questions which the Board may have prior to Board approval.

G. Failure of the Board to approve and/or ratify any Consent Order shall result in an administrative hearing before the Board as originally scheduled in order to resolve all matters as outlined in the Notice of Hearing and Complaint.

H. Hearings for matters in which Consent Orders are considered by the Board shall be conducted according to the Board's Rules of Procedures for Administrative Hearings.

VI. SUBPOENAS

A. For the purpose of disciplinary hearings, the Board acting by and through its Executive Director, may subpoena persons and papers on its own behalf and on behalf of a Respondent.

B. Before the Board shall issue on behalf of a Respondent any subpoena for person or papers, the Respondent shall;
   1. File with the Board a written request for the issuance of said subpoenas, identifying with certainty the identity and address of all individuals to be subpoenaed, along with a concise description of the records to be subpoenaed with the identity and address of the custodian of said records.
   2. All subpoenas issued by the Board on behalf of Respondent shall be affected by registered mail.
   3. All requests for issuance of subpoenas shall be filed with the Board sufficiently distant in time to allow for the preparation and mailing of said subpoenas at least ten (10) working days before the scheduled hearing date. The Board shall not be responsible for the timely receipt of subpoenas issued after the aforementioned deadline.

C. The Board shall charge a Respondent a reasonable fee, not to exceed $25.00 per subpoena, for preparation and mailing of subpoenas.

6.

7. **III. ORAL PROCEEDINGS ON PROPOSED REGULATIONS**

1.Scope. These rules set forth the Mississippi Board of Pharmacy, hereinafter "Board," rules governing the form and content of requests for all oral proceedings held for the purpose of providing the public with an opportunity to make oral presentations on proposed new regulations and amendments to regulations before the Board pursuant to §25-43-3.104.

2.When Oral Proceedings will be Scheduled on Proposed Regulations. The Board will conduct an oral proceeding on a proposed regulation or amendment if requested by a political subdivision, an agency or ten (10) persons in writing within twenty (20) days after the filing of the notice of the proposed regulation.

3. Request Format. Each request must be printed or typewritten, or must be in legible handwriting. Each request must be submitted on standard business letter-size paper (8-1/2 inches by 11 inches). Requests may be in the form of a letter addressed to the Board and signed by the requestor(s).

4. Notification of Oral Proceeding. The date, time and place of all oral proceedings shall be filed with the Secretary of State's office and mailed to each requestor. The oral proceedings will be scheduled no earlier than twenty (20) days from the filing of this information with the Secretary of State.

5. Presiding Officer. The Board President or his designee, who is familiar with the substance of the proposed regulation, shall preside at the oral proceeding on a proposed regulation.

6. Public Presentations and Participation.

(a) At an oral proceeding on a proposed regulation, persons may make oral statements and make documentary and physical submissions, which may include data, views, comments or arguments concerning the proposed regulation.

(b) Persons wishing to make oral presentations at such a proceeding shall notify the Board at least one business day prior to the proceeding and indicate the general subject of their presentations. The presiding officer in his or her discretion may allow individuals to participate that have not previously contacted the Board.

(c) At the proceeding, those who participate shall indicate their names and addresses, identify any persons or organizations they may represent, and provide any other information relating to their participation deemed appropriate by the presiding officer.

(d) The presiding officer may place time limitations on individual oral presentations when necessary to assure the orderly and expeditious conduct of the oral proceeding. To encourage joint oral presentations and to avoid repetition, additional time may be provided for persons whose presentations represent the views of other individuals as well as their own views.

(e) Persons making oral presentations are encouraged to avoid restating matters that have already been submitted in writing.

(f) There shall be no interruption of a participant who has been given the floor by the presiding officer, except that the presiding officer may in his or her discretion interrupt or end the partisan's time where the orderly conduct of the proceeding so requires.

7. Conduct of Oral Proceeding.

(a) Presiding officer. The presiding officer shall have authority to conduct the proceeding in his or her discretion for the orderly conduct of the proceeding. The presiding officer shall (i) call proceeding to order; (ii) give a brief synopsis of the proposed regulation, a statement of the statutory authority for the proposed regulation, and the reasons provided by the Board for the proposed regulation; (ii)call on those individuals who have contacted the Board about speaking on or against the proposed regulation; (iii) allow for rebuttal statements following all participant's comments; (iv) adjourn the proceeding.

(b) Questions. The presiding officer, where time permits and to facilitate the exchange of information, may open the floor to questions or general discussion. The presiding officer may question participants and permit the questioning of participants by other participants about any matter relating to that regulation-making proceeding, including any prior written submissions made by those participants in that proceeding; but no participant shall be required to answer any question.

(c) Physical and Documentary Submissions. Submissions presented by participants in an oral proceeding shall be submitted to the presiding officer. Such submissions become the property of the Board and are subject to the Board's public records request procedure.

(d) Recording. The Board may record oral proceedings by stenographic or electronic means.

IV. DECLARATORY OPINIONS

1. Scope. These rules set forth the Mississippi Board of Pharmacy, hereinafter "Board," rules governing the form and content of requests for declaratory opinions, and the Board's procedures regarding the requests, as required by Mississippi Code § 25-43-2.103. These rules are intended to supplement and be read in conjunction with the provisions of the Mississippi Administrative Procedures Law, which may contain additional information regarding the issuance of declaratory opinions. In the event of any conflict between these rules and the Mississippi Administrative Procedures Law, the latter shall govern.

2. Persons Who May Request Declaratory Opinions. Any person with a substantial interest in the subject matter may request a declaratory opinion from the Board by following the specified procedures. "Substantial interest in the subject matter" means: an individual, business, group or other entity that is directly affected by the Board's administration of the laws within its primary jurisdiction. "Primary jurisdiction of the Board" means the Board has a constitutional or statutory grant of authority in the subject matter at issue.

3. Subjects Which May Be Addressed In Declaratory Opinions. The Board will issue declaratory opinions regarding the applicability to specified facts of: (1) a statute administered or enforceable by the Board or (2) a regulation promulgated by the Board. The Board will not issue

a declaratory opinion regarding a statute or regulation which is outside the primary jurisdiction of the Board.

4. Circumstances In which Declaratory Opinions Will Not Be Issued. The Board may, for good cause, refuse to issue a declaratory opinion. The circumstances in which declaratory opinions will not be issued include, but are not necessarily limited to:

(a) lack of clarity concerning the question presented;

(b) there is pending or anticipated litigation, administrative action, or other adjudication which may either answer the question presented by the request or otherwise make an answer unnecessary;

(c) the statute or regulation on which a declaratory opinion is sought is clear and not in need of interpretation to answer the question presented by the request;

(d) the facts presented in the request are not sufficient to answer the question presented;

(e) the request fails to contain information required by these rules or the requestor failed to follow the procedure set forth in these rules;

(f) the request seeks to resolve issues which have become moot, or are abstract or hypothetical such that the requestor is not substantially affected by the statute or regulation on which a declaratory opinion is sought;

(g) no controversy exists concerning the issue as the requestor is not faced with existing facts or those certain to arise which raise a question concerning the application of the statute or regulation;

(h) the question presented by the request concerns the legal validity of a statute or rule;

(i) the request is not based upon facts calculated to aid in the planning of future conduct but is, instead, based on past conduct in an effort to establish the effect of that conduct;

(j) no clear answer is determinable;

(k) the question presented by the request involves the application of a criminal statute or a sets of facts which may constitute a crime;

(l) the answer to the question presented would require the disclosure of information which is privileged or otherwise protected by law from disclosure;

(m) The question is currently the subject of an Attorney General's opinion request or has been answered by an Attorney General's opinion;

(n) A similar request is pending before this Board or any other agency or a proceeding is pending on the same subject matter before any agency, administrative or judicial tribunal, or where such a opinion would constitute the unauthorized practice of law.

(o) Where issuance of a declaratory opinion may adversely affect the interests of the State, the Board or any of their officers or employees in any litigation which is pending or may reasonably be expected to arise;

(p) The question involves eligibility for a license, permit, registration or other approval by the Board or some other agency, and there is a statutory or regulatory application process by which eligibility for said license, permit, registration or other approval would be determined.

5. Written Request Required. Each request must be printed or typewritten, or must be in legible handwriting. Each request must be submitted on standard business letter-size paper (8-1/2 inches by 11 inches). Requests may be in the form of a letter addressed to the Board.

6. Where to Send Requests. All requests must be mailed, delivered or transmitted via facsimile to the Board. The request shall clearly state that it is a request for a declaratory opinion. No oral, telephone requests or email requests will be accepted for official opinions.

7. Name, Address and Signature of Requestor. Each request must include the full name, telephone number, and mailing address of the requestor. All requests shall be signed by the person filing the request, who shall attest that the request complies with the requirements set forth in these rules, including but not limited to a full, complete, and accurate statement of relevant facts and that there are no related proceedings pending before any other administrative or judicial tribunal.

8. Question Presented. Each request shall contain the following:

(a) a clear and concise statement of all facts on which the opinion is requested;

(b) a citation to the statute or regulation at issue;

(c) the question(s) sought to be answered in the opinion, stated clearly;

(d) a suggested proposed opinion from the requestor, stating the answers desired by petitioner and a summary of the reasons in support of those answers;

(e) the identity of all other known persons involved in or impacted by the described factual situation, including their relationship to the facts, name, mailing address and telephone number; and

(f) a statement to show that the person seeking the opinion has a substantial interest in the subject matter.

10. Time for Board's Response. Within forty-five (45) days after the receipt of a request for a declaratory opinion which complies with the requirements of these rules, the Board shall, in writing:

(a) issue a declaratory opinion regarding the specified statute or regulation as applied to the specified circumstances;

(b) decline to issue a declaratory opinion, stating the reasons for its action; or

(c) agree to issue a declaratory opinion by a specified time but not later than ninety (90) days after receipt of the written request;

The forty-five (45) day period shall begin running on the first State of Mississippi business day on or after the request is received by the Board, whichever is sooner.

11. Opinion Not Final for Sixty Days. A declaratory opinion shall not become final until the expiration of sixty (60) days after the issuance of the opinion. Prior to the expiration of sixty (60) days, the Board may, in its discretion, withdraw or amend the declaratory opinion for any reason which is not arbitrary or capricious. Reasons for withdrawing or amending an opinion include, but are not limited to, a determination that the request failed to meet the requirements of these rules or that the opinion issued contains a legal or factual error.

12. Notice by Board to third parties. The Board may give notice to any person, agency or entity that a declaratory opinion has been requested and may receive and consider data, facts, arguments and opinions from other persons, agencies or other entities other than the requestor.

13. Public Availability of Requests and Declaratory Opinions. Declaratory opinions and requests for declaratory opinions shall be available for public inspection and copying in accordance with the Public Records Act and the Board's public records request procedure. All declaratory opinions and requests shall be indexed by name and subject. Declaratory opinions and requests which contain information which is confidential or exempt from disclosure under the Mississippi Public Records Act or other laws shall be exempt from this requirement and shall remain confidential.

14. Effect of a Declaratory Opinion. The Board will not pursue any civil, criminal or administrative action against a person who is issued a declaratory opinion from the Board and who, in good faith, follows the direction of the opinion and acts in accordance therewith unless a court of competent jurisdiction holds that the opinion is manifestly wrong. Any declaratory opinion rendered by the Board shall be binding only on the Board and the person to whom the opinion is issued. No declaratory opinion will be used as precedent for any other transaction or occurrence beyond that set forth by the requesting person.

TITLE 30: PROFESSIONS AND OCCUPATIO NS

PART 3001: MISSISSIPPI PHARMACY PRACTICE REGUALTIONS

MISSISSIPPI PHARMACY PRACTICE REGULATIONS

Mississippi Board of Pharmacy
204 Key Drive, Suite C
Madison, MS 39110
Telephone: 601-605-5388-----Fax: 601-605-9546

Effective January 24, 2013

For the latest revisions, updates and other news and information visit our web site:
www.mbp.state.ms.us

MISSISSIPPI BOARD OF PHARMACY

PHARMACY PRACTICE REGULATIONS

AND

PHARMACY PRACTICE ACT

PART 3001
BOARD REGULATIONS
(Effective January 31, 2011)

PART 3002

ADMINISTRATIVE RULES

PHARMACY PRACTICE REGULATIONS

Whereas, the Mississippi Board of Pharmacy in accordance with Section 73-21-81, Mississippi Code of 1972, finds it necessary to adopt new regulations governing the practice of pharmacy and the distribution and sale of prescription drugs, and

Whereas, the Mississippi Board of Pharmacy having given careful consideration to the needs of the public in the preparation of these regulations, and having complied with Title 25, Chapter 43, Mississippi Code of 1972, annotated, the Mississippi Board of Pharmacy, on November 15, 2012, adopted these regulations to become effective January 1, 2013. In these regulations, any reference to the "Code" or a section thereof, refers to the Mississippi Code of 1972, annotated.

All regulations in effect prior to the effective date of these regulations are rescinded effective December 31, 2012. Individuals who are charged with a violation during the time of the effective dates of previous regulations will be charged under the regulations in effect at the time of the violation.

GENERAL INFORMATION
PHARMACISTS

CHANGE OF ADDRESS

A pharmacist must notify the Board in writing by mail or fax of change of address within ten (10) days of the change. To ensure the correct changes are made to the Board records, a pharmacist should include the following information:

(1) Name and license number of pharmacist;
(2) New address;
(3) Former address;
(4) Current telephone number.

Keeping this information current with the Board office will assure pharmacists of receiving license renewal and controlled substance registration applications and their *Board of Pharmacy Newsletter*.

CHANGE OF EMPLOYMENT

Pharmacists must notify the Board in writing by mail or fax within ten (10) days of a change of employment. To ensure the correct changes are made to the Board records, a pharmacist should include the following information:

(1) Name and license number of pharmacist;
(2) Name, address and permit number of the pharmacy where presently employed;
(3) Name, address and permit number of the pharmacy where he/she was formerly employed.

CHANGE OF LEGAL NAME

The Board's records and a pharmacist's renewal certificate must accurately reflect the legal name used in pharmacy practice by that pharmacist. Pharmacists who change the legal name, under which they practice, through a legal name change, e.g., marriage or divorce, must notify the Board within ten (10) days of receipt of the legal document effecting the change. The following must be included in the notification of change of pharmacist's name:

(1) A letter of explanation which includes the new name, clearly printed or typed as it is to appear on the renewal card and in the Board records;
(2) A copy of the legal document that changed the name, e.g., marriage license, divorce decree or court order;
(3) The current renewal card (wallet card);
(4) A check or money order in the amount of fifteen dollars ($15.00) for each wallet card.

Changing your name on the wall certificate is optional. If you desire a new wall certificate reflecting your new legal name, you must send the following additional information:

(1) A check or money order for twenty-five ($25.00).

OBTAINING DUPLICATE DOCUMENTS

The Board will replace, under certain conditions e.g., lost or stolen, a pharmacist's wall certificate and/or wallet registration card. To obtain duplicates of these documents, the following should be observed:

(1) A written statement signed by the pharmacist outlining the circumstances under which the card(s) was lost or stolen;
(2) The name, address and license number on the lost or stolen card(s);
(3) A check or money order in the amount of fifteen ($15.00) for each wallet card;
(4) A check or money order in the amount of twenty-five dollars ($25.00) for a duplicate wall certificate.

PHARMACIES

LOSS OF CONTROLLED SUBSTANCES

When a pharmacy has a loss of controlled substances or suspected loss, the pharmacist-in-charge must comply with the following:

(1) Any loss or suspected loss must be reported directly to the office of the Board by telephone (601-605-5388) immediately on discovery;
(2) Within forty-eight hours of the discovery of the loss, a complete inventory of controlled substances shall be made. This inventory must be dated and signed by the pharmacist-in-charge;
(3) Within fifteen days of the discovery of the loss, a written report shall be forwarded to the office of the Board. This written report shall include a copy of the controlled substance inventory as required by paragraph (2) above.

FAILURE TO REPORT ANY LOSS OR SUSPECTED LOSS DIRECTLY TO THE BOARD MAY BE GROUNDS FOR DISCIPLINARY ACTION BY THE BOARD.

CHANGE OF PHARMACIST-IN-CHARGE

If the employment of a pharmacist-in-charge is terminated or if for any other reason he/she wishes to be relieved of the responsibilities of the pharmacist-in-charge, he/she must:

(1) Return the pharmacy permit to the office of the Board with written notice that he/she is no longer the pharmacist-in-charge at that facility. Advise the Board of the effective date of the change;
(2) The pharmacist-in-charge shall conduct a complete inventory of controlled substances and send it to the Board along with the pharmacy permit.

When the relinquishing pharmacist-in-charge cannot or does not comply with paragraphs (1) and (2) as listed above, it shall be the responsibility of the new pharmacist-in-charge to send to the Board an inventory of controlled substances on hand at the time he/she assumes responsibility as pharmacist-in-charge.

PROCEDURES FOR PERMANENT CLOSURE OF BUSINESS

Requirements under Board regulations:

(1) The pharmacist-in-charge shall give notice to the Board of the effective date of closure at least fourteen (14) days prior to the closure and shall notify the Board in writing fourteen (14) days by what means and as to whom controlled substances were transferred or disposed of; and

(2) Take a complete inventory of any controlled substances on hand, including out-of-date drugs; and

(3) Send the pharmacy permit, controlled substances registration and a copy of the controlled substances inventory to the Board; and

(4) Remaining controlled substances may be transferred to another registrant. Schedule II drugs must be transferred by use of DEA form 222 Narcotic Order Blank. Schedule III, IV and V drugs may be transferred between registrants by an inventory listing agreed upon between registrants. The closing business PIC should maintain a copy of the inventory and a copy should be maintained by the business receiving the inventory.

Requirements under DEA regulations:

(1) Return for cancellation the DEA registration Certificate and any unexecuted DEA 222 order forms to:
Registration Unit
DEA, Department of Justice
P. O. Box 28083
Central Station
Washington, DC 20005

(2) Submit notice fourteen (14) days in advance of closure in person or by Registered or Certified Mail return receipt requested to:
Special Agent in Charge
DEA- U.S. Department of Justice
3838 N. Causeway Blvd., Suite 1800
Three Lakeway Center
Metarie, LA 70002
Include the following information:

(A) Name, address, DEA registration number and authorized business activity of registrant closing business; and

(B) Name, address, DEA Registration Number and authorized business activity of person acquiring the business; and

(C) Whether the business activity will be continued at the location registered by the person discontinuing the business, or moved to another location; and

(D) The date on which the transfer of controlled substances will occur.

OTHER AGENCIES

DRUG ENFORCEMENT ADMINISTRATION (DEA)

Drug Enforcement Administration
Registration Unit
P. O. Box 28083
Central Station
Washington, DC 20038-8083
telephone: (800)-882-9539 (24 hour automated system)

New Orleans Divisional Office

Drug Enforcement Administration
3838 North Causeway Blvd.
Suite 1800
3 Lakeway Center
Metairie, LA 70002
telephone: 504-840-1100

MISSISSIPPI BUREAU OF NARCOTICS

6090 I-55 South
Jackson, MS 39272
telephone 601-371-3600
toll free: 800-844-6272

MISSISSIPPI BOARD OF NURSING

Mississippi Board of Nursing
1080 River Oaks Drive Suite A100
Flowood, MS 39232
telephone: 601-664-9303------fax: 601-664-9304

MISSISSIPPI STATE BOARD OF DENTAL EXAMINERS

Mississippi State Board of Dental Examiners
600 East Amite Street
Jackson, MS 39201-2801
telephone: 601-944-9622------fax: 601-944-9624

MISSISSIPPI STATE BOARD OF MEDICAL LICENSURE

Mississippi State Board of Medical Licensure
1867 Crain Ridge Dr.
Suite 200B

Jackson, MS 39216
telephone: 601-987-3079 fax: 601-987-4159

U. S. FOOD AND DRUG ADMINISTRATION

Food and Drug Administration
100 West Capitol
Suite 340
Jackson, MS 39269
telephone: 601-965-4581------fax: 601-965-4584

DIVISION OF MEDICAID

550 High Street Suite 1000
Jackson, MS 39201
telephone: 601-359-6050
toll free: 800-421-2408

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DEFINITIONS:

As used in these regulations unless the context requires otherwise:

1. "Administer" shall mean the direct application of a prescription drug pursuant to a lawful order of a practitioner to the body of a patient by injection, inhalation, ingestion or any other means.

2. “Advisory Board” shall mean the advisory board established in conjunction with the Prescription Monitoring Program.

3. “Application” shall mean a document either paper or electronic required to be completed by an application for initial licensure, permit, registration or renewal of said licensure, permit or registration..

4. "Authentication of Product History" means but is not limited to, identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical.

5. “Automated Pharmacy Systems” include, but are not limited to, mechanical systems which perform operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing, or distribution of medications, and which collect, control, and maintain all transaction information.

6. "Biological Safety Cabinet" shall mean a containment unit suitable for the preparation of low to moderate risk agents where there is a need for protection of the product, personnel, and environment, according to National Sanitation Foundation (NSF) Standard 49.

7. "Board of Pharmacy", "Pharmacy Board", "Board" or "M~~S~~BP", shall mean the Mississippi Board of Pharmacy.

8. “Cease and Desist” is an order of the Board prohibiting a licensee or other person or entity from continuing a particular course of conduct which violates the Pharmacy Practice Act or its rules or regulations.

9. “Centralized Prescription Processing” shall mean the processing by a pharmacy of a request from another pharmacy to fill or refill a prescription drug order or to perform processing functions such as dispensing, DUR, claims adjudication, refill authorizations, and therapeutic interventions.

10. “Certified Pharmacy Technician” shall mean those supportive persons, registered with the Mississippi Board of Pharmacy, who have successfully completed the Pharmacy Technician

Certification Board Examination or a Board approved pharmacy technician examination

11. "Class 100 Environment" shall mean an atmospheric environment which contains less than 100 particles 0.5 microns in diameter per cubic foot of air, according to Federal Standard 209B.

12. “Collaborative Pharmacy Practice” is that practice of pharmacy whereby one or more pharmacists have jointly agreed, on a voluntary basis, to work in conjunction with one or more practitioners under protocol whereby the pharmacist may perform certain patient care functions authorized by the practitioner or practitioners under certain specified conditions and or limitations.

13. “Collaborative Pharmacy Practice Agreement” is a written and signed agreement between one or more pharmacists and one or more practitioners that provides for Collaborative Pharmacy Practice for the purpose of Drug Therapy Management of patients.

14. "Component" is any ingredient intended for use in the compounding of a medication.

15. "Compounding" means (1) the production, preparation, propagation, conversion, or processing of a sterile or non-sterile drug or device either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis or from bulk chemicals or the preparation, mixing, measuring, assembling, packaging, or labeling of a drug or device as a result of a practitioner's prescription drug order or initiative based on the practitioner/patient/pharmacist relationship in the course of professional practice or (2) for the purpose of, as an incident to, research, teaching or chemical analysis and not for sale or dispensing. Compounding also includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine regularly observed prescribing patterns.

16. "Confidential Information" shall mean information obtained and/or maintained by the pharmacist, which is privileged and released only to the patient or, as the patient directs; to those health care professionals where, in the pharmacist's professional judgment, such release is necessary to protect the patient's health and well being; and to such other persons or governmental agencies authorized by law to receive such confidential information.

17. "Consultant Pharmacist" shall mean a pharmacist who provides services which includes but is not limited to; providing consultation on matters related to drugs, reviewing patients drug therapy regimen, serving on appropriate committees, disposing of drugs which are no longer needed, ensuring complete and accurate records of acquisition and disposition of controlled substance medications and who has attended, within the last two years, a qualifying seminar which has been approved by the Board of Pharmacy.

18. "Continuing Education Unit" shall mean ten (10) clock hours of study or other activity and shall include either of the following:

A. Programs which have been approved by the American Council on Pharmaceutical Education. (A.C.P.E.)

B. Programs which have been approved by the Mississippi Board of Pharmacy prior to presentation.

19. "Cytotoxic" shall mean a pharmaceutical that has the capability of killing living human cells.

20. "Deliver" or "Delivery" shall mean the actual, constructive or attempted transfer of a drug or device from one person to another, whether or not for a consideration.

21. “Digital Signature” shall mean an electronic signature based upon cryptographic methods of originator authentication, and computed by using a set of rules and a set of parameters so that the identity of the signer and the integrity of the data can be verified.

22. "Dispense" or "Dispensing" shall mean the interpretation of a valid prescription or order of a practitioner by a pharmacist and the subsequent preparation of the drug or device for administration to or use by a patient or other individual entitled to receive the drug.

23. “Dispenser” shall mean, as it pertains to the Prescription Monitoring Program, a person authorized in this state to distribute to the ultimate user a substance monitored by the prescription monitoring program, but does not include:
(a) a licensed hospital pharmacy that distributes such substances for the purposes of inpatient hospital care or the dispensing of prescriptions for controlled substances at the time of discharge from such a facility.
(b) a licensed nurse or medication aide who administers such substances at the direction of a licensed physician; or
(c) a wholesale distributor of a substance monitored by the prescription monitoring system.

24 ."Device" shall mean an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component part or accessory, that is required under federal or state law to be ordered or prescribed by a practitioner and dispensed by a pharmacist.

25. "Distribute" shall mean the delivery of a drug or device other than by administering or dispensing to persons other than the ultimate consumer.

26. “Drug” shall mean:

(1) articles recognized as Drugs in any official compendium, or supplement thereto, designated from time to time by the Board for use in the diagnosis, cure, mitigation,

treatment, or prevention of disease in humans or other animals;

(2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals;

(3) articles (other than food) intended to affect the structure or any function of the body of humans or other animals; and

(4) articles intended for use as a component of any articles specified in item (1), (2), or (3) of this definition.

27. “Electronic Signature” shall mean an electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record.

28. “Electronic Transmission” shall mean a transmission of information in electronic form or the transmission of the exact visual image of a document by way of electronic equipment.

29. "Emergency Medication Supplies", "Boxes", "Kits" or "Carts" are those drugs which may be required to meet the immediate therapeutic needs of patients and which are not available from any other authorized source in sufficient time to prevent risk of harm to patients.

30. "Enteral" shall mean within or by way of the intestine.

31. “Embargo” shall mean to restrict prescription drugs or devices from being dispensed by placing them under seal or in a secure area.

32 ."Foreign pharmacy graduate" shall mean a person whose undergraduate pharmacy degree was conferred by a recognized school of pharmacy outside of the United States, the District of Columbia and Puerto Rico. Recognized schools of pharmacy are those colleges and universities listed in the World Health Organization's World Directory of Schools of Pharmacy, or otherwise approved by the Foreign Pharmacy Graduate Examination Committee (FPGEC) certification program as established by the National Association of Boards of Pharmacy.

33. "Generic Equivalent Drug" shall mean a drug product which contains the identical active chemical ingredient of the identical strength, quantity and dosage form and which can be expected to have the same therapeutic effect when administered to the patient under the conditions specified in the labeling.

34. “Good Moral Character” shall mean an applicant for licensure or registration has not been adjudicated guilty of any act which would provide grounds for disciplinary action by the Board as evidenced by having undergone and successfully passed a criminal background check conducted by the Board.

35. “Home Health/Hospice” shall mean a business, which does not require the services of a pharmacist and where certain prescription drugs or prescription devices as approved by the Board are bought, sold, maintained or provided to consumers.

36. “Home Infusion Pharmacy” shall mean a pharmacy which compounds solutions for direct administration to a patient in a private residence, long-term care facility, or hospice setting by means of parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion.

37. "In-patient" is one who receives treatment or undergoes tests as a resident of an institutional facility.

38. "Inpatient Medication" shall mean medication dispensed for a person who is a patient in the facility where the medication is dispensed.

39. "Institutional Facility" or "Organized Health Care Setting" is defined as:

    (1) Hospital;
    (2) Convalescent Home;
    (3) Nursing Home;
    (4) Extended Care Facility;
    (5) Mental Institution;
    (6) Rehabilitation Center;
    (7) Psychiatric Center;
    (8) Developmental Disability Center;
    (9) Drug Abuse Treatment Center;
    (10) Retardation Center;
    (11) Correctional Facility;
    (12) Hospice;
    (13) Out-patient surgery facilities;
    (14) Any other such organization whose primary purpose is to provide a residential environment for patients to obtain health care services, and shall not include those places where physicians, dentists, veterinarians or other practitioners of the healing arts, who are duly license, engage in private practice.

40. "Institutional Pharmacy" is defined as that portion of an institutional facility which is engaged in the compounding, production, storage, sale, dispensing or distribution of drugs, medications, devices and other materials used in the diagnosis and treatment of injury, illness and disease, and registered with the Mississippi Board of Pharmacy and operating under a valid institutional permit issued thereby.

41. "Internal Test Assessment" means, but is not limited to, conducting those tests of quality assurance necessary to ensure the integrity of the test.

42. "IV Additive Program" is a pharmacy based program in which the addition of drugs to IV fluids and the preparation of small volume parenterals are under the supervision of a pharmacist.

43. “Long Term Care Facility (LTCF)” shall mean any nursing home, convalescent home, extended care facility, personal care home, or inpatient hospice, which has been issued a permit by the Board but does not include a Hospital.

44. "Manufacturing" of prescription products shall mean the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from substances from natural origin or independently by means of chemical or biological synthesis, or from bulk chemicals and includes any packaging or repackaging of the substance(s) or labeling or relabeling of its container, if such actions are associated with promotion and marketing of such drug or devices.

45. “Non-Resident Pharmacy” means a Pharmacy located outside this State.

46. "Nuclear Pharmacy" is a pharmacy providing the services of storing, compounding, dispensing, labeling or distributing radiopharmaceuticals.

47. "Out-patient" is one who receives treatment or undergoes tests without in-patient admission to an institutional facility.

48. "Outpatient Medication" shall mean medication which is dispensed for a person who is not a patient in the facility where the medication is dispensed.

49. "Parenteral" means sterile preparations of drugs for injection through one or more layers of skin.

50. "Patient Counseling" shall mean the oral communication by a pharmacist of information to the patient or care giver to improve therapeutic outcomes by optimizing proper use of prescription drugs or devices. Alternative forms of patient information may be used to supplement verbal patient counseling when appropriate. Examples to include written information leaflets, pictogram labels, video programs, auxiliary labels on the prescription vial, etc.

51. "Patient Med-Pak" is a package prepared by a pharmacist for a specific patient comprising a series of containers or cells and containing two or more prescribed solid oral dosage forms. The med-pak is designed and labeled to indicate the day and time or period of time that the contents within each container or cell are to be taken.

52. "Person" shall mean an individual, corporation, partnership, association, or any other legal entity.

53. "Pharmaceutical Care/Pharmacist Care" is the provision of drug therapy by a pharmacist and other pharmacist 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.

54. "Pharmacist" shall mean an individual health care provider licensed by this state to engage in the practice of pharmacy. This recognizes a pharmacist as a learned professional who is authorized to provide patient services.

55. “Pharmacist-in-Charge” shall mean a Pharmacist currently licensed in this state who accepts responsibility for the operation of a Pharmacy in conformance with all laws and rules pertinent to the Practice of Pharmacy and the Distribution of Drugs and Devices, and who is personally in full and actual charge of such Pharmacy and personnel.

56. "Pharmacy" shall mean any location for which a pharmacy permit is required and in which prescription drugs are compounded, maintained and/or dispensed for patients by a pharmacist. This definition includes any location where pharmacy related services are provided by a pharmacist.

57. “Pharmacy Extern" shall mean a student in the professional program of a school of pharmacy who is making normal progress toward completion of a degree in pharmacy.

58. “Pharmacy Intern” means an individual who is:

(1) currently licensed by this State to engage in the Practice of Pharmacy while under the personal supervision of a Pharmacist and is satisfactorily progressing toward meeting the requirements for licensure as a Pharmacist; or
(2) a graduate of an approved college of Pharmacy or a graduate who has established educational equivalency by obtaining a Foreign Pharmacy Graduate Examination Committee (FPGEC) Certificate, who is currently licensed by the Board of Pharmacy for the purpose of obtaining practical experience as a requirement for licensure as a Pharmacist; or
(3) a qualified applicant awaiting examination for licensure.

59. "Pharmacy Technician" shall mean those supportive persons, registered with the Mississippi Board of Pharmacy, utilized in pharmacies whose responsibilities are to provide non-judgemental technical services concerned with the preparation for dispensing of drugs under the direct supervision and responsibility of a pharmacist.

60. “Physician/Patient Relationship” shall mean that a practitioner has obtained a thorough medical history and has conducted an appropriate physical and/or mental examination of a patient prior to the prescribing of any medication.

61. "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; proper and safe storage of Drugs and 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.

62. "Practitioner" shall mean a physician, dentist, veterinarian, or other health care provider authorized by law to diagnose and prescribe drugs.

63. “Preceptor” shall mean an individual who is currently licensed as a Pharmacist by the Board of Pharmacy and participates in the instructional training of Pharmacy externs.

64. "Prepackaging" shall mean the act of placing small precounted quantities of drug products in containers suitable for dispensing or administering in anticipation of prescriptions or orders.

65. “Prescriber” means a licensed health care professional with prescriptive authority.

66. "Prescription" shall mean a written, verbal or electronically transmitted order issued by a practitioner for a drug or device to be dispensed for a patient by a pharmacist. An electronically transmitted order for a prescription drug or controlled substance is considered to be a written order.

67. "Prescription Drug" or "Legend Drug" shall mean a drug which is required under federal law to be labeled with either of the following statements prior to being dispensed or delivered:
(1) “Rx Only” or
(2) "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian";
or a drug which is required by an applicable federal or state law or regulation to be dispensed on prescription only or is restricted to use by practitioners only.

68. "Prescription Drug Order" shall mean a prescription as defined in the pharmacy laws and regulations of the State of Mississippi.

69. “Prescription Monitoring Information” means information submitted to and maintained by the Prescription Monitoring Program.

70. “Prescription Monitoring Program (PMP)” means a program established for the purpose of monitoring the dispensing and appropriate use of certain controlled substances and specified drugs within the state.

71. “Probation” shall mean the restriction of a license, permit or registration for a specified period of time.

72. "Product Selection" shall mean the dispensing of a generic equivalent drug product in lieu of the drug product ordered by the prescriber.

73. "Prospective Drug Review" shall mean the monitoring by a pharmacist, for therapeutic appropriateness, over-utilization and under-utilization, appropriate use of generic products, therapeutic duplications, drug-disease contraindications, drug-drug interaction(s), incorrect dosage or duration of drug treatment, and clinical abuse/misuse by a pharmacist prior to the drug being dispensed.

74. "Qualified Licensed Professional" means an individual (such as a physician, nurse, or technologist) who possesses a current state license if applicable, and who has sufficient training and experience to safely handle radiopharmaceuticals as defined by the Mississippi State Department of Health, Division of Radiological Health.

75. "Qualified Nuclear Pharmacist" means a currently licensed pharmacist in the state of Mississippi who is certified by the Mississippi State Department of Health, Division of Radiological Health, or who meets the following standards:
    (1) Minimum standards of training for "authorized user status" of radioactive materials as defined by Mississippi State Department of Health, Division of Radiological Health.
    (2) Completed a minimum of two hundred (200) contact hours of instruction in nuclear pharmacy and the safe handling and the use of radioactive materials from a program approved by the Mississippi Board of Pharmacy, with emphasis in the following areas:
        (i) Radiation Physics and Instrumentation;
        (ii) Radiation Protection;
        (iii) Mathematics of Radioactivity;
        (iv) Radiation Biology; and
        (v) Radiopharmaceutical Chemistry.
    (3) Attain a minimum of five hundred (500) hours of clinical nuclear pharmacy training under the supervision of a qualified nuclear pharmacist.

76. “Quarantine” shall mean the act of isolating prescription drugs or devices for the purpose of preventing dispensing or introduction into or intermingling with other prescription drug stock or devices at a permitted location.

77. "Radiopharmaceutical" is any substance defined as a drug in Section 201(g) (1) of the Federal Food, Drug and Cosmetic Act which also contains unstable nuclei which undergo

spontaneous disintegration with the emission of nuclear radiation. Radiopharmaceuticals also include any non-radioactive reagent kit or radionuclide generator which is intended to be used in the preparation of radiopharmaceutical doses.

78. "Radiopharmaceutical Service" means, but shall not be limited to the procurement, storage, handling, preparation, labeling, quality assurance testing, dispensing, delivery, record keeping, and disposal of radiopharmaceutical and other drugs.

79. "Radiopharmaceutical Quality Assurance" means, but is not limited to, the performance of appropriate chemical, biological and physical tests on potential radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans including internal test assessment, authentication of product history and the keeping of proper records.

80. "Registrant" shall mean a pharmacy or other entity which is registered with the Mississippi Board of Pharmacy to buy, sell, destroy or maintain controlled substances.

81. "Repackager" means a person registered by the Federal Food and Drug Administration as a repackager who removes a prescription drug product from its marketed container and places it into another, usually of smaller size, to be distributed to persons other than the consumer.

82. “Reprimand” shall mean the formal reproof of a licensee for violation of the Pharmacy Practice Act or Rules and Regulations of the Board.

83. "Retrospective Drug Review" shall mean the monitoring for therapeutic appropriateness, over-utilization and under-utilization, appropriate use of generic products, therapeutic duplications, drug-disease contraindications, drug-drug interaction(s), incorrect dosage or duration of drug treatment, and clinical abuse/misuse after the drug has been dispensed.

84. “Reverse Distributor” shall mean those business operations which are responsible for the receipt and appropriate disposal of un-wanted and un-needed stocks of controlled and non-controlled medications.

85. “Revocation” shall mean the withdrawal of the license to practice Pharmacy. The individual no longer has the privilege of practicing Pharmacy in this state.

86. "Sterile Pharmaceuticals" shall mean a dosage form free from living micro-organisms (aseptic).

87. “Summary Suspension” shall mean the Suspension of a license or permit which requires a licensee to cease Pharmacy Practice immediately pending the results of a timely hearing.

88. “Suspension” shall mean the withdrawal of the license to practice Pharmacy in the state for

a specified period of time.

89. “Telemedicine” shall mean the practice of medicine using electronic communication, information technology or other means between a physician in one location and a patient in another location with or without an intervening health care provider. This definition does not include the practice of medicine through postal or courier services.

90. "Unit Dose Packaging" is the packaging of individual doses of medication in containers which will preserve their identity and integrity from the point of packaging to patient consumption.

91. "Unlawful" or "Unauthorized Possession" shall mean physical holding or control by a pharmacist, pharmacy technician, or other person, of a controlled substance or other habit forming prescription drug outside the usual and lawful course of employment.

92. "Valid Prescription" or "Valid Order" shall mean one issued in compliance with applicable rules and regulations of the regulatory authority by an individual licensed or authorized to prescribe a product to be used by a named and identifiable individual for a bona fide medical purpose. To be valid in Mississippi, a prescription written in another state must be written so as to comply with the requirements of the regulatory authority of that state and with the requirements of the regulatory authority of this state. A prescription which is written in code or for any other reason does not provide adequate information for the interpretation of the prescription and the safe dispensing of the drug product is not a valid prescription. The dispensing of prescription drugs or controlled substances pursuant to prescription documents which the pharmacist knows or should know were issued by a practitioner when a valid practitioner/patient relationship did not exist are not valid prescriptions. A valid practitioner/patient relationship shall mean that the practitioner has obtained a thorough medical history and has conducted an appropriate physical and/or mental examination prior to the prescribing of any medication. Prescriptions or orders issued for the dispensing of medications on an out-patient basis in the absence of a physician/patient relationship in which a practitioner has not conducted an appropriate examination of the patient and established a diagnosis are not valid prescriptions.

93. "Wholesaler" shall mean a person who buys/acquires prescription drugs or prescription devices for resale or distribution, or for repackaging for resale or distribution, to persons other than consumers.

94. "Written guideline or protocol" shall mean an agreement in which any practitioner authorized to prescribe drugs, delegates to a pharmacist authority to conduct specific prescribing functions in an institutional setting, or with individual patients, provided that a specific protocol agreement is signed on each patient and is filed as required by law or by rule or regulation of the Board.

ARTICLE I LICENSURE

A license for the practice of pharmacy shall be obtained from the Mississippi Board of Pharmacy by all persons prior to their engaging in the practice of pharmacy in this state and every pharmacist licensed in this state shall keep the Board informed as to his/her current mailing address and place of employment.

1. To obtain a license to engage in the practice of pharmacy by examination, the applicant shall:
   A. Have submitted a written application on the form prescribed by the Board;
   B. Be of good moral character as evidenced by having undergone and successfully passed a criminal background check conducted by the Board;
   C. Have graduated and received a degree from a school or college of pharmacy accredited by the American Council on Pharmaceutical Education or as approved by the Board;
   D. Have successfully passed an examination approved by the Board;
   E. Have submitted documented evidence of the required practical experience;
   F. Have paid the initial licensure fee (not to exceed two-hundred dollars ($200.00).

2. To obtain a license to engage in the practice of pharmacy by licensure transfer, the applicant shall:
   A. Have submitted a written application on the Official Application for Transfer of Pharmaceutic Licensure Form of the National Association of Boards of Pharmacy;
   B. Have graduated and received a degree from a school or college of pharmacy accredited by the American Council on Pharmaceutical Education or as approved by the Board;
   C. At the discretion of the Board, appear before the Board of Pharmacy for a personal interview;
   D. Have successfully passed an examination approved by the Board;
   E. Be of good moral character as evidenced by having undergone and successfully passed a criminal background check conducted by the Board;
   F. Present to the Board proof that the license(s) granted to the applicant by any other state has not been suspended, revoked, canceled, surrendered, or otherwise restricted for any reason;
   G. Have paid the initial licensure fee not to exceed two-hundred dollars ($200.00).

   No applicant shall be eligible for license transfer unless the state in which the applicant was licensed as a Pharmacist also grants licensure transfer to Pharmacists duly licensed by examination in the State, under like circumstances and conditions.

3. To obtain a license to engage in the practice of pharmacy, a foreign pharmacy graduate applicant shall obtain the National Association of Boards of Pharmacy's Foreign Pharmacy Graduate Examination Committee's certification which shall include, but not be limited to, successfully passing the Foreign Pharmacy Graduate Equivalency Examination and

attaining a total score of at least 550 on the Test of English as a Foreign Language (TOEFL); and

A. Have submitted a written application on the form prescribed by the Board; and
B. Be of good moral character as evidenced by having undergone and successfully passed a criminal background check conducted by the Board; and
C. Have graduated and been granted a pharmacy degree from a college or school of pharmacy recognized and approved by the National Association of Boards of Pharmacy's Foreign Pharmacy Graduate Examination Committee; and
   May at the discretion of the Board appear before the Board of Pharmacy and demonstrate adequate spoken English Language skills; and
D. Have paid all fees specified by the Board for examination; and
E. Have successfully passed an examination approved by the Board; and
F. Have completed sixteen hundred hours of extern/internship hours approved by the Board; and
G. Have paid the initial licensure fee, not to exceed two-hundred dollars ($200.00).

ARTICLE II PHARMACY BOARD EXAMINATION

The examination shall consist of the North American Pharmacist Licensure Examination (NAPLEX) and the Multi-State Pharmacy Jurisprudence Examination (MPJE) or a test on Mississippi Pharmacy Law and Pharmacy Board Regulations administered by the Board.

To be eligible to take the NAPLEX examination, a person shall be a graduate of a school of pharmacy which is accredited by the American Council on Pharmaceutical Education or which has been approved by the Board.

A person desiring to take the examination for licensure as a pharmacist must make application for the examination on the form prescribed by the Board. The required fee for the examination must accompany the application.

To successfully complete the examination, the candidate must make a score of at least seventy five (75) on the NAPLEX part of the examination, a score of at least seventy five (75) on the MPJE part of the examination, or a score of at least seventy five (75) on the test of Mississippi Pharmacy Law and Pharmacy Board Regulations.

A person who takes the examination and fails the examination may repeat the examination; however, a person may not take the examination more than four (4) times without permission from the Board. A person who is not eligible to take the Mississippi Board of Pharmacy examination may not practice as an intern. A person who takes the examination and successfully completes the examination must become licensed within two (2) years of the examination date or the results of the examination become invalid.

ARTICLE III PRACTICAL EXPERIENCE REQUIREMENT

1. The externship/internship practical experience required for licensure is defined as a total of sixteen hundred (1,600) hours of pharmacy experience. The said sixteen hundred (1,600) hours of practical experience shall be obtained after the student is enrolled in the professional program of a school of pharmacy. Practical experience hours gained through clerkships and externships, while enrolled in a school of pharmacy whose externship rotations are approved by the Board, may be used to satisfy these requirements. In order for a pharmacy student to be considered as a valid extern in such a program, he/she must be certified by a school of pharmacy as a bona fide student making normal progress toward completion of either a Bachelor of Science or a Doctor of Pharmacy degree in pharmacy.

   Any remaining practical experience required for licensure, not obtained by the extern through externship rotations, may be obtained during official vacation periods when the extern is not enrolled as a full time student or as an intern after graduation. No more than fifty (50) hours per week of practical experience shall be credited during any of these periods.

2. All practical experience gained in Mississippi, which is related to the dispensing of drugs, must be under the direct and immediate supervision of a pharmacist registered in Mississippi and in good standing with the Mississippi Board of Pharmacy. The direct and immediate supervision by the pharmacist requires the physical presence of the supervising pharmacist at all times and includes the constant personal supervision and monitoring of the extern or intern by the supervising pharmacist. The supervising pharmacist shall be responsible for the activities of the extern or intern.

3. No practical experience obtained in this state shall be credited to an extern or intern unless such extern or intern be registered with the Mississippi Board of Pharmacy as a pharmacy extern/intern and be issued a registration to dispense controlled substances by the Board.

4. For practical experience obtained in another state and for which the Mississippi Board of Pharmacy is requested to grant credit toward the experience requirements, the applicant shall:
   A. Submit the affidavits certifying the work experience to the Board of pharmacy in the state in which the experience was obtained;
   B. Request that Board of Pharmacy to send copies of the affidavits to the Mississippi Board of Pharmacy along with certification that the hours of experience claimed are acceptable to that Board.

Upon receipt of copies of the affidavits and the statement of their acceptance by the Board of Pharmacy in the state in which the experience was obtained, the Mississippi Board of Pharmacy may grant the same credit toward practical experience requirements.
For purposes of these Regulations the term "practical experience" shall include, but not be limited to, the compounding, dispensing and labeling of drugs, interpreting and evaluating

prescriptions, maintaining prescription drug records and any other activity included in the practice of pharmacy.

ARTICLE IV LICENSE RENEWAL AND CONTINUING EDUCATION

Each pharmacist shall renew his/her license annually.

1. To renew his/her license, a pharmacist shall:
   A. Submit an application for renewal on the form prescribed by the Board or through the online process found at the Mississippi Board of Pharmacy webpage;
   B. On the application, indicate and certify the number of continuing education hours earned for Licensure:
      One (1) continuing education unit~~s~~ (10 hours) is required for each licensure period.
   C. Pay renewal fees as follows:
      One-hundred dollars ($100.00) for the annual licensure period January 1, 2011 through December 31, 2011, and each annual licensure period thereafter, plus a surcharge of five dollars ($5.00) to fund a program to aid impaired pharmacists and pharmacy students for a total fee of one-hundred and five dollars ($105.00) .
   D. Any pharmacist license renewal application postmarked after December 31 of the renewal period or submitted online after 11:59 P.M. CST shall be returned or rejected and a fifty dollar ($50.00) late renewal fee shall be assessed prior to renewal.
   E. Any license not renewed by January 15th may be considered invalid and may be subject to disciplinary action by the Board.

2. Any person who has not renewed or possessed a valid license to practice pharmacy in Mississippi for a current period of time exceeding two years must:
   A. Petition the Board for license reinstatement;
   B. Appear before the Board in support of said petition;
   C. Work as an intern for a Board approved pharmacist and site for twenty (20) clock hours for each year that the person was without a valid license;
   D. Provide a record from the supervising pharmacist showing the satisfactory completion of the intern hours;
   E. Provide proof of ten (10) hours of continuing education for the current licensing period;
   F. Pay all license renewal fees in arrears; and
   G. Satisfactorily pass an examination on Pharmacy Law and Board regulations approved by the board.

3. Those persons who have been actively engaged in the practice of pharmacy pursuant to a license issued by another state, but who have not renewed the Mississippi Pharmacist License for a period of time exceeding two years must:
   A. Petition the Board for reinstatement;
   B. May appear before the Board in support of said petition, or furnish proof of a continuing valid pharmacy license in another state during the period of license lapse in Mississippi;
   C. Provide proof of ten (10) hours of continuing education for the current licensing period; and

D. Pay all license renewal fees in arrears; and
E. Satisfactorily pass an examination on Pharmacy Law and Board regulations approved by the Board.

4. For purposes of these regulations, one (1) continuing education unit shall consist of ten (10) clock hours of study or other activity and shall include either of the following:
   A. Programs, which have been approved by the American Council on Pharmaceutical Education (A.C.P.E.);
   B. Programs, which have been approved by the Mississippi Board of Pharmacy prior to presentation.

5. The continuing education required for license renewal shall be obtained in the licensure period preceding the renewal date. Evidence of continuing education shall be submitted to the Board of Pharmacy on request by audit or at any time on request by any agent of the Board of Pharmacy. Documentation of evidence of continuing education should indicate the name and address of the participant, date of the continuing education, the program title, the amount of continuing education credit received and the signature of the person authorized to issue certification of continuing education credit. Documentation of continuing education credit must be received within five (5) working days of a request. Failure to submit evidence of continuing education credit will result in disciplinary action by the Board.

6. Continuing education obtained in another state may be accepted by the Mississippi Board of Pharmacy provided that it is acceptable to the Board of Pharmacy in the state where it was obtained.

7. A request for Pharmacy Board approval of a program as continuing education shall be made on a form prescribed by the Board.

8. The subject matter of the program, the objectives of the program and the qualifying credentials of the person or persons presenting the program must be sufficiently detailed in the request for Board approval so as to give the Board a sound basis for evaluating the merits of the program.

9. In approving programs for continuing education the policy of the Board shall be that no program will be approved:
   A. After the program has been presented;
   B. If program attendance is expected or required as part of a person's employment (an example would be an inservice or training seminar);
   C. That is not made available to all pharmacists who wish to attend (an exception may be a program that is specifically directed to a particular group such as hospital pharmacists, retail pharmacists or consultant pharmacists).

10. Continuing education obtained by a pharmacist who is also licensed by another approved

health care regulatory agency shall be acceptable to the Board provided the continuing education is approved by that respective regulatory agency. A pharmacist enrolled full time in any recognized school of the healing arts may receive credit for the continuing education requirements of this ARTICLE upon submitting proof of full time enrollment.

11. The Board, at its discretion, may grant extension periods and waivers for the completion of license renewal and continuing education requirements for ACTIVE Military Service members.

ARTICLE V ACTION AGAINST PHARMACIST LICENSE

1. The Board of Pharmacy may refuse to issue or renew, or may suspend, summarily suspend, place on probation, revoke, reprimand or restrict the license of any pharmacist and/or impose a monetary penalty upon one or more of the following grounds:
   A. Violation of the rules and regulations of the Board of Pharmacy;
   B. Violation of any of the provisions of the Mississippi Pharmacy Practice Act or the Mississippi Uniform Controlled Substances Law;
   C. Violation of pharmacy or drug laws of any other state or the federal government or rules or regulations pertaining thereto;
   D. Fraud or intentional misrepresentation by a licensee in securing the issuance or renewal of a license or failing to report to the Board any adverse action taken by another licensing jurisdiction, government agency, law enforcement agency, or court that would constitute grounds for action;
   E. Aiding and abetting an individual to engage in the practice of pharmacy without a license;
   F. Addiction to or dependence on alcohol, controlled substances or other habit forming legend drugs or the unauthorized use, possession, or theft of controlled substances or other habit forming legend drugs;
   G. Unprofessional conduct. Unprofessional conduct shall include, but is not limited to:
      (1) Condoning or assisting in the dispensing, promotion or distribution of drugs:
         (a)Which do not meet the standards required by law;
         (b)Which the pharmacist knows, or should know, are not obtained for a legitimate medical need.
      (2) Committing any fraudulent act including, but not limited to:
         (a)Destruction or alteration of any records such as prescriptions, profiles, purchase invoices, third-party vouchers and receipts required to be kept;
         (b)The placement of any advertisement which is false or misleading;
         (c)Filing a claim or assisting in the filing of a claim for reimbursement for drugs or professional services which were not provided or which were not authorized to be provided.
      (3) Dispensing, selling, bartering, receiving, or maintaining drugs which the pharmacist knows, or should know, have been stolen or diverted from the purpose for which they were distributed by a legitimate source;
      (4) Practicing in a location which is not properly permitted or registered by the Mississippi Board of Pharmacy;
      (5) Selling or bartering a prescription drug sample;
      (6) Receiving, dispensing, or maintaining a prescription drug sample unless the pharmacy is owned by a charitable organization and is not operated for profit and has prior approval in writing by the Board. Institutional pharmacies may receive, dispense and maintain prescription drug samples that are provided by a practitioner and intended solely for administration to his/her patients confined to the institution provided no charge is made to the patient by the

institution for the sample;

(7) No pharmacist shall have possession of a prescription drug sample unless such sample is for treatment of a diagnosed personal medical condition;

(8) Denying a patient freedom of choice in selecting who will fill their prescription needs;

(9) Willfully and knowingly failing to maintain complete and accurate records of all prescription drugs received, disposed of or dispensed at a permitted facility.

(10) Failure to report fraudulent prescription activity to the appropriate authorities.

H. Physical or mental incapacity that prevents a pharmacist from practicing pharmacy with reasonable skill and safety to the public.

I. Failure to comply with any lawful order of the Board.

J. Being found guilty by the licensing agency in another state or violating the statutes, rules or regulations of that jurisdiction.

K. Divulging or revealing patient confidential or protected health information to any person other than as authorized by Board regulations.

L. Termination of employees suspected of theft of pharmaceuticals or merchandise without contacting the Board prior to termination.

M. Failure to report directly to the Board, losses or suspected losses of controlled substances or prescription drugs.

N. Theft from a permitted facility.

O. Theft or embezzlement of prescription drugs, controlled substances or medical devices from a permitted facility.

P. Jeopardizing, compromising, interfering or failing to cooperate with any lawful investigation conducted by the Board or any state or federal regulatory or law enforcement agency.

Q. 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.

R. 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 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.

S. Failure to furnish to the Board, its investigators, or representatives any information legally requested by the Board.

T. Failing to pay costs assessed in a disciplinary hearing.

U. Failing to submit prescription monitoring information to the Prescription Monitoring Program within the time interval prescribed.

V. The unlawful disclosure of information from the Prescription Monitoring Program or using information obtained from the Prescription Monitoring Program for unlawful or unethical purposes.

W. Failure to produce continuing educations credits within required time period set forth in these regulations.

X. The Board may issue a cease and desist order to prevent a person from engaging in the practice of pharmacy which endangers the public.

ARTICLE VI PHARMACY PERMITS

1. Every business or location in this state where prescription drugs are maintained and/or pharmacy services are provided shall obtain a permit as a pharmacy from the Mississippi Board of Pharmacy. Effective January 31, 2011, every pharmacy issued a permit by the Board shall renew this permit biennially. The Board shall identify written criteria and issue permits accordingly in one of the following general classifications:
   A. Community Pharmacy; or
   B. Institutional Pharmacy; or
   E. Limited Closed Door Pharmacy; or
   F. Nonresident Pharmacy.

2. For purposes of this ARTICLE, definitions are as follows:
   D. A Community Pharmacy shall mean any place, other than an Institutional Pharmacy or a Limited Closed Door Pharmacy, which is accessible to the general public and where pharmacy services are offered. These pharmacies may include but are not limited to independent retail or chain retail pharmacies.

      A Specialty Community Pharmacy shall mean any place other than an Institutional Pharmacy, Limited Closed Door Pharmacy or a Community Pharmacy where the practice of pharmacy occurs and pharmacy services are provided to patients. These services may include, but are not limited to the following: dispensing sterile pharmaceuticals for home infusion, nuclear pharmacy services, compounding, consulting pharmacist services, disease state management, respiratory services and dispensing of nursing home medications. These pharmacies may be open on a full or part time basis.
   B. An Institutional Pharmacy shall mean that portion of an institutional facility where the practice of pharmacy occurs and where medications, devices and other materials are dispensed to their patients.
      (4) An Institutional I Pharmacy shall mean that portion of a hospital where the practice of pharmacy occurs and which is engaged in the compounding, production, and dispensing of drugs, medications, devices and other materials which are used in the diagnosis and treatment of injury, illness and disease. For purposes of these regulations a hospital shall mean any institution for the care and treatment of the sick and injured which is licensed and approved by the Mississippi State Department of Health, Health Facilities, Licensure and Certification.
      (5) An Institutional II Pharmacy shall mean that portion of an institution, other than a hospital, where the practice of pharmacy occurs and which is engaged in the compounding, production and dispensing of drugs, medications, devices and other materials used in the diagnosis and treatment of injury, illness and disease.

      Various categories of Institutional Pharmacies are recognized as follows:

"Institutional Facility" or "Organized Health Care Setting" is a:

(1) Hospital;
(2) Convalescent Home;
(3) Nursing Home;
(4) Extended Care Facility;
(5) Mental Institution;
(6) Rehabilitation Center;
(6) Retardation Center;
(8) Correctional Facility;
(9) Hospice;
(11) Out-patient surgery facilities;
(11) Any other such organization whose primary purpose is to provide a residential environment for patients to obtain health care services, and shall not include those places where physicians, dentists, veterinarians or other practitioners of the healing arts, who are duly licensed, engage in private practice.

C. Limited Closed Door Pharmacy shall mean any place where pharmacy services are provided and where preferentially priced prescription drugs are purchased for the pharmacy's own use to dispense only to their own patients. These pharmacies are not accessible to the general public and may or may not provide full time pharmacy services.

A Limited Closed Door Pharmacy may include, but is not limited to, pharmacies owned by any city, county or state government and federally, state or privately funded non-profit community health clinics.

F. A Nonresident Pharmacy shall mean any pharmacy that is located outside the State of Mississippi which ships, mails or delivers prescription or legend drugs or devices to patients residing in this state.

3. To obtain a pharmacy permit or renew a pharmacy permit, the applicant shall have:
   A. Submitted a written application on a form(s) prescribed by the Board;
   B. Submitted the required fees as follows:
      Three hundred dollars ($300.00) for the registration period January 1, 2011 through December 31, 2012, and each biennial registration period thereafter.
   C. Any Pharmacy permit renewal application postmarked after December 31 of the renewal period shall be returned and a fifty ($50.00) late renewal fee shall be assessed prior to renewal.

4. Newly issued permits which do not coincide with the registration period shall be valid for the following periods of time: If the permit is issued in the first half of the registration period, it must be renewed at the end of the registration period. If the permit is issued in the second half of the registration period, it must be renewed at the end of the next registration period.

5. Permits issued to any type facility become null and void sixty (60) days from the date of

issuance if inspection reveals a lack of legitimate business activity.

6. A permit for a pharmacy shall not be issued or renewed on the application of any person unless such person be a pharmacist licensed in this state.

7. Original permits, once issued for a new facility, may be returned to the Board and a new permit issued without being assessed an additional permit fee provided:
   A. The change is on a one time basis and is within sixty (60) days of original issuance; and
   B. Controlled substance inventory requirements are met; and
   C. A twenty-five dollar ($25.00) processing fee is paid to the Board.

ARTICLE VII RESPONSIBILITY OF PHARMACIST-IN-CHARGE (PIC)

1. The person who signs the application for a pharmacy permit or the renewal of a pharmacy permit shall be the pharmacist-in-charge (PIC) for that facility.
   A. Authority. The PIC of the pharmacy shall be responsible for complete supervision, management and compliance with all federal and state pharmacy laws and regulations pertaining to the practice of pharmacy in the entire prescription department. He/She shall have the cooperation and support of all pharmacy staff in carrying out these responsibilities. The pharmacist-in-charge is responsible for assuring that all personnel are properly registered or licensed with the Board and, that all pharmacy permits are current and appropriate for the type of pharmacy operation being conducted.
   A pharmacist shall not be the PIC at more than one Community Pharmacy or Institutional I Pharmacy and shall not be the pharmacist-in-charge or have personal supervision of more than one facility which is open to the general public on a full time basis.
   B. Recommended Guidelines:
      (1) That each individual work space is designed to provide space and a work flow design that will accommodate the workload in an organized fashion; and
      (2) That the computer's software should be of a design so that drug interactions and contraindications must be reviewed by the pharmacist. Further, the computer system should support counseling and drug utilization review documentation; and
      (3) That trained supportive staff should be maintained to meet the demands of the practice site, workload and the clientele served; and
      (4) That all staff should have the opportunity to take periodic breaks and/or meal periods to relieve fatigue and mental and physical stress. Nothing in this paragraph suggests closing the pharmacy; and
      (5) That all staff should be afforded and encouraged to participate in training and continuing education in order to keep them abreast of new information and changes in the field; and
      (6) That if quotas or formulas such as prescription volume are used to set staffing, conditions such as peak workload periods, workplace design and the training of staff must be taken into consideration.

   C. Circumvention. It is a violation of this section for any person to subvert the authority of the pharmacist-in-charge by impeding the management of the prescription department for the compliance with federal and state drug or pharmacy laws and regulations. Any such circumvention may result in charges being filed against the pharmacy permit.

2. A permit for a pharmacy located within the state shall not be issued or renewed unless such person be a pharmacist-licensed in this state.

If the pharmacist license of the pharmacist-in-charge becomes void or inactive due to surrender, revocation, suspension, restriction or for any other reason, application must be made for a new pharmacy permit by another pharmacist within ten (10) days.

3. If the employment of a pharmacist-in-charge is terminated or if for any other reason he/she wishes to be relieved of the responsibilities of the PIC, he/she must:
   A. Return the permit to the Mississippi Board of Pharmacy with written notice that he/she is no longer the pharmacist-in-charge for that facility and;
   B. In accordance with the provision of paragraph 2 of ARTICLE XXV of the Regulations, send to the Board of Pharmacy an inventory of any controlled substances on hand at the facility at the time of his/her termination as pharmacist-in-charge.
   C. When the relinquishing PIC cannot or does not comply with the inventory requirements of this paragraph it shall be the responsibility of the new PIC to send to the Board of Pharmacy an inventory of any controlled substances on hand at the time he/she assumes responsibility as PIC.
   D. The relinquishing PIC is responsible for notification of appropriate supervisors or owners of the surrender of the permit.

   When a permit is thus returned for a facility, application for a new permit for that facility must be made to the Mississippi Board of Pharmacy within ten (10) days.

4. If a permitted facility is permanently closed or has a change of ownership, the pharmacist-in-charge for that facility shall give notice to the Board of the effective date of closure or change in ownership and include the storage location of the businesses records and appropriate contact information. If a permitted facility has a change in name or location, application for a new permit must be made to the Board at least ten (10) days prior to the change in name or location. Once issued, a permit cannot be amended, transferred or assigned to another person.

5. On the premises where a pharmacy is maintained in conjunction with other services or business activities, the pharmacy shall be physically secured from such other services or activities during those times a pharmacist is not present and the pharmacy is not open and other services or activities are being provided on the premises.
   A. The Pharmacy shall be secured by a physical barrier to detect entry at a time when the Pharmacist is not present.
   B. Each pharmacist while on duty shall be responsible for the security of the Pharmacy, including provisions for effective control against theft or diversion of Drugs and/or Devices.
   C. The pharmacist-in-charge shall be responsible for adequate security being maintained on drugs in all areas of the permitted facility at all times and is responsible for reporting any loss or suspected loss of controlled substances or legend drugs directly to the Board immediately (this does not relieve any pharmacist who discovers a loss from the requirement of reporting the loss directly to the Board).

6. Each facility issued a pharmacy permit by the Mississippi Board of Pharmacy shall maintain:
   A. An area of sufficient size to accommodate the dispensing functions of the facility and which is adequately equipped to provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation and security. All areas where Drugs and Devices are stored shall be dry, well lighted, well ventilated, and maintained in a clean and orderly condition. Storage areas shall be maintained at temperatures which will ensure the integrity of the Drugs prior to their dispensing as stipulated by the USP-NF and/or the Manufacturer's or Distributor's labeling.
   B. A sink with hot and cold running water which is convenient to the dispensing area;
   C. An inventory which shall include such drugs, chemicals and preparations as may be necessary to fill ordinary prescriptions as indicated by experience in the area where the pharmacy is located;
   D. Technical equipment which may include measuring graduates, mortar and pestle, spatulas, funnels, ointment slab or paper, balance and such other items of equipment found to be necessary for the filling of prescriptions or rendering of other pharmacist services; and,
   E. Current reference material adequate for professional and consumer information.
   F. Pharmacy permits, facility controlled substance registrations, and DEA registrations must be conspicuously posted. Evidence of current pharmacist licensure and pharmacy technician registration must be provided on request by any agent of the Board.
   G. A current and updated copy of the Mississippi Board of Pharmacy Practice Regulations and Pharmacy Practice Act.

7. It is the responsibility of the Pharmacist-in-charge to establish and implement procedures to ensure compliance with the Article entitled Prescription Monitoring Program.

8. 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.

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 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 IX ACTION AGAINST PERMITS

1. The Board of Pharmacy may refuse to issue or renew, or may suspend, summarily suspend, place on probation, revoke, reprimand, or restrict the permit of any permitted facility and/or impose a monetary penalty upon one or more of the following grounds:
   - A. Any act by any person in the conduct of the activities of the facility which is a violation of any of the provisions of the Mississippi Pharmacy Practice Act or the Mississippi Uniform Controlled Substances Law. Further, that any act by any person which subverts the authority of the pharmacist-in-charge by impeding the management of the prescription department or the practice of pharmacy in the compliance with federal and state drug or pharmacy laws and regulations shall be deemed a violation of this section. Any such circumvention may result in charges being filed against the pharmacy permit.
   - B. Any act by any person in the conduct of the activities of the facility which is a violation of the rules and regulations of the Board of Pharmacy.
   - C. Fraud or intentional misrepresentation in securing the issuance or renewal of a permit.
   - D. Failure to comply with any lawful order of the Board.
   - E. Engaging in or aiding and abetting an individual to engage in the practice of pharmacy without a license.
   - F. Unprofessional conduct by any person in any activity relating to the operation of a pharmacy. Unprofessional conduct includes, but is not limited to:
     - (1) Condoning or assisting in the dispensing, promotion or distribution of drugs which do not meet the standards required by law.
     - (2) Committing any fraudulent act including, but not limited to:
       - (a) Destruction or alteration of any records such as purchase invoices, prescriptions, patient profiles, third-party vouchers and receipts required to be kept;
       - (b) The placement of any advertisement which is false or misleading;
       - (c) Filing a claim or assisting in the filing of a claim for reimbursement for drugs or professional services which were not provided.
     - (3) Dispensing, selling, bartering, receiving, or maintaining drugs which the pharmacist knows, or should know, have been stolen or diverted from the purpose for which they were distributed by a legitimate source.
     - (4) Selling or bartering a prescription drug sample.
     - (5) Receiving, dispensing, or maintaining a prescription drug sample unless the pharmacy is owned by a charitable organization, and is not operated for profit and has prior approval in writing by the Board. Institutional pharmacies may receive, dispense and maintain prescription drug samples that are provided by a practitioner and intended solely for administration to his/her patient confined to the institution provided no charges made to the patient by the institution for the sample.
     - (6) No pharmacist shall have possession of a prescription drug sample unless such sample is for treatment of a diagnosed personal medical condition.
     - (7) Willfully and knowingly failing to maintain complete and accurate records of

all prescription drugs received, disposed of or dispensed at a permitted facility.

(8) Divulging or revealing confidential patient information to any person other than as authorized by Board regulations.

G. Termination of employees suspected of theft of pharmaceuticals or merchandise without contacting the Board prior to termination.

H. Failure to report directly to the Board, losses or suspected losses of controlled substances or prescription drugs.

I. Jeopardizing, compromising, interfering or failing to cooperate with any lawful investigation conducted by the Board or any state or federal regulatory or law enforcement agency.

J. 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.

K. 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.

L. Failure to furnish to the Board, its investigators, or representatives any information legally requested by the Board within the required time frame.

M. Failing to pay costs assessed in a disciplinary hearing as directed by a lawful order of the Board.

N. Knowingly failing to submit Prescription Monitoring Information to the Prescription Monitoring Program within the time interval prescribed.

O. The unlawful disclosure of information from the Prescription Monitoring Program. Using information obtained from the Prescription Monitoring Program for unlawful or unethical purposes.

P. Retaliation against pharmacy employees for providing information to the Board.

Q. Hindering, interfering with, or restriction the reporting of suspected unlawful activity to the appropriate authorities.

R. Failure by any representative of a permitted facility to acknowledge completion of an inspection by placement of a signature on the inspection form.

ARTICLE X DRUG PRODUCT SELECTION

When a generic equivalent drug product is available, drug product selection by the pharmacist shall be made in accordance with this regulation.

For purposes of this ARTICLE, "drug product selection" shall mean the dispensing of a generic equivalent drug product in lieu of the brand name drug product ordered by the prescriber.

1. Each prescription written in this state shall contain two signature lines, either of which, when signed by the prescriber, shall validate the prescription and, depending upon which line the prescriber's signature appears, will indicate the prescriber's approval or denial of drug product selection by the pharmacist. The two line provision of the prescription and the prescriber's approval or denial of drug product selection shall be as follows:
   A. There shall be a signature line in the lower right-hand corner of the prescription form beneath which shall be imprinted the words "Substitution Permitted".
   B. There shall be a signature line in the lower left-hand corner of the prescription form beneath which shall be imprinted the words "Dispense as Written".

      If the prescriber utilizes a prescription form which does not contain the two signature lines, the prescriber must write in his own handwriting the words "Dispense as Written", otherwise the pharmacist may select a generic equivalent drug product.

      On electronically transmitted prescriptions, the prescriber must specify if the brand name drug must be dispensed.

   The requirements of this paragraph shall not apply to the dispensing of medication for Medicaid recipients. Pharmacists must comply with current Division of Medicaid guidelines regarding the dispensing of medications for Medicaid recipients.

2. When drug product selection is made under the provisions of this ARTICLE, the purchaser shall be informed of the drug product selection.

3. If a generic equivalent drug product is available, a pharmacist may select and dispense a generic equivalent drug product when the following three conditions are present:
   A. The purchaser requests the selection of a generic equivalent drug product;
   B. The prescriber has not prohibited drug product selection;
   C. Drug product selection will result in a lower cost to the purchaser.

4. Unless the prescriber indicates that the name of the drug product shall not appear on the label of the dispensed medication container, the pharmacist, having made product selection of a drug, shall place on the label of the finished dispensed container one of the following:
   A. The proprietary name of the generic product dispensed; or
   B. The generic name of the product dispensed and the name of the manufacturer or repackager, either written in full or appropriately abbreviated.

5. In addition to the labeling described in A. and B. of the previous paragraph, the pharmacist may add a statement such as "Substituted for _____" and add to this statement the brand name of the prescribed drug product.

6. The pharmacist shall not select a generic equivalent drug product when the purchaser requests the drug product to be dispensed as ordered by the prescriber. Pharmacists must abide by Medicaid regulations concerning Brand and generic drugs for Medicaid Recipients.

7. A pharmacist may not select a drug product to substitute for a prescribed brand name drug unless such drug product is the generic equivalent of the prescribed brand name and has been manufactured under the Federal Food and Drug Administration's current Good Manufacturing Practice Regulations and meets U.S.P. or other official specifications, and has an approved New Drug Application (NDA) or Abbreviated New Drug Application (ANDA), or Antibiotic Form 5 or 6 Application approved by the U. S. Food and Drug Administration under the provisions of Section 505 and 507 of the Federal Food, Drug and Cosmetic Act (21 U.S.C.A., 301, et seq.).

   Generic equivalent drugs shall include, but not be limited to, any drug listed by the Food and Drug Administration list of therapeutically equivalent drugs as contained in APPROVED DRUG PRODUCTS.

   For purposes of this ARTICLE, the term "if available" means if the generic drug product is available in the pharmacy at the time the prescription is presented.

   Nothing in this ARTICLE shall be construed to prohibit the implementation of a drug formulary system within an institution.

ARTICLE XI STOCK CONTAINER LABELING, OUTDATED MERCHANDISE, SANITATION, DISPENSING AND STORAGE REQUIREMENTS

1. All drug products which are stored or maintained in a facility permitted by the Board of Pharmacy shall remain in the manufacturer's or repackager's original container. The label of any container in which drugs are maintained must bear the drug name, strength, the manufacturer's control lot number and the expiration date.

   Drugs which are precounted and prepackaged, or placed in automatic tablet counting machines, for purposes of dispensing shall be identifiable as to expiration date and manufacturer's control lot number. The containers in which drug products are maintained shall not be labeled in any false or misleading manner. The labeling requirements of this ARTICLE are in addition to, and not in lieu of, other labeling requirements of the laws of the state of Mississippi, rules and regulations of the Mississippi Board of Pharmacy, and laws of the United States, or federal regulations.

2. A pharmacist shall not dispense out-of-date drugs and a pharmacy shall not maintain out-of-date drugs intermixed with the stock of current drugs. Out-of-date drugs shall be promptly removed from current stock and stored separately until proper disposal shall be made.

   The Board or its representative may seize, embargo, quarantine, or place under seal, any prescription drug, controlled substance, or medical device which may constitute an imminent danger to the public health and safety.

   At the conclusion of proceedings, the Board may asses fees associated with the storage of, destruction, or disposal of any seized, embargoed, or quarantined prescription drugs, controlled substances or medical devices

   The Board may place under seal all Drugs or Devices that are owned by or in the possession, custody, or control of a licensee at the time his or her license is Suspended or Revoked or at the time the Board refuses to renew his or her license. Drugs or devices so sealed shall not be disposed of until appeal rights have expired or disposal is ordered by the Board.

3. Pharmacies shall be maintained in an orderly and sanitary fashion.

4. A pharmacist or a pharmacy shall not accept the return for subsequent resale or exchange any drug after such drug has been taken from the premises where sold, distributed or dispensed and from the control of the pharmacist.

5. All drug products shall be maintained, stored and dispensed in such a manner as to maintain the integrity of the product.

6. Unless requested not to do so, all medication dispensed in a liquid or solid dosage form shall be dispensed in child resistant packaging.

7. Disasters, accidents or emergencies which may affect the strength, purity or labeling of drugs shall be immediately reported to the Board.

8. Customized Patient Medication Packages:
In lieu of dispensing two or more prescribed drug products in separate containers, a pharmacist may, with the consent of the patient, a patient's care giver, or the prescriber, provide a customized package, known as a patient med-pak provided:
   A. Patient med-paks shall bear a label (or labels) including all information required on a traditional prescription label. In addition, the med-pak shall bear an identification number unique to that patient med-pak, the date of preparation and the beyond-use date of the patient med-pak (not to exceed ninety(90) days from the date of preparation). If the patient med-pak allows for the removal or separation of individual cells within the med-pak, each cell shall bear a label identifying each of the drug products contained.
   B. It is the responsibility of the dispensing pharmacist when preparing the med-pak, to take into account any applicable compendia requirements or guidelines and the physical and chemical compatibility of the dosage forms placed within each cell of the med-pak, as well as any therapeutic incompatibilities that may attend the simultaneous administration of the drugs.
   C. In addition to individual prescription filing requirements, a record of each patient med-pak shall be made and filed. Each record shall contain at a minimum:
      (1) The name and address of the patient;
      (2) The unique identification number of the patient med-pak;
      (3) The prescription number for each drug product contained;
      (4) The drug name, manufacturer or distributor name and lot number of each drug product contained;
      (5) Any special labeling instructions;
      (6) Information identifying or describing the design, characteristics, or specifications of the med-pak, sufficient to allow subsequent preparation of the med-pak for the patient;
      (7) The date of preparation of the patient med-pak and the beyond-use date that was assigned; and
      (8) The name or initials of the pharmacist responsible for preparing the med-pak.

ARTICLE XII PRESCRIPTION/ORDER REQUIRED AND REFILL AUTHORIZATION/RECORD KEEPING

1. Prescription drugs shall be dispensed only pursuant to a valid prescription or a valid order. A pharmacist shall not dispense a prescription which the pharmacist knows or should know is not a valid prescription. A Prescription Drug Order, to be effective, must be issued for a legitimate medical purpose by a Practitioner acting within the course of legitimate professional practice.

   A Prescription Drug Order shall contain the following information at a minimum:
   (1) full name and street address (if required by law) of the patient;
   (2) name, address, and, if required by law or rules of the Board, DEA registration number of the prescribing Practitioner;
   (3) date of issuance;
   (4) name, strength, dosage form, and quantity of Drug prescribed;
   (5) directions for use;
   (6) refills authorized, if any;
   (7) if a written Prescription Drug Order, prescribing Practitioner's signature;
   (8) if an electronically transmitted Prescription Drug Order, prescribing Practitioner's electronic or digital signature;

2. A Prescription Drug Order must be communicated directly to a Pharmacist, or when recorded, in such a way that the Pharmacist may review the Prescription Drug Order as transmitted. A prescription/order may be accepted by a pharmacist in written form, orally, or electronically unless the order is for a Schedule II controlled substance (refer to ARTICLE XIX) of these regulations. If transmitted orally or electronically, the prescription drug order shall be filed and maintained on paper of permanent quality by the pharmacist in accordance with ARTICLE XIII of these regulations. Electronically transmitted prescription drug orders shall meet the following requirements:
   A. Electronically transmitted prescription drug orders shall meet the following criteria:
      (1) be transmitted only to the pharmacy of the patients choice; and
      (2) be transmitted by an authorized Practitioner or his or her designated agent provided that the identity of the transmitting agent is included in the order; and
   B. Prescription drug orders transmitted by facsimile or computer shall include:
      (1) The complete name, address, and DEA Registration Number of the practitioner if required;
      (2) The transmitters telephone number or any other suitable means to contact the transmitter for verbal and/or written confirmation;
      (3) The name, address, and age of the patient;
      (4) The time and date of the transmission; and,
      (5) The full name of the person transmitting the order; and
      (6) The identity of the Pharmacy intended to receive the transmission, as well as any other information required by federal or state law.
   C. An electronically transmitted drug order which meets the requirements of this

ARTICLE shall be deemed the original order.

D. The pharmacist shall exercise professional judgment regarding the accuracy, validity, and authenticity of the transmitted prescription drug order consistent with federal or state laws and rules and regulations adopted pursuant to the same.

E. An electronically transmitted prescription/order from a prescriber to a pharmacist shall be considered a highly confidential transaction and the said transmission shall not be compromised by interventions, control, change, altering or manipulation by any other person or parties in any manner whatsoever.

F. Any pharmacist that transmits, receives or maintains any prescription or prescription refill either orally, in writing or electronically shall ensure the security, integrity and confidentiality of the prescription and any information contained therein.

G. To maintain the confidentiality of patient and prescriber records, a computer system shall have security and system safeguards designed to prevent and detect unauthorized access, modification or manipulation of patient records. Once the drug has been dispensed, any alterations in prescription drug order data shall be documented to include the identification of the individual responsible for the alteration.

H. Electronic transmission of prescription orders for controlled substances must comply with DEA Regulations.

3. Pharmacists must maintain complete and accurate records of all prescription drugs received, disposed of, or dispensed at a permitted facility.

4. A prescription may not be refilled without authorization. When refills are dispensed pursuant to authorization contained on the original prescription or when no refills are authorized on the original prescription but refills are subsequently authorized by the prescriber, the refill authorization shall be recorded on the original prescription document and the record of any refill made shall be maintained on the back of the original prescription document or on some other uniformly maintained record and the dispensing pharmacist shall record the date of the refill, the quantity of the drug dispensed and his/her initials; however, an original prescription for a controlled substance which contains no refill information may not be authorized to be refilled more than five (5) times or after six (6) months from the date of issuance. Authorization for any additional refill of a controlled substance prescription in excess of those refills originally authorized or after six (6) months from the date of issuance of the prescription shall be treated as a new prescription.

5. When filling a prescription or refilling a prescription which may be refilled, the pharmacist shall exercise professional judgment in the matter. No prescription shall be filled or refilled with greater frequency than the approximate interval of time that the dosage regimen ordered by the prescriber would indicate, unless extenuating circumstances are documented which would justify a shorter interval of time before the filling or refilling of the prescription.

6. The pharmacist who fills or refills a prescription shall record the date of the dispensing and indicate his/her identity as the dispensing pharmacist on the prescription document or some other appropriate and uniformly maintained record. If this record is maintained on the original prescription document, the original dispensing and any refills must be recorded on the back of the prescription.

7. A prescription shall not be refilled after twelve (12) months from the date of issuance.

8. A prescription becomes invalid thirty (30) days after the prescriber/patient relationship is terminated. When the patient is no longer able to seek personal consultation or treatment from the prescriber the prescriber/patient relationship is terminated.

9. A written prescription document prepared by the prescriber or his agent must bear an original signature of the prescriber, facsimile stamps are not acceptable. When an oral prescription or the oral authorization for the refilling of a prescription is received which is transmitted by someone other than the prescriber, the name of the transmitter and the date of the transmission must be recorded on the original prescription document by the pharmacist receiving the transmission.

10. A pharmacist licensed by the Mississippi Board of Pharmacy may dispense a one-time emergency dispensing of a prescription of up to a seventy-two (72) hour supply of a prescribed medication in the event the pharmacist is unable to contact the prescriber to obtain refill authorization, provided that;
    A. The prescription is not for a controlled substance;
    B. In the pharmacist's professional judgment, the interruption of therapy might reasonably produce undesirable health consequences or may cause physical or mental discomfort;
    C. The dispensing pharmacist notifies the prescriber or his agent of the emergency dispensing within seven (7) working days after the one-time emergency dispensing;
    D. The pharmacist properly records the dispensing as a separate non-refillable prescription. Said document shall be filed as is required of all other prescription records. This document shall be serially numbered and contain all information required of other prescriptions. In addition it shall contain the number of the prescription from which it was refilled; and
    E. The pharmacist shall record on the new document the circumstances which warrant this emergency dispensing.

    This emergency dispensing shall be done only in the permitted facility which contains the non-refillable prescription.

ARTICLE XIII PRESCRIPTIONS TO BE FILED

1. All prescriptions shall be filed in one of the following ways:
   A. Three separate files may be maintained; a file for Schedule II prescriptions dispensed; a file for Schedule III, IV and V prescriptions dispensed; and a file for all other prescriptions dispensed.
   B. Two files may be maintained; a file for all Schedule II prescriptions dispensed and another file for all other prescriptions dispensed, including those in Schedule III, IV and V.

2. A hard copy of original prescriptions, whether records are maintained manually or in a data processing system, shall be assigned a serial number and maintained by the pharmacy in numerical and chronological order. All prescriptions shall be maintained for at least six (6) years from the date of original dispensing.

3. If a pharmacy utilizes a data processing system for record keeping, all computer generated labels should be affixed to the prescription document in such a manner as not to obscure information on the face of the document.

ARTICLE XIV LABELING REQUIREMENTS

1. Before a dispensed drug for an outpatient is released from the dispensing area, it shall bear a label containing the name and address of the pharmacy, a prescription number, the name of the prescriber, the name of the patient, directions for taking the medication, the date of the filling or refilling of the prescription, the initials or identifying code of the dispensing pharmacist and any other information which is necessary or required.

2. The pharmacist who fills a prescription shall indicate his or her identity as the dispensing pharmacist on the label of the dispensed medication. Identification may be made by placing initials on the label of the dispensed medication. The label shall be affixed to the outside of the container of the dispensed medication by means of adhesive or tape or any other means which will assure that the label remains attached to the container.

ARTICLE XV ISSUANCE AND RECEIPT OF PRESCRIPTION COPIES

1. Prescriptions for drugs which are controlled substances as defined by the Mississippi Uniform Controlled Substances Law shall not be transferred. Prescriptions for non-controlled drugs may be transferred orally by telephone or electronically by pharmacists between pharmacies for the purpose of refill dispensing provided:
   A. That in pharmacies with a manual record keeping system the transferor pharmacist invalidates the prescription on file as of the date the copy is given by writing "Void" on its face; and records on the back of the invalidated prescription order that a copy has been issued, to whom, the date of issuance of such copy and the initials of the pharmacist issuing the transferred prescription.
   B. That in pharmacies with a computerized record keeping system the transferor pharmacist records in the system a cancellation of the prescription. This cancellation shall record that a copy of the prescription has been issued, to whom it was issued, the date of issuance of such copy and the initials of the pharmacist issuing the copy. This required information must be immediately retrievable (via CRT display or hard copy printout).
   C. The transferee pharmacist, upon receiving such prescription directly from another pharmacist, records the following and enters into the data processing system:
      (1) The name and address of the pharmacy from which the prescription was transferred and the original prescription number used by that pharmacy;
      (2) The name of the transferor pharmacist;
      (3) All information constituting a prescription order, including the following:
         (a)Patient's name.
         (b)Date of issuance of original prescription and date of original dispensing.
         (c)Original number of refills authorized on original prescription;
         (d)Number of valid refills remaining.
   D. The receiving pharmacist informs the patient that the original prescription has been canceled at the pharmacy from which it was obtained.

2. Computerized systems must satisfy all requirements of paragraph 1. of this ARTICLE.

3. Presentation of a written prescription copy or label from dispensed medication shall be for information purposes only and has no legal status as a valid prescription order. The recipient pharmacist of such copy or prescription label shall contact the prescribing practitioner for authorization to dispense the prescription, which is the same as obtaining an original prescription order, or transfer the prescription in accordance with the provisions of paragraph 1. of this ARTICLE.

ARTICLE XVI REGISTRATION WITH THE BOARD TO HANDLE CONTROLLED SUBSTANCES

1. Every facility/business under the jurisdiction of the Board of Pharmacy where controlled substances are manufactured, distributed, sold, bought, dispensed, or maintained within this state or that distributes or dispenses any controlled substance into this state from an out-of-state location, or who proposes to engage in the manufacture, distribution or dispensing of any controlled substance within this state or the distribution or dispensing of any controlled substance into this state from an out-of-state location, except those persons exempted by law, shall obtain and maintain a Controlled Substance Registration issued to that facility/business by the Mississippi Board of Pharmacy. Every pharmacist or pharmacy extern/intern who dispenses controlled substances in the usual and lawful course of business within this state shall obtain and maintain a controlled substance registration issued by the Board.

2. These registrations shall be renewed annually and shall be valid for the following period of time: If the registration is issued before or during the first half of the registration period, the registration shall expire at the end of the registration period and if the registration is issued in the second half of the registration period, the registration shall expire at the end of the succeeding registration period. A fee of fifty dollars ($50.00) shall be charged for this registration or the renewal of this registration.

   Extern or intern registrations shall be valid for a period of four (4) years or until six months after graduation.

   Any controlled substance renewal application postmarked after December 31 of the renewal period shall be returned and a fifty dollar ($50.00) late renewal fee shall be assessed prior to renewal.

3. Application for issuance or renewal of a Controlled Substance Registration shall be made on a form prescribed by the Board which specifies the activities to be engaged in and the Schedules of Controlled Substances which may be manufactured, distributed, dispensed, sold, purchased, or maintained by the registrant. A registrant shall not manufacture, distribute, dispense, sell, purchase, or maintain a controlled substance not authorized by his registration.

4. The application for the issuance or the renewal of a Controlled Substance Registration for a pharmacy shall be signed by a pharmacist. If the services of a pharmacist are not required at the facility the application for the Controlled Substance Registration shall be signed by the individual who will be responsible for conducting the business activities of the facility.

5. Persons who handle controlled substances or who maintain controlled substances on the premises must be registered. This includes all facilities which do not maintain dispensing areas containing controlled substance drugs, but which do maintain controlled substances

for inpatient use at nursing stations or in emergency medication supplies.

6. The administrator or the consultant pharmacist of the nursing home may sign the application for a controlled substance registration issued by the Board. The nursing home shall have policies and procedures for the security, control, and disposal of any controlled substances at the facility. A pharmacist shall not serve as a consultant to a nursing home which does not have a Controlled Substance Registration with the Mississippi Board of Pharmacy.

7. When requested by an agent of the Board of Pharmacy, evidence of a Controlled Substance Registration issued by the Board, all controlled substances, all areas where controlled substances are maintained, and all required controlled substance records shall be made available for inspection.

ARTICLE XVII REQUIREMENTS OF CONTROLLED SUBSTANCES PRESCRIPTIONS

Before they may be dispensed by a pharmacist, all prescriptions for controlled substances shall be dated and signed on the day when issued and shall bear the name and address of the patient and the name, address and registration number of the prescriber. The prescription must bear an original signature of the prescriber, facsimile stamps are not acceptable. The signature requirement does not apply to Schedule III, IV or V prescriptions which are transmitted orally or electronically by the prescriber or his authorized agent to the pharmacist. Electronically transmitted orders for controlled substances must comply with DEA regulations.

ARTICLE XVIII DISPENSING OF CONTROLLED SUBSTANCES

1. A controlled substance in Schedule II, III, IV or V, which is a prescription drug, shall not be dispensed without a valid prescription or a valid order.

2. A controlled substance in Schedule V which is not a prescription drug may be dispensed pursuant to a valid prescription or it may be dispensed without a prescription provided that:
   A. The substance is dispensed by a pharmacist. The pharmacist shall be responsible for the record keeping of the dispensing.
   B. No more than 120cc (4 ounces) is dispensed to the same purchaser or for the same person in any given 72 hour period.
   C. No more than two (2) sales in any seven (7) day period and no more than three (3) sales in any thirty (30) day period of any non-prescription controlled substance is made to the same purchaser or made for the same person. Additional sales shall be by prescription only.
   D. The substance is dispensed bearing a label which contains the expiration date and any other information needed by the consumer for the safe and effective use of the substance.
   E. The substance is dispensed for a bona fide medical need and the purchaser furnishes information to the pharmacist which establishes a bona fide need for the controlled substance.
   F. The purchaser furnishes to the pharmacist identification which shall include the purchaser's name, address and date of birth. The purchaser must be at least eighteen (18) years of age.
   G. A bound record book is maintained which contains the name and address of the purchaser, name and quantity of controlled substances sold, date of each sale, initials of the dispensing pharmacist, and the legible signature of the purchaser. This book shall be maintained for a period of two (2) years form the date of the last transaction and must be made available for inspection and copying by agents of the Mississippi Board of Pharmacy.
3. A prescription for an anorectic and/or central nervous system stimulant classified in Schedule II which is written for the treatment of obesity is not a valid prescription.

ARTICLE XIX DISPENSING OF SCHEDULE II CONTROLLED SUBSTANCES

1. A pharmacist may dispense a Schedule II controlled substance only pursuant to a valid written prescription/order signed by the prescribing practitioner except as described as follows:
   A. When a Schedule II controlled substance is needed in a situation in which a written prescription cannot reasonably be obtained it may be considered an emergency situation and a pharmacist may dispense a Schedule II controlled substance pursuant to an oral prescription of a practitioner. A Schedule II controlled substance prescription given in this manner shall be reduced to writing by the pharmacist and shall be for a quantity of medication sufficient for the emergency period, not to exceed 48 hours. Within seven (7) days of the receipt of an oral prescription for a Schedule II controlled substance, the pharmacist shall obtain a prescription signed by the prescribing practitioner for the medication dispensed. This prescription shall be attached to the copy of the prescription prepared by the pharmacist pursuant to the prescriber's oral order.
   B. A prescription for a controlled substance in Schedule II may be transmitted from the prescribing practitioner to a pharmacy via facsimile provided the original signed prescription is presented to the pharmacist for review prior to dispensing of the controlled substance. The original prescription shall be maintained in accordance with ARTICLE XIII of these regulations.
   C. A prescription/order written for a Schedule II controlled substance to be compounded for direct administration to the patient by parenteral, intravenous, subcutaneous or intraspinal infusion may be transmitted directly from the prescribing practitioner to a pharmacy by facsimile. The facsimile serves as the original prescription for purposes of this ARTICLE and it shall be maintained in accordance with ARTICLE XIII of these regulations.
   D. A prescription/order written for a Schedule II controlled substance for a resident of a long term care facility or for a patient in a hospice certified by Medicare under Title XVIII or licensed by the state may be transmitted directly from the prescribing practitioner to a pharmacy by facsimile. The facsimile serves as the original prescription for purposes of this ARTICLE and should be filed in accordance with ARTICLE XIII of these regulations.

2. A prescription for a controlled substance in Schedule II may not be refilled. In accordance with current DEA requirements, a pharmacist may dispense up to a ninety (90) day supply of a Schedule II controlled substance pursuant to multiple prescriptions signed on the date of issuance which indicate a “DO NOT FILL BEFORE” date listed elsewhere on the prescription document. Schedule II controlled substances shall not be dispensed for a patient with greater frequency than the approximate interval of time that the dosage regimen ordered by the prescriber would indicate unless circumstances are documented which would justify a shorter interval of time. Schedule II prescriptions shall not be filled after six (6) months from the date of issuance.

ARTICLE XX PARTIAL FILLING OF SCHEDULE II PRESCRIPTIONS

1. Partial filling of Schedule II prescriptions shall be as follows:
   A. The partial filling of a Schedule II controlled substance prescription is permissible if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription. He/she may supply a part of the quantity prescribed provided he/she makes a notation of the quantity supplied on the face of the written prescription (or written record of the emergency oral prescription). The remaining quantity may be supplied within 72 hours of the first dispensing; however, if the remaining quantity is not or cannot be supplied within the 72 hour period, the pharmacist must notify the prescribing practitioner. No further quantity may be supplied on the partially filled prescription beyond the 72 hours unless:
      (1) The prescription is for a nursing home patient or for a patient who is receiving long term therapy as a home health patient or a patient who is terminally ill as defined by the Federal Health Care Financing Administration (42 CFR 418.3). If such a prescription is partially filled, the pharmacist must record on the back of the prescription or on another appropriate uniformly maintained record the date of each partial filling, the quantity dispensed, the remaining quantity authorized to be dispensed, the remaining quantity authorized to be dispensed and the identity of the dispensing pharmacist. All partial filling of the prescription must be completed within 50 days of the date of issuance of the prescription.

ARTICLE XXI SCHEDULE III, IV AND V PRESCRIPTIONS NOT TO BE FILLED AFTER SIX MONTHS

A prescription for a controlled substance in Schedules III, IV and V may not be filled or refilled after six (6) months from the date of issuance of the prescription or be refilled more than five (5) times for the full amount prescribed.

ARTICLE XXII RECORDING REFILLS AND PARTIAL FILLING OF SCHEDULE III, IV, AND V PRESCRIPTIONS

1. Partial filling or refilling of prescriptions for controlled substances in Schedules III, IV, or V is permitted provided the pharmacist filling or refilling the prescription sets forth the quantity dispensed, the date and his/her initials or identifying code as the dispensing pharmacist on the prescription or on some other uniformly maintained record system. If a manual record is maintained on the original prescription document, the original dispensing and any refill must be recorded on the back of the prescription. The total quantity of dosage units authorized on the prescription may be dispensed by partial filling or refilling of the prescription provided the dispensing is done within six (6) months of the date the prescription was issued.

2. If the pharmacist records the refill without specifying the quantity of drug dispensed, he/she shall be deemed to have dispensed a refill for the full face amount of the prescription.

ARTICLE XXIII RECORD KEEPING ON CONTROLLED SUBSTANCES

1. Every facility permitted by the Board of Pharmacy shall keep complete and accurate records of the acquisition and disposition of all controlled substances. Records of acquisition must be maintained for a period of two (2) years. Records of disposition must be maintained for a period of six (6) years.

   These records shall include:
   A. A current dated and signed inventory of all controlled substances on hand on the inventory date;
   B. Complete and accurate records of receipt of all controlled substances;
   C. Complete and accurate records of ~~disposal~~ disposition of all controlled substances.

   These records shall be kept in such a manner that an audit will show the beginning inventory and record of acquisition of controlled substances to balance with the controlled substances on hand and the record of disposition of controlled substances.

2. Unless authorized by the Federal Drug Enforcement Administration to maintain records of controlled substances at a location other than the location permitted by the Mississippi Board of Pharmacy, these records shall be maintained at the permitted location. All records pertaining to controlled substances shall be made available for inspection and copying by agents of the Mississippi Board of Pharmacy. A pharmacy may use a data processing system or a manual record keeping system for the storage and retrieval of all prescription order information. A hard copy of original prescriptions, whether records are maintained manually or in a data processing system, shall be maintained and filed in accordance with the provisions of ARTICLE XIII of these regulations.

   All records of controlled substances in Schedule II shall be maintained separately from all other records of the registrant. All records of controlled substances in Schedule III, IV and V, whether maintained manually or in a data processing system, shall be maintained separately or in such a manner that they are readily retrievable from the other business records. Invoices for controlled substances shall be dated and initialed by the person receiving the order.

3. If a pharmacy utilizes a data processing system it must provide immediate retrieval of original prescription order information for those prescription orders which are currently authorized for refilling and of the refill history for the past six months for controlled substances prescription orders. The data processing system must have the capability of producing a hard copy printout of this information. The data processing system must also have the capability of producing a hard copy printout of all dispensing information required to be kept by the pharmacy, including an audit trail for any specified strength and dosage form of any controlled substance either by brand name or generic name or both for any time period in the prior two (2) years. The audit trail specified by this Article must be produced on verbal or written request of any Compliance Agent of the Board. Failure to

produce and provide this audit trail within twenty-four (24), constitutes prima facie evidence of failure to keep and maintain records as defined in paragraph 1., C., of this ARTICLE.

The records of controlled substances in Schedules II, III, IV and V, which are maintained in a data processing system shall be maintained as follows:

A. The following information pertaining to the initial dispensing of the prescription shall be entered into the data processing system:
   (1) Prescription number;
   (2) Date of initial dispensing;
   (3) Name and address of patient;
   (4) Prescribing practitioner's name and DEA registration number;
   (5) The name, strength, dosage form and quantity of the controlled substance ordered and dispensed;
   (6) Total number of refills authorized; and,
   (7) The initials or identifying code of the dispensing pharmacist.

B. Additionally, the following information pertaining to the refilling of the prescription shall be maintained by the data processing system:
   (1) The date of the refill dispensing, and the total number of refills dispensed to date, or the total number of refills remaining for that prescription order; and,
   (2) The initials or identifying code of the dispensing pharmacist;

4. A permanent record of the dispensing of all controlled substances shall be made and maintained as follows:

A. Each time a prescription is filled or refilled a record of such filling shall be entered into the data processing system. A hard-copy printout containing only the dispensing record of original filling of Schedule II controlled substance prescriptions and the record of original filling and the refill history for Schedule III, IV or V controlled substance prescription orders shall be produced daily, or at regular intervals, not to exceed seven (7) days. These hard-copy printouts shall be filed chronologically and stored in an orderly manner in a separate file at the pharmacy and be maintained for a two-year period from the date of the last dispensing. The hard-copy printout shall include:
   (1) Prescription number;
   (2) Name of the patient;
   (3) The prescribing practitioner's name;
   (4) The name, strength, dosage form and quantity of the controlled substance dispensed;
   (5) Number of refills originally authorized;
   (6) Date of initial dispensing if an original prescription or if a refill, the date of refilling and the date of initial dispensing, and the total number of refills dispensed to date or the total number of refills remaining for that prescription order; and,
   (7) The initials or identifying code of the dispensing pharmacist.

(8) Hard copy printouts shall only contain information regarding prescriptions dispensed.

B. The hard copy printout containing the information required by this paragraph shall be signed and dated by the pharmacist who produces the printout. The signature of the pharmacist on the printout shall serve as verification by that pharmacist that the information contained on the printout is complete.

5. A record of all controlled substance dispensing information shall be transmitted to the Prescription Monitoring Program on a time basis determined by the program by all pharmacies dispensing controlled substances (greater than a 48 hours supply) on an out-patient basis for the purpose of tracking the dispensing of Schedules II, III, IV and V controlled substances by the Prescription Monitoring Program. Dispensers will be required to collect and transmit the following information:

(A) The recipient's name.
(B) The recipient's or the recipient representative's identification number.
(C) The recipient's date of birth.
(D) The national drug code (NDC) number of the controlled substance dispensed.
(E) The date the controlled substance is dispensed.
(F) The quantity of the controlled substance dispensed.
(G) The number of days supply dispensed.
(H) The dispenser's NABP or NCPDP registration number.
(I) The prescriber's U. S. DEA registration number.
(J) The method of payment of the prescription purchase.

6. Records of controlled substances in Schedule III, IV and V which are maintained manually shall be maintained as follows:

A. A pharmacist, who fills or refills a prescription for a controlled substance in Schedule III, IV or V, must enter on that prescription or some other uniformly maintained record system, his/her initials or identifying code as the dispensing pharmacist, the date the prescription was filled or refilled and the quantity of the controlled substance dispensed if different from the original quantity prescribed.

If this record is maintained on the original prescription document, the original dispensing must be recorded on the face of the prescription and any refills must be recorded on the back of the prescription.

B. Original prescription documents shall be filed and maintained in accordance with the provisions of ARTICLE XII of these regulations.

For purposes of this ARTICLE, "hard-copy" means a physical document that is readable without the use of a special device (i.e., cathode ray tube, microfiche reader, etc.).

ARTICLE XXIV SECURITY OF CONTROLLED SUBSTANCES

1. In all places where controlled substances are maintained, they shall be maintained in a manner to deter loss by theft or burglary. When a person who has a controlled substances registration with the Board of Pharmacy has a loss of controlled substances, the Board may issue an order to that person to appear before the Board to present a plan to the Board designed to prevent further loss of controlled substances or he/she may be ordered by the Board to implement any other reasonable measure to improve security on controlled substances deemed necessary by the Board to prevent further loss of controlled substances.

2. Storage of controlled substances shall be as follows:
   A. In a pharmacy, storage of controlled substances in any schedule may be made in a securely locked, substantially constructed container or area; or they may be dispersed throughout the stock of non-controlled substances in such a manner as to obstruct the theft or diversion of the controlled substances; or they may be stored by a combination of these methods.

      When an institutional pharmacy dispensing area is closed and the permitted location is accessible to non-pharmacist personnel all controlled substances must be stored in a securely locked, substantially constructed container or area. Only the pharmacist or person authorized by the pharmacist shall have access to this storage area. Authorization for access to this controlled substances storage area may be granted by the pharmacist in accordance with written policy of the pharmacy department of the facility.
   B. In a nursing home or other institution which does not maintain a pharmacy, a securely locked, substantially constructed area shall be provided for storage of all controlled substances. Controlled substances left by the death or discharge of a patient shall be maintained in the drug storage area of the institution until proper disposition of such controlled substances is made. Controlled substances thus maintained in the drug storage area shall be kept in a locked cabinet, drawer, or other suitable locked container and only the consultant pharmacist or a person designated by the consultant pharmacist shall have access to the container.
   C. Expired medication must be secured.

ARTICLE XXV INVENTORY REQUIREMENTS FOR CONTROLLED SUBSTANCES

1. If a facility has a loss of controlled substances, a complete inventory of all remaining controlled substances shall be made within forty-eight (48) hours of discovery of the loss of controlled substances. This inventory shall be dated and signed by the pharmacist conducting the inventory. Any loss or suspected loss of controlled substances shall be reported directly to the Mississippi Board of Pharmacy immediately upon discovery and a written report made to the Mississippi Board of Pharmacy within fifteen (15) days; this written report shall include a copy of the inventory required by this ARTICLE.

2. When a facility has a change in ownership or a change in pharmacist-in-charge, or is permanently closed, a complete inventory shall be made of all controlled substances at the time of the change. A copy of this inventory shall be kept with other records of controlled substances in the facility and a copy shall be sent to the office of the Board of Pharmacy. When a facility is permanently closed, the pharmacist-in-charge shall notify the Board in writing within fifteen (15) days by what means and as to whom controlled substances were transferred or disposed of.

3. Every facility permitted by the Mississippi Board of Pharmacy shall take an annual inventory of all controlled substances on hand on or about May 1 but no later than May 15 ~~on May 1~~, or at such a time as to be in compliance with the inventory requirements of the Federal Drug Enforcement Administration. This inventory shall be maintained with the other controlled substance records of the facility.

ARTICLE XXVI DISPOSAL OF CONTROLLED SUBSTANCES

1. Any registrant of the Board authorized to possess controlled substances in the course of their professional practice or the course of their business may dispose of any expired, excess or unwanted controlled substances by contacting and utilizing the services of a reverse distributor as defined by the Federal Drug Enforcement Administration. Any such reverse distributor must hold a valid Certificate of Registration Number issued by the Federal Drug Enforcement Administration and the Mississippi Board of Pharmacy. All records of the disposal of controlled substances shall be maintained for a period of two (2) years.

2. An institution permitted or registered by the Mississippi Board of Pharmacy in which controlled substances are administered to patients, may make on-premises destruction of controlled substances provided:
   A. The controlled substance is the remainder of a prepackaged single dosage unit or unit of use.
   B. At least part of the unit dose or unit of use was administered.
   C. The destruction is recorded showing:
      (1) The name of the drug;
      (2) The amount of the drug which was administered and the amount of the drug which was destroyed;
      (3) The time and the date of destruction;
      (4) The name of the patient;
      (5) The room number of the patient;
      (6) The name of the person administering the drug;
      (7) The signature of the person (pharmacist or nurse) making the destruction;
      (8) The signature of a second person who witnessed the destruction.
   D. The record of the destruction is maintained by the facility.
   E. A single dosage unit or any unit of use of a controlled substance which (1) is broken, (2) becomes contaminated, (3) or for any reason cannot be used, must be returned to the control of the pharmacy for proper disposal. When it is not possible to return a broken or contaminated or unwanted dosage unit or unit of use to the pharmacy, documentation of the loss may be substituted. Broken or contaminated single dosage units or units of use returned to the pharmacy for destruction may be destroyed on premise provided the destruction is documented.

3. If for any reason a registrant is unable to dispose of excess or undesired stock of controlled substances under other provisions of this ARTICLE, the registrant may contact the Board of Pharmacy and the disposal shall be made as follows:

   An agent of the Pharmacy Board shall obtain an inventory of the controlled substances to be disposed of and make two (2) copies of this inventory. The first copy of this inventory shall be retained by the Pharmacy Board; the second copy shall be given to the registrant. After complying with this inventory requirement, the agent of the Pharmacy Board shall

take possession of the controlled substances. The controlled substances thus taken by the Pharmacy Board Agent shall be placed in a sealed container and labeled with the date and the name and address of the registrant and stored by the Board of Pharmacy until such time as they are disposed.

4. Except as provided for in this ARTICLE, no controlled substance may be destroyed or disposed of by a registrant without written permission of the Regional Director of the Federal Drug Enforcement Administration.

ARTICLE XXVII NUCLEAR/RADIOLOGIC PHARMACY

In addition to all other applicable sections of the Mississippi Code of 1972, ARTICLE XXVII of the Mississippi Board of Pharmacy Regulation pertains specifically to nuclear pharmacy and radiopharmaceuticals.

1. DEFINITIONS

   A. Authentication of product history means, but is not limited to, identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical;
   B. A nuclear pharmacy is a pharmacy providing the services of storing, compounding, dispensing, labeling or distributing radiopharmaceuticals;
   C. Practice of Nuclear Pharmacy means a patient-orient service that embodies the scientific knowledge and professional judgment required to improve and promote health through the assurance of the safe and efficacious use of radiopharmaceuticals and other related drugs.
   D. A qualified licensed professional means an individual (such as a physician, nurse, or technologist) who possesses a current state license if applicable, and who has sufficient training and experience to safely handle radiopharmaceuticals as defined by the Mississippi State Department of Health, Division of Radiological Health;
   E. A qualified nuclear pharmacist means a currently licensed pharmacist in the state of Mississippi who is certified by the Mississippi State Department of Health, Division of Radiological Health, or who meets the following standards:
      (1) Minimum standards of training for "authorized user status" of radioactive materials as defined by Mississippi State Department of Health, Division of Radiological Health;
      (2) Completed a minimum of two hundred (200) contact hours of instruction in nuclear pharmacy and the safe handling and the use of radioactive materials from a program approved by the Mississippi Board of Pharmacy, and United States Nuclear Regulatory Commission or Agreement State Agency, with emphasis in the following areas:
         (a)Radiation Physics and Instrumentation;
         (b)Radiation Protection;
         (c)Mathematics of Radioactivity;
         (d)Radiation Biology;
         (e)Radiopharmaceutical Chemistry.
      (3) Attain a minimum of five hundred (500) hours of clinical nuclear pharmacy training under the supervision of a qualified nuclear pharmacist.
   F. Nuclear pharmacy technician means a person who works under the supervision of a qualified nuclear pharmacist and who is currently registered with the Mississippi Board of Pharmacy. The duties and responsibilities of these personnel must be consistent with their training and experience.

G. Radiopharmaceutical is any substance defined as a drug in Section 201(g) (1) of the Federal Food, Drug and Cosmetic Act which also contains unstable nuclei which undergo spontaneous disintegration with the emission of nuclear radiation. Radiopharmaceuticals also include any non-radioactive reagent kit or radionuclide generator which is intended to be used in the preparation of radiopharmaceutical doses.

H. Radiopharmaceutical Service means, but shall not be limited to the procurement, storage, handling, compounding, quality control testing, dispensing, delivery, recordkeeping, and disposal of radiopharmaceutical and other drugs as well as quality control procedure, radiological health activities, any consulting activities associated with the use of radiopharmaceuticals, health physics and any other activities required for provision of pharmaceutical care.

I. Radiopharmaceutical Compounding means the preparation, mixing assembling, packaging, or labeling of a reagent kit or biological substance with radioactivity.

J. Radiopharmaceutical quality control means, but is not limited to, the performance of appropriate chemical, biological and physical tests on potential and prepared radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans or animals.
Assurance that variances in the processes are clearly identified, assessed and improved upon if necessary is required for adequate quality control. All quality control procedures must be a set of planned, defined and systematic activities to provide adequate confidence that the product optimally fulfils professional expectations and requirements.

K. The restricted area of a Nuclear Pharmacy is an area with limited access for the purpose of protecting individuals against the undue risks from exposure to radiation and radioactive materials. Generally, the restricted area(s) consists of the compounding/dispensing area, radioactive material storage area and radioactive dose return or breakdown area.

2. NUCLEAR PHARMACY STANDARDS AND EQUIPMENT

Written procedures and policy showing proof of adequate space and equipment for all operations involving radioactive material must be submitted to the Mississippi Board of Pharmacy along with a certified copy of the RADIOACTIVE MATERIAL LICENSE issued by the Mississippi State Department of Health, Division of Radiological Health, before a permit to operate as a Nuclear Pharmacy is issued.
Compliance with applicable radiation protection regulations of the Mississippi State Department of Health, Division of Radiological Health, is further required. Violation of rules and regulations established by the Mississippi State Department of Health, Division of Radiological Health, that directly affects public health and safety, shall serve as prima facie evidence of violation of this ARTICLE.

The restricted area of a nuclear pharmacy shall have at least the following supplies and equipment:

C. Radiation detection and measuring instruments capable of accurately measuring quantities of radioactivity and radiation; and
D. Refrigerator, microscope and a hemacytometer; and
C. Radiochemical fume hood and filter system with suitable air sampling equipment if storing or dispensing volatile substances; and
D. Laminar air flow hood and appropriate supplies to ensure sterile practices for parental solutions; and
E. Syringes, vials, filters and other necessary supplies needed to compound and dispense any oral or sterile parenteral drug product; and
F. Adequate shielding for syringes vials drawing stations and returned dose storage area: and
G Materials needed for decontamination; and
H. All supplies needed to perform quality control ~~assurance~~ testing; and
I. Appropriate shielding for the transportation of D. O. T. approved outer transport containers; and
J. Required labels and other supplies for proper shipment of radioactive material.

A pharmacy exclusively handling radiopharmaceuticals may be exempt from the general requirements of conventional pharmacies as regards to equipment and inventory.

3. OPERATION OF A NUCLEAR PHARMACY

A. Nuclear Pharmacy License. A license to operate a pharmacy providing radiopharmaceutical services shall only be issued to a qualified nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radioactive drugs shall be under the direct supervision of a qualified nuclear pharmacist. A qualified nuclear pharmacist shall be responsible for all operations of the pharmacy.
B. Nuclear pharmacies shall have adequate space and equipment, commensurate with the scope of services required and provided.
C. The nuclear pharmacy restricted area shall be secured from unobserved entry and/or unauthorized personnel.
D. Nuclear pharmacies shall maintain complete and accurate records of acquisition, inventory, and disposition of all radioactive drugs and other radioactive materials, in accordance with guidelines established by the Mississippi State Department of Health, Division of Radiological Health.
E. All pharmacies handling radiopharmaceuticals shall provide a radioactive storage and product decay area in accordance with guidelines established by the Mississippi State Department of Health, Division of Radiological Health.
F. Radiopharmaceuticals are to be dispensed only upon receipt of a prescription drug order, from a licensed practitioner or his agent. Validation that he is authorized to possess, use or administer radiopharmaceuticals is required.
H. Nuclear pharmacies shall, in addition to this ARTICLE XXVII and the Mississippi State Department of Health, Division of Radiological Health's applicable regulations, comply with any applicable requirements of other governing agencies regarding its

daily operations and the disposal of any biohazardous medical waste.

4. DISPENSING OF RADIOPHARMACEUTICALS

Radiopharmaceuticals shall be dispensed/transferred only to a licensed practitioner authorized by the Nuclear Regulatory Commission and/or the Mississippi State Department of Health, Division of Radiological Health to possess, use and administer such drug. A radiopharmaceutical shall be dispensed for medical use only upon receipt of a prescription or medication order from such authorized practitioner. Otherwise, a radiopharmaceutical may be transferred to a person who is authorized by federal or state law to possess and use such drug for non-medical applications. All prescriptions/orders shall be readily retrievable if requested by any governing agency.

A nuclear pharmacy, upon receiving an oral prescription order for a radiopharmaceutical, shall have the prescription order reduced to writing or recorded in a data processing system, which the written or electronic record shall contain at least the following:

A. The name of the institution and prescriber or if applicable the prescriber's agent;
B. The date of dispensing and the calibration time of the radiopharmaceutical;
C. The name of the procedure;
D. The name of the radiopharmaceutical;
E. The activity of the dose or quantity of the radiopharmaceutical;
F. The serial number assigned to the order for the radiopharmaceutical;
G. Any specific instructions; and
H. The initials of the pharmacist who dispensed the order.

Whenever an order is for a therapeutic or blood-product radiopharmaceutical, the patient's name must be obtained and recorded prior to dispensing.

The immediate outer container transportation shield of a radiopharmaceutical to be dispensed shall be labeled with:

A. The name and address of the pharmacy and prescriber;
B. Activity dispensed, expiration date and time, calibration time, serial number and date of dispensing;
C. The standard radiation symbol and the words "Caution Radioactive Material";
D. The name of the procedure and the radiopharmaceutical, including pharmacy oot number associated with dose;
E. If a liquid, the volume, if a gas, the number of ampules or vials and if a solid, the number of items or weight;
F. Molybdenum 99 content to USP limits (<0.15 mCi Mo-99 per 1.0 mCi Tc 99m at time of administration or expiration); and
G. The name of the patient or the words "per physician order" in the absence of a patients name.

When the prescription is for a therapeutic or blood product radiopharmaceutical, the

patient's name shall appear on the label. The requirements of this subsection shall be met when the name of the patient is readily retrievable from the physician upon demand.

The immediate inner container label of a radiopharmaceutical to be dispensed shall be labeled with:

A. Identity of the radiopharmaceutical and the serial number;
B. The standard radiation symbol and the words "Caution Radioactive Material";
C. The chemical form; and
D. The name of the procedure and date dispensed.

For a radiopharmaceutical intended for a specific patient, the immediate inner container shall be labeled with:

A. The standard radiation symbol and the words, "Caution - Radioactive Material";
B. The prescription number and name of patient;
C. Identity and activity or quantity, of the radiopharmaceutical.

When a radiopharmaceutical is dispensed under the authority of an Investigational New Drug Application (IND) the nuclear pharmacy records shall include an investigator's protocol for the preparation of the radiopharmaceutical, a copy of the Institutional Review Board approval form or letter, and a letter from the manufacturer (sponsor) indicating that the physician requesting the radiopharmaceutical is a qualified investigator.

ARTICLE XXVIII REGULATIONS FOR PREPARATION OF STERILE PHARMACEUTICALS

Every facility under the jurisdiction of the Mississippi Board of Pharmacy shall comply with the following regulations relating to the preparation, labeling, and distribution of sterile pharmaceuticals.

1. POLICY AND PROCEDURE MANUAL

Each facility shall develop and maintain a policy and procedure manual. This manual shall be reviewed and revised on an annual basis and be available for inspection by an agent of the Board of Pharmacy. This manual shall include policies and procedures as necessary for:

A. Clinical services;
B. Cytotoxics handling, storage, disposal and spills;
C. Disposal of unused supplies and medications;
D. Drug destruction and returns;
E. Drug dispensing;
F. Drug labeling-relabeling;
G. Drug storage;
H. Duties and qualifications for professional and non-professional staff;
I. Equipment;
J. Handling of infectious wastes;
K. Infusion devices and drug delivery systems;
L. Investigational drugs;
M. Obtaining a protocol on investigational drugs from the principal investigator;
N. Public safety;
O. Quality assurance procedures to include:
    (1) Recall procedures;
    (2) Storage and dating;
    (3) Educational procedures for professional staff, non-professional staff and patient;
    (4) Sterile procedures to include a record of the routine maintenance and report of hood certification;
    (5) Sterility testing.
P. Record keeping;
Q. Reference materials;
R. Sanitation;
S. Security;
T. Sterile product preparation procedures;
U. Transportation.

In facilities permitted by the Mississippi Board of Pharmacy the Policy and Procedure Manual shall, except in emergency situations, require that all sterile pharmaceuticals be prepared using the appropriate hood. Such hood shall be inspected and certified at least annually by a qualified technician.

2. PHYSICAL REQUIREMENTS

A. Space:
The facility shall have a designated area with entry restricted to designated personnel for preparing compounded sterile products. This area shall be designed to avoid unnecessary traffic and airflow disturbances from activity within the facility. This designated area shall be used only for the preparation of these specialty products. It shall be of sufficient size to accommodate a laminar airflow hood and to provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation, and security.

B. Equipment:
The facility shall have:
(1) Appropriate environmental control devices capable of maintaining at least Class 100 conditions in the work space where critical objects are exposed and critical activities are performed; furthermore, these devices are capable of maintaining Class 100 conditions during normal activity. Examples of appropriate devices include laminar airflow hoods and zonal laminar flow of HEPA - filtered air;
(2) Sink with hot and cold running water which is convenient to the compounding area for the purpose of hand scrubs prior to compounding;
(3) Appropriate disposal containers for used needles, syringes, etc., and if applicable for cytotoxic waste from the preparation of chemotherapy agents, and infectious wastes;
(4) When cytotoxic drug products are prepared, appropriate environmental control also includes appropriate biohazard cabinetry;
(5) Refrigerator/Freezer with a thermometer;
(6) Appropriate delivery container including temperature controlled container when needed;
(7) Infusion devices, if appropriate.

C. Supplies:
The facility shall maintain:
(1) Disposable needles, syringes, and other supplies needed for aseptic admixture;
(2) Disinfectant cleaning solutions;
(3) Hand washing agent with germicidal action;
(4) Disposable, lint free towels or wipes;
(5) Appropriate filters and filtration equipment;
(6) Disposable masks, caps, gown, and sterile disposable gloves if applicable.

D. Security:
The facility shall provide adequate security for all drugs and shall comply with requirements of other ARTICLES of these regulations relative to security on controlled substances.

E. Reference Library:
The facility shall have adequate reference materials related to the preparation, labeling, and distribution of sterile products. Some suggested sources include;

Handbook on Injectable Drugs (ASHP)
King's Guide to Parenteral Admixtures
USP/NF
American Hospital Formulary Service
Procedures for Handling Cytotoxic Drugs (ASHP)

The pharmacy shall have copies of applicable state and federal laws and OSHA requirements.

3. PERSONNEL

A. Pharmacist In Charge: Each facility shall be supervised by a pharmacist who is licensed to practice pharmacy in this state and who is knowledgeable in the specialized functions of preparing and dispensing compounded, sterile pharmaceuticals, including the principles of aseptic technique and quality assurance. This knowledge may be obtained through residency training programs, continuing education programs, or experience in an IV admixture facility. The pharmacist-in-charge shall be responsible for the purchasing, storage, compounding, repackaging, dispensing, and distribution of all drugs and pharmaceuticals. He/she shall also be responsible for the development and continuing review of all policies and procedures, training manuals, and the quality assurance programs, as well as participation in those aspects of the facility's patient care evaluation program relating to pharmaceutical material utilization and effectiveness. The pharmacist-in-charge may be assisted by additional pharmacists adequately trained in this area of practice.

B. Pharmacy Technicians: The pharmacist-in-charge may be assisted by pharmacy technicians. The duties and responsibilities of these personnel must be consistent with their training and experience.

C. Staffing: A pharmacist shall be accessible at all times at each facility to respond to patients and other health professionals questions and needs.

4. DRUG DISTRIBUTION AND CONTROL

A. Drug Orders: The pharmacist must receive a written, electronic or verbal order from an authorized prescriber before dispensing any compounded, sterile products.
If the drug order is for an inpatient in an institutional facility, a copy of the patient's

medication order may serve as an order for the preparation and dispensing of the sterile product. This and the record of administration as recorded on the medication administration record may be maintained as the permanent record in medical records at the facility. Sterile products prepared for inpatient administration shall be labeled, stored and delivered in accordance with written policy and procedure which comply with all requirements of The Joint Commission on Accreditation of Health Care Organizations or the Mississippi State Department of Health.

If the drug order is for an outpatient, the order must be in the form of a prescription document or a patient medication order sheet which contains, at a minimum, the following:

(1) Patient name;
(2) Patient address;
(3) Name of IV medication and strength and amount of additives;
(4) Directions for use;
(5) Date;
(6) Prescriber's name;
(7) Physician's address and Drug Enforcement Administration registration number, if applicable;
(8) Refill instructions.

B. Records required to be maintained: Prescriptions for sterile products shall be filed in accordance with the provisions of ARTICLE XII of these regulations. Patients medication order sheets used as authorization for the dispensing of drugs shall be filed in an easily retrievable manner.

Additionally, a facility which dispenses outpatient prescriptions for sterile products shall produce and maintain a patient profile or medication record system which is separate from the prescription file and/or file of patient medication order sheets. The patient profile or medication record system shall be maintained for a period of two (2) years from the date of the last dispensing. The patient profile or medication record system shall contain, at a minimum:

(1) Patient's name;
(2) Date of birth or age;
(3) Weight;
(4) Sex;
(5) Sterile products dispensed;
(6) Date dispensed;
(7) Drug content and quantity;
(8) Patient directions;
(9) Identifying number;
(10) Identification of dispensing pharmacist;
(11) Complete record of other drugs patient is receiving;
(12) Known drug sensitivities and allergies to drugs and foods;
(13) Primary diagnosis, chronic conditions.

It shall be the responsibility of the pharmacist-in-charge to ensure that the patient profile or medication record is monitored in accordance with provisions of ARTICLE VIII of these regulations.

C. Labeling: Each sterile pharmaceutical dispensed for an outpatient shall bear a label with the following information:
   (1) Name and address of the facility;
   (2) Date and identifying number;
   (3) Patient's name;
   (4) Name of medication and strength, and amount of additives;
   (5) Directions for use, including infusion rate;
   (6) Prescriber's name;
   (7) Date of compounding;
   (8) Expiration date and time;
   (9) Identity of pharmacist responsible for compounding and dispensing;
   (10) Storage requirements;
   (11) Auxiliary labels, where applicable.

D. Storage and Delivery: The pharmacist-in-charge shall be responsible for the proper storage in the pharmacy of all sterile pharmaceuticals after they are compounded. It shall be the responsibility of the pharmacist-in-charge to assure that all sterile pharmaceuticals dispensed as outpatient prescriptions are shipped or delivered to the patient in appropriate temperature controlled (as defined by USP Standards) delivery containers and stored appropriately in the patient's home. The pharmacist-in-charge shall also be responsible for security on controlled substance prescriptions until delivered to the patient's home.

E. Disposal of Infectious Wastes: The pharmacist-in-charge is responsible for assuring that there are written policies and procedures for safe collection and disposal of any medical or infectious waste resulting from the dispensing of sterile products. These policies and procedures shall extend to any location where sterile products are administered.

5. CYTOTOXIC MEDICATION

A. Additional Requirements: To insure the protection of personnel involved, the pharmacist-in-charge shall assure that the following requirements are met in facilities that prepare cytotoxic medications;
   (1) All cytotoxic medications should be compounded in a vertical flow, Class II, biological safety cabinet;
   (2) Disposal of cytotoxic waste shall comply with all applicable local, state and federal requirements;
   (3) Prepared doses of cytotoxic medications must be dispensed, labeled with proper precautions inside and outside, and shipped in a manner to minimize the risk of accidental rupture of the primary container.

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) 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 (2) 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 XXX INSTITUTIONAL/LONG TERM CARE FACILITIES (LTCF)

A. CONSULTING PHARMACISTS TO INSTITUTIONAL (LTC) FACILITIES

2. Unless specifically authorized by the Board to do so, no person shall serve as a consultant pharmacist or act or purport to act in this capacity to any institutional facility unless he/she possesses the following qualifications:
   A. Have and maintain a license to practice pharmacy within the State of Mississippi;
   B. Have attended within the last two years a training course of not less than eight (8) hours in institutional pharmacy services that has been approved by the Board of Pharmacy;
   C. In order to be approved by the Board of Pharmacy, the training course for a consultant pharmacist to an institutional facility shall provide instruction in the areas of clinical pharmacy services, drug distribution systems and state and federal pharmacy regulations governing the practice of institutional pharmacy.

2. For purposes of this ARTICLE a Consultant Pharmacist shall mean a Mississippi licensed pharmacist who is responsible for developing, coordinating and supervising pharmaceutical services on a regularly scheduled basis in an institutional facility as well as the following responsibilities.

   A. Reviewing policies and procedures regarding the distribution and storage of medications within the facility and as necessary making recommendations to the facility and provider pharmacist;
   B. Monitoring utilization and therapeutic response of medications prescribed for and administered to residents of the facility as well as providing consultation on matters related to medications;
   C. Serving as a resource for pharmacy related educational services within the facility;
   D. Communication and discussion with the provider pharmacist regarding areas of concern and resolution thereof;
   E. Serving on appropriate committees;
   F. Supervising and assisting in the disposal of all discontinued, expired or otherwise un-needed controlled substance medications;
   G. Reviewing records of the destruction of all medications and verification of the reasons for destruction;
   H. Ensuring that complete and accurate records of the acquisition and disposition of controlled substance medications which have been dispensed for residents of the institutional facility are maintained;
   I. Attending, within the last two (2) years, a consultant pharmacist seminar which has been approved by the Board;
   J. Maintain consultant pharmacist eligibility as described in Section 1.

3. A Long Term Care Facility which is permitted by the Board and where the services of a consultant pharmacist are required shall have the following responsibilities:

A. Policy Manual. The institution shall develop policies and procedures regarding pharmacy services which includes, but is not limited to proper labeling of patient medications and emergency drugs, security of patient medications and emergency drugs, administration and controlled substances record-keeping and accountability. This procedural manual shall be the responsibility of the institution and is to be promulgated with the concurrence of the consultant pharmacist, nursing home administrator and the directors of medical and nursing services.

E. Reference. Reference materials shall be located in the nursing stations(s) and contain current editions of appropriate reference materials as may be deemed necessary by the consultant pharmacist and the medical and nursing directors.

F. Reporting. The institution shall establish policies and procedures which assures that all medication errors and adverse drug reactions are reported immediately to the patient's physician and the consultant pharmacist and an entry made in the patient's record. These procedures should assure that corrective measures are implemented. The consultant pharmacist should be notified within twenty-four (24) hours of discovery of any discrepancy in counts or of a loss of any controlled substances. The consultant pharmacist should notify the Board immediately upon his/her notification with a plan to investigate the loss.

D. Emergency Medication Kits. The institution shall establish policies and procedures which assure that the institution is in compliance with ARTICLE XXXV INSTITUTIONAL EMERGENCY MEDICATION KIT PERMITS of these Pharmacy Practice Regulations.

G. Disposal of Patient Medication. The Long Term Care Facility, with the assistance of the consultant pharmacist shall establish policies and procedures which assures the proper disposal of any discontinued, expired, or otherwise unwanted patient medications. Policies and procedures should ensure that any medication, removed subject to destruction, does not have a current valid order for the medication on the patient's medication profile. Policies and Procedures for disposal of these medications should include as follows:

(1) All unwanted patient medications should remain in a secured location at the institution until proper disposal is made; and

(2) Documentation of any disposal of patient medications should include a paper trail from the time the medication was logged into the discontinued ~~patient~~ drug storage area until destruction is made. This paper trail shall include a log containing the patient name, medication and strength, and quantity to be destroyed as well as the initials of the person logging in the medication for destruction. This documentation should be stored at the institution and be readily retrievable for inspection by Board Agents for a period of two (2) years; and

(3) Discontinued and unwanted patient medications should be destroyed on a timely basis not to exceed ninety (90) days from the date that the medication was discontinued. Any such destruction should be performed by two licensed personnel and documented for their signatures.

4. A consultant pharmacist shall document communication of the findings of his/her reviews to the attending physician and director of nursing along with their response and maintain these records for a period of two (2) years. A copy of these reviews must be maintained at the facility and available for inspection.

B. UNIT DOSE DISPENSING SYSTEMS FOR (LTCF)

Definitions: For the purpose of this ARTICLE XXX, the following definitions apply:

A. "Provider pharmacist, means a pharmacist licensed to practice pharmacy by the Board who is responsible for supervising the accurate dispensing and proper delivery of medications to a (LTCF) located within this state. These services shall include, at a minimum, proper medication labeling, storage, transport, record keeping and prospective drug utilization review in compliance with all federal, state and local laws and regulations.

B. "Provider Pharmacy" means any pharmacy permitted by the Board where medications are dispensed to residents of a long term care facility located in this state.

C. "Single unit dose package" is a package, which contains one discrete pharmaceutical medication dosage form.

D. "Unit dose dispensing systems" are those drug medication distribution systems determined by the Board, which involve single unit, unit dose or unit of issue packaging in a manner which helps reduce or remove traditional drug stocks from patient care areas and enables the selection and distribution of medications to be provider pharmacy based and controlled. A unit dose dispensing system shall preserve the identity and the integrity of the medication until the time of administration.

E. "Unit dose package" is a package, which contains that particular dose of a medication ordered for the patient for one administration time. A unit dose package is not always a single unit dose package.

F, "Unit of issue package" is a medication package issued by a provider pharmacy, which provides multiple units/dosages of medications attached to each other but separated in a card or a specifically designed container;

1. Packaging for all non-sterile medications stored and dispensed in single unit dose, unit dose or unit of issue packages for use in (LTCF) other than hospitals shall:

A. Preserve and protect the identity and integrity of the drug medication from the point of packaging to the point of patient administration;

B. When packaged by the manufacturer or distributor, be in compliance with Federal Food and Drug Administration guidelines;

C. Shall be in containers clean and free of extraneous matter when the dosage unit(s) are placed into the package;

D. Utilize containers, which are classified according to USP Standard 671 as being Class A or Class B for oral solid dosage forms or is a tight container for liquid dosage forms.

2. Labeling for single unit dose or unit dose packaging shall comply with the following;

A. Single unit doses or unit doses packaged by the manufacturer or distributor shall be

properly labeled according to Federal Food and Drug Administration requirements;
B. Single unit doses or unit doses packaged by the provider pharmacy shall be properly labeled according to ARTICLE XXIX paragraph 7.;

3. Labeling for unit of issue packages shall contain the following information:
A. Name and room or bed number of patient, name of prescribing practitioner, name and strength of drug, directions for use, and the name and address of the provider pharmacy when a unit of issue package is utilized for patients in an (LTCF) setting.

4. If a pharmacist selects a generically equivalent drug product for a brand name drug product prescribed by a practitioner, labeling must comply with ARTICLE X of the Pharmacy Practice Regulations of the Board.

5. Expiration dating for non-sterile medications dispensed and packaged into single unit doses, unit doses and unit of issue packages shall meet the following conditions:
A. Not exceed the manufacturer's original expiration date;
B. Have an expiration date assigned based on the unit dose container manufacturer's recommendations;
C. May exceed Ninety (90) days from date of repackaging provided that the container is classified according to USP Standard 671 as being Class A or Class B for oral solid dose forms or is a tight container for liquid dosage forms, the container is light resistant when the manufacturer has labeled the drug product "sensitive to light" and the expiration date is not greater than twelve (12) months;
D. Drugs or dosage forms having known stability problems are assigned an expiration date of less than ninety (90) days or are not repackaged as determined by policies developed by the provider pharmacy.
The shortest time span of any of the listed conditions shall be the expiration date assigned to the medication.

C. RETURN OF MEDICATIONS FROM AN INSTITUTIONAL FACILITY TO THE PROVIDER PHARMACY

1. Medication that has been dispensed for a patient residing in an institutional facility may be returned to the provider pharmacy provided that the medication has an approved reason for return as follows:
A. Medication was discontinued prior to delivery;
B. Patient expired prior to medication being delivered;
C. Patient in the hospital (discharge status) at time of delivery;
D. Medication dosage changed prior to delivery;
E. Patient has excessive medications remaining from previous cycle (requires written explanation by the Director of Nurses).
F. Medication is considered to be dispensed when it leaves the dispensing pharmacy and is delivered to the institutional facility.
Any such medication subject to return must be intact with no doses removed from

blister package (unit dose). Medications, which have been dispensed and placed in bulk packages and accepted by a responsible person at the LTCF, shall not be returned to the dispensing pharmacy for any reason. All medication subject to return, must be returned to the provider pharmacy by pharmacy personnel within five (5) days. No controlled substances may be returned.

The provider pharmacy must implement approved procedures, which ensure that any returned medication has been properly stored, has not been tampered with, and the integrity of the medication remains intact. Paper trails tracking these procedures must be maintained by the provider pharmacy for a period of two (2) years and be readily retrievable for inspection by agents of the Board.

ARTICLE XXXI COMPOUNDING GUIDELINES

GOOD COMPOUNDING GUIDELINES

The following Good Compounding Practices (GCP's) are meant to apply only to the compounding of medication by pharmacies licensed in the State of Mississippi. Applicable portions of the Pharmacy Practice Act formed the basis for the development of these rules and regulations.

1. GENERAL PROVISIONS

   A. These rules and regulations are considered to be the minimum current good compounding practices for the preparation of medications by pharmacists licensed in the State of Mississippi for dispensing and/or administration to humans or animals.
   B. Pharmacists engaged in the compounding of drugs shall operate in conformance with applicable law regulating the practice of pharmacy.
   C. Based on the existence of a pharmacist/patient/practitioner relationship and the presentation of a valid prescription, or in anticipation of prescription medication orders based on routine, regularly observed prescribing patterns, pharmacists may compound, for an individual patient, medications that are not commercially available in the marketplace. No compounding and manufacturing shall take place at the same location.
   D. Pharmacists shall receive, store, or use drug substances for compounding that meet official compendia requirements, or of a chemical grade in one of the following categories: Chemically Pure (CP), Analytical Reagent (AR), American Chemical Society (ACS), or, if other than this, drug substances which in the professional judgment of the pharmacist are obtained from acceptable and reliable alternatives.
   E. Pharmacists may compound drugs prior to receiving a valid prescription based on a history of receiving valid prescriptions that have been generated solely within an established pharmacist/patient/practitioner relationship, and provided that they maintain the prescriptions on file for all such products compounded at the pharmacy as required by the Mississippi Board of Pharmacy.
   F. Pharmacists shall not offer compounded medications to other pharmacies for resale; however, practitioners may obtain compounded medications to administer to patients. Compounding pharmacies/pharmacists may advertise or otherwise promote the fact that they provide prescription compounding services (e.g., chemicals, devices and information when requested); however, they shall not solicit business by promoting to compound specific drug products (e.g., like a manufacturer).
   G. The compounding of inordinate amounts of drugs in anticipation of receiving prescriptions without any historical basis or the distribution of inordinate amounts of compounded products without a patient/practitioner/pharmacist relationship is considered manufacturing.

2. ORGANIZATION AND PERSONNEL

A. Pharmacists engaging in compounding shall maintain proficiency through current awareness and training. Continuing education should include training in the art and science of compounding and the rules and regulations of compounding.
B. Pharmacy technicians may assist the pharmacist in compounding. It is the responsibility of the pharmacist to train and monitor the pharmacy technician. Their duties shall be consistent with the training received.
C. Personnel engaged in the compounding of medications shall wear clean clothing appropriate to the operation being performed. Protective apparel, such as coats/jackets, aprons, gowns, hand or arm coverings, or masks shall be worn as necessary to protect personnel from chemical exposure and medication or chemical contamination.
D. Only personnel authorized by the responsible pharmacist shall be in the immediate vicinity of the drug compounding operation. Any person shown at any time (either by medical examination or pharmacist determination) to have an apparent illness or open lesions that may adversely affect the safety or quality of a drug product being compounded shall be excluded from direct contact with components, medication containers, closures, in-process materials, and medication products until the condition is corrected or determined by competent medical personnel not to jeopardize the safety or quality of the product(s) being compounded. All personnel who assist the pharmacist in compounding procedures shall be instructed to report to the pharmacist any health conditions that may have an adverse effect on drug products.

3. DRUG COMPOUNDING FACILITIES

A. Pharmacies engaging in compounding shall have a specifically designated and adequate area (space) for the orderly compounding of prescriptions that is maintained in a good state of repair and for the placement of materials and equipment. Sterile compounding shall be performed in a separate area in compliance with ARTICLE XXVIII of these regulations.
B. Bulk medications and other chemicals or materials used in the compounding of medications must be stored in adequately labeled containers in a clean, dry, and temperature controlled area or, if required, under proper refrigeration.
C. Adequate lighting and ventilation shall be provided in all drug compounding areas. Potable water shall be supplied under continuous positive pressure in a plumbing system free of defects that could contribute contamination to any compounded drug product. Adequate washing facilities, easily accessible to the compounding area(s) of the pharmacy, shall be provided. These facilities shall include, but not be limited to, hot and cold water, soap or detergent, and air-driers or single use towels.
D. The area(s) used for the compounding of drugs shall be maintained in a clean and sanitary condition. It shall be free of infestation by insects, rodents, and other vermin. Trash shall be held and disposed of in a timely and sanitary manner. Sewage and other refuse in and from the pharmacy and immediate medication compounding

area(s) shall be disposed of in a safe and sanitary manner.

E. If sterile products are being compounded, the pharmacist shall follow ARTICLE XXVIII, (2), (3), (4) AND (5), of these regulations as applicable to the procedure.

F. If radiopharmaceuticals are being compounded, the pharmacist shall follow ARTICLE XXVII and ARTICLE XXVIII (2), (3), (4) and (5) of these regulations as applicable to the procedure.

G. If drug products with special precautions for contamination, such as penicillin, are involved in a compounding procedure, appropriate measures, including either the dedication of equipment or meticulous cleaning of contaminated equipment prior to its use for the preparation of other drugs, must be utilized in order to prevent cross-contamination.

4. EQUIPMENT

A. Equipment and utensils used for compounding shall be of appropriate design and appropriate capacity and stored in a manner to protect from contamination. In addition, all equipment and utensils shall be cleaned and sanitized prior to use to prevent contamination that would alter the safety or quality of the drug product beyond that desired. The pharmacist is responsible for determining suitability for use. In the case of sterile compounding, follow ARTICLE XXVIII of these regulations as applicable to equipment and utensils.

B. Automatic, mechanical, electronic or other equipment used in compounding shall be routinely inspected, calibrated (if necessary) or checked to ensure proper performance.

C. It shall be the responsibility of the pharmacist to ensure that the proper container is selected to dispense the finished compounded prescription, whether sterile or non-sterile.

5. MEDICATION COMPOUNDING CONTROLS

A. The pharmacist shall ensure that there are formulas and logs maintained either electronically or manually. Formulas shall be comprehensive to include: ingredients, amounts, methodology and equipment, if needed and special information regarding sterile compounding.

B. The pharmacist shall ensure that components used in compounding are accurately weighed, measured, or subdivided as appropriate at each stage of the compounding procedure to conform to the formula being prepared. Any chemical transferred to a container from the original container shall be labeled with the same information as on the original container and the date of transfer placed on the label.

C. The pharmacist shall establish and conduct procedures so as to monitor the output of compounded prescriptions, i.e., capsule weight variation, adequacy of mixing, clarity and pH of solutions and where appropriate procedures to prevent microbial contamination of medications purported to be sterile (refer to ARTICLE XXVIII of these regulations as applicable).

6. LABELING CONTROL OF EXCESS PRODUCTS

A. The pharmacist shall label any excess compounded product so as to reference it to the formula used and the assigned control number and estimated beyond use date based on the pharmacist's professional judgment, appropriate testing or published data. The product shall be stored appropriately.
B. At the completion of compounding the prescription, the pharmacist shall examine the prescription for correct labeling.

7. RECORDS AND REPORTS

The pharmacist shall keep records of all compounded products for a period of time as other prescriptions as required by the Mississippi Board of Pharmacy. Such records shall be readily available for authorized inspection during the retention period at the establishment. These records shall be subject to duplication by photocopying or other means of reproduction as part of any such inspection.

ARTICLE XXXII WHOLESALER/MANUFACTURER PERMITS

1. Every facility/business that shall engage in the wholesale distribution of prescription drugs, to include without limitation, manufacturing in this state, distribution into this state, or selling or offering to sell in this state, or distribution from or within this state, shall register biennially with the Mississippi Board of Pharmacy by applying for a permit on a form supplied by the Board and accompanied by a fee not to exceed five-hundred dollars ($500.00). Every facility/business that shall engage in distribution of prescription drugs into this state to an affiliated or related company under common ownership and control of a corporate entity must register biennially with the Board. The Board shall determine criteria and classification of permits as required.

   Permits issued to any wholesaler/manufacturer facility become null and void sixty (60) days from the date of issuance if inspection reveals a lack of legitimate business activity.

2. To obtain a permit or renew a permit for a drug wholesaler the applicant shall:
   A. Submit a written application on a form prescribed by the Board which provides at a minimum the following information:
      (1) Name of the business, including all trade or business names used by the business;
      (2) Address of the business;
      (3) Ownership of the business;
      (4) Information identifying the type of activities to be conducted by the business;
      (5) Signature, telephone number and complete address of the individual applying for the permit;
      (6) Complete name, telephone number and address of all officers and directors and the name of the state of incorporation, if a corporation;
      (7) Complete name, telephone number and address of all partners if a partnership;
      (8) If a sole proprietorship, the complete name, telephone number and address of the sole proprietor and the business entity.
   B. Submit the required fees as follows:
      A fee not to exceed five hundred ($500.00) dollars for the registration period January 1, 2012 through December 31, 2013, and each biennial registration period thereafter.
   C. Wholesaler permits shall not be issued for the same location occupied by a Pharmacy Permit after January 1, 2012.

3. Each Mississippi wholesaler that maintains or distributes controlled substances shall apply for and obtain a controlled substance registration issued by the Board. To obtain a controlled substance registration or renew a controlled substance registration the applicant shall:
   A. Submit a written application on a form prescribed by the Board;
   B. Submit the required fees as follows:
      Fifty dollars ($50.00) for the registration period January 1, 2012, through December

31, 2012, and each annual registration period thereafter.

Any loss or suspected loss of controlled substances shall be reported directly to the Mississippi Board of Pharmacy immediately upon discovery and a written report made to the Mississippi Board of Pharmacy within fifteen (15) days.

4. The Mississippi Board of Pharmacy will consider the following factors in determining eligibility for issuing or renewing a permit for persons who engage in the wholesale distribution of prescription drugs:

   A. Any convictions of the applicant under any federal, state, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;
   B. Any felony convictions of the applicant under federal, state or local laws;
   C. The applicant's past experience in the distribution of prescription drugs, including controlled substances;
   D. The furnishing by the applicant of false or fraudulent information in any application made in connection with drug distribution;
   E. Suspension or revocation by federal, state, or local government of any permit currently or previously held by the applicant for the distribution of any drugs, including controlled substances;
   F. Compliance with requirements under previously granted permits or registrations, if any;
   G. Compliance with the requirements to maintain and/or make available to state and federal regulatory authorities those records required to be maintained by wholesale drug distributors; and
   H. Any other factors or qualifications the Mississippi Board of Pharmacy considers relevant to and consistent with the public health and safety.

   The Mississippi Board of Pharmacy reserves the right to deny a permit or a registration to an applicant if it determines that the granting of such a permit or registration would not be in the public interest.

5. Every business issued a wholesaler permit by the Board shall renew this permit biennially. Newly issued permits which do not coincide with the registration period shall be valid for the following periods of time: If the permit is issued in the first half of the registration period, it must be renewed at the end of the registration period, or if the permit is issued in the second half of the registration period, it must be renewed at the end of the next registration period.

6. The operations manager shall sign the application for a wholesaler permit or the renewal of a wholesaler permit and shall be the operations manager for that facility and shall be responsible for all activities in the permitted facility which are subject to regulation by the Board. Once issued, a permit cannot be amended, transferred or assigned to another person. Failure to comply with this paragraph invalidates the permit.

7. If the employment of a permit holder is terminated, or if for any other reason he/she wished to be relieved of the responsibilities of the permit holder, he/she must return the wholesaler permit to the Mississippi Board of Pharmacy with written notice that he/she is no longer the permit holder for that facility. When a permit is thus returned, application for a new permit for that facility must be made to the Mississippi Board of Pharmacy within ten (10) days.

8. If a permitted facility is permanently closed or has a change of ownership, the permit holder for that facility shall give notice to the Board of the effective date of closure or change in ownership at least ten (10) days prior to the closure or change in ownership.

9. If a permitted facility has a change in name or location, a new permit must be obtained. Application for this new permit must be made to the Board at least ten (10) days prior to the change.

10. All drug wholesalers permitted by the Mississippi Board of Pharmacy shall comply with the following:
    A. Storage Conditions;
        (1) Each facility where legend drugs or devices are repackaged, wholesaled, manufactured, distributed, stored, held, sold or offered for sale, shall provide storage areas that assure proper lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions. All legend drugs or chemicals shall be stored at appropriate temperatures and under appropriate condition per label requirements or official compendium requirements to assure that the identity, strength, quality, and purity of the products are not affected. If no storage requirements are established for a prescription drug they may be stored at controlled room temperature as defined in an official compendium such as the United States Pharmacopeia/Nation Formulary. Appropriate manual, electro-mechanical or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of prescription drugs. This data shall be recorded daily.
        (2) A separate storage section shall be provided for legend drugs that are deteriorated, outdated, misbranded, or otherwise adulterated.
    B. Facilities:
        (1) All buildings in which legend drugs or devices are wholesaled, repackaged, manufactured, distributed, stored, held, sold, or offered for sale, shall be of suitable size, construction, and location to facilitate cleaning, maintenance, and proper operations. Buildings shall meet all applicable federal, state, and local standards and shall be maintained in a clean and orderly condition and be free from infestation by insects, rodents, birds or vermin of any kind.
        (2) Each facility shall have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that

are in immediate or sealed outer or sealed secondary container that have been opened.

(3) A facility may not be located in a residence.

C. Security:

(1) All facilities shall be equipped with an electronic security system that will provide suitable protection against theft and diversion.
When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(2) Drug wholesalers shall ensure that access from outside their premises is reduced to a minimum and be well controlled. This includes, but is not limited to, the installation of adequate lighting at the outside perimeter of the premises. Entry into areas where prescription drugs are stored or held shall be limited to authorized personnel.

(3) Drug wholesalers shall maintain written internal security policies which provide protection against theft and diversion by personnel. These policies shall provide protection against computer theft and crimes.

D. Recordkeeping:

(1) Drug wholesalers shall establish and maintain inventories and other records of all transactions regarding the receipt, distribution and disposition of legend drugs including the name and principle address of the seller or transferor and the address of the location from which the drugs were shipped. These records shall be maintained for a period of two (2) years following disposition of the drugs. These records shall be made available for inspection and copying by agents of the Mississippi Board of Pharmacy or other authorized federal, state, or local law enforcement agency officials. These records shall contain source of supply (items received, quantity, and date) and distribution (items distributed, quantity, and date).

(2) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by an agent of the Mississippi Board of Pharmacy or other authorized federal, state, or local law enforcement agency officials.

(3) Upon request by the Board, drug wholesalers that are permitted by the Board and who distribute prescription drugs to persons within this state shall make available to the Board the following:

(a)A complete Mississippi customer roster;

(b)Distribution and sales records for any period during the past two (2) years listing all sales or distribution of prescription drugs to authorized persons located in this state upon request by the Board. This request shall be made in writing and may be signed by a compliance agent of

the Board. This data shall be supplied to the Board within five (5) working days and shall consist of the following:

(i) Identity of the purchaser;
(ii) Identity of the distributor;
(iii) Drug name, strength, dosage form and quantity distributed;
(iv) The invoice number;
(v) Date distributed;
(vi) All records of returns or credits.

E. Written Policies and Procedures:

Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories.

(1) There shall be written policies and procedures to assure that the drug wholesaler prepares for, protects against, and handles crisis situations that affect the security or operation of the facility. Such crises may include fires, floods, or other natural disasters, and situations of local, state, or national emergency.

(2) A procedure whereby the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate.

(3) There shall be written policies and procedures to assure that any outdated stock, or any stock with an expiration date that does not allow sufficient time for repacking or resale shall be segregated from other stock and shall be prepared for return to the manufacturer or otherwise appropriately destroyed. This procedure shall provide for written documentation of the disposition of out dated prescription drugs. This documentation shall be maintained for a period of two (2) years after the disposition of the outdated drugs.

(4) There shall be written policies and procedures by which the drug wholesaler exercises control over the shipping and receiving of all stock within the operation.

(a) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(b) Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

(c) The recordkeeping requirements in paragraph (D.) of this section shall be followed for all incoming and outgoing prescription drugs.

F. Returned, Damaged and Outdated Prescription Drugs:

(1) Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier.

(2) Any prescription drug whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.

(3) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed, or returned to the supplier, unless examination, testing or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, the wholesale drug distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton or labeling, as a result of storage or shipping.

(4) The recordkeeping requirements in paragraph D. of this section shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs. Written policies and procedures shall be maintained at the permitted facility to implement the above requirements.

G. Handling Recalls:

(1) A wholesale operation must maintain and follow written policies and procedures for handling recalls and withdrawals of products. Such a policy should cover all recalls and withdrawals of drug products due to:

(a) Any voluntary action on the part of the manufacturer;

(b) The direction of the Food and Drug Administration, or any other federal, state, or local government agency; and

(c) Replacement of existing merchandise with an improved product or new package design.

H. Compliance with Local, State and Federal Law; Inspections, Violations and Penalties:

(1) Each drug wholesaler shall comply with all applicable local, state and federal laws and regulations.

(2) The Board may conduct inspections upon all premises purporting or appearing to be used by persons permitted under this ARTICLE. The Board in its discretion may accept a satisfactory inspection by the Federal Food and Drug Administration or a state agency of another state which the Board determines to be comparable to that made by the Federal Food and Drug Administration or the Board. The permit holder of the permitted location, upon request, shall furnish to the Board a copy of any and all reports of inspections conducted by the Federal Food an Drug Administration or the state agency of another state.

(3) Mississippi wholesalers that deal in controlled substances shall obtain a controlled substance registration from the MS Board of Pharmacy and a

registration number from the Federal Drug Enforcement Administration and shall comply with all applicable state and federal DEA regulations.

(4) The Board or it's representatives may enter to inspect, during reasonable hours, a wholesaler's facility which has obtained or applied for a permit with the Board relative to the following:
(a)Drug storage and security;
(b)Equipment;
(c)Sanitary conditions;
(d)Records, reports or other documents required to be kept by the Board.

(5) The Board shall have the authority to suspend, revoke or restrict any permit or registration issued under this ARTICLE upon conviction of violations of this ARTICLE or other federal, state or local drug laws or regulations.

(6) The Board may impose monetary penalties of not less than ($100.00) and not more than ($25,000.00) for each violation.

(7) Before any wholesaler permit may be suspended, restricted or revoked or monetary penalties imposed, a wholesaler shall have the right to prior notice and a hearing pursuant to Section 73-21-99, Mississippi Code of 1972.

I. Personnel

(1) Each drug wholesaler shall employ adequate personnel with the education and experience necessary to safely and lawfully engage in the wholesale distribution of prescription drugs.

(2) Each wholesaler shall maintain a list of all personnel who have access to controlled substances and shall make available to the Board proof of background searches on any such employee. No person who has access to controlled substances shall have been convicted in any federal or state court of any drug related crime.

(3) Wholesale drug distributors shall establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

J. Salvaging and Reprocessing:

(1) Wholesale drug distributors shall be subject to the provisions of any applicable federal, state, or local laws or regulations that relate to prescription drug product salvaging or reprocessing, including Chapter 21, parts 207, 210d, 211 of the Code of Federal Regulations.

K. Repackaging:

(1) Every wholesaler permitted by the Board that repackages prescription drugs for distribution shall register with the Federal Food and Drug Administration and shall be in compliance with all laws, rules, and regulations regarding such registration. Written notification furnished by the Federal Food and Drug Administration citing violations of federal laws, rules, and regulations shall be prima facie evidence of violation of this ARTICLE.

(2) In wholesaler facilities permitted by the Board where prescription drugs are repackaged for distribution, all drug products shall be maintained in the

manufacturer's original container except as allowed by federal laws, rules, and regulations regarding prescription drug repackaging. Once distributed, repackaged prescription drug products which are returned to the repackager shall be immediately quarantined and either destroyed or returned to the original manufacturer.

(3) In addition every wholesaler that repackages prescription drugs shall comply with the following:

(a) Maintain and provide documentation showing that solid oral dosage form drug products are repackaged into a container/closure system that is equivalent to the manufacturer's container closure system if the manufacturer's expiration date is placed on the repackaged container. In the absence of stability testing, the repackager shall obtain and maintain certification from the container/closure manufacturer, supporting the expiration date placed on the label of the repackaged drug product;

(b) Maintain and provide documentation of stability testing to support any expiration date placed on containers wherein liquid oral dosage forms have been repackaged;

(c) Maintain written specifications for labeling repackaged products and written procedures that assure only correct labels are used. Documentation should be maintained showing that labeling placed on the repackaged containers is examined for correctness before and after the drug is repackaged;

(d) The label placed on a repackaged product shall indicate at a minimum:

(i) All active ingredients, dosage form and strength;

(ii) Name and address of the repackager;

(iii) Name and address of the manufacturer;

(iv) Storage requirements; and

(v) Control lot number and expiration date.

(e) Assures that penicillin drug products or penicillin synthetics shall not be repackaged in the same room, on the same equipment, and using the same air handling system, where other drug products are repackaged;

(f) Maintain documentation that cleaning procedures are followed when equipment and other surfaces are cleaned to assure that no drug residue remains on or near repackaging equipment; and

(g) Assures that drug products that are known to have stability problems such as, but not limited to nitroglycerin sublingual tablets or other drug products that interact with packaging materials not be repackaged in the absence of specific test data demonstrating the stability of the repackaged drug product and the actual container/closure system used.

11. A facility, located in this state, and permitted by the Mississippi Board of Pharmacy as a wholesaler shall not sell or distribute a prescription drug to any individual or business unless the individual or business is licensed or permitted to prescribe, dispense, or possess

prescription drugs by an agency of the state in which the individual or business is located.

A facility permitted by the Board as a wholesaler shall not distribute prescription drugs to persons in this state unless such person is either a licensed physician, osteopath, or podiatrist, licensed by the Mississippi Board of Medical Licensure, a licensed dentist, licensed by the Mississippi Board of Dental Examiners, a licensed veterinarian, licensed by the Mississippi Board of Veterinary Medicine, pharmacies and wholesalers permitted by the Board. An optometrist licensed by the Mississippi State Board of Optometry, may purchase prescription drugs as authorized by said Board of Optometry.

12. For purposes of these regulations the following definitions shall apply:
    - A. "Blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.
    - B. "Blood Component" means that part of blood separated by physical or mechanical means.
    - C. "Drug Sample" means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.
    - D. "Manufacturer" means a person engaged in the manufacturing preparing, propagating, compounding, processing, packaging, repackaging, distributing or labeling of a prescription drug.
    - E. "Prescription Drug" means any human drug including, but not limited to medical oxygen, which is required by federal law or regulation to be dispensed only by a prescription, and drugs which are required under federal law to be labeled with either of the following statements prior to being dispensed or delivered:
        - (1) "Caution: Federal law prohibits dispensing without prescription," or
        - (2) "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian"; or a drug which is required by any applicable federal or state law or regulation to be dispensed on prescription only or is restricted to use by practitioners only.
    - F. "Wholesale Distribution" means distribution of prescription drugs to a person other than a consumer or patient, but does not include:
        - (1) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons; for purposes of these regulations "emergency medical reasons" includes transfers of prescription drugs from one permitted facility to another permitted facility to alleviate a temporary shortage;
        - (2) The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription;
        - (3) The lawful distribution of drug samples by manufacturers' representatives or distributors' representatives;
        - (4) The sale, purchase, or trade of blood and blood components intended for transfusion;
        - (5) The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for its own

use from the group purchasing organization or from other hospitals or health care entities that are members of such organizations;

(6) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals that are under common control; for purposes of these regulations, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, by contract or otherwise;

(7) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in section 501© (3) of the U.S. Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(8) Any entity that distributes prescription drugs or controlled substances into the state must hold a wholesaler permit issued by the Mississippi Board of Pharmacy.

(9) The sale/purchase of a prescription drug by a retail pharmacy to other retail pharmacies or to a licensed practitioner for office use, if the total annual dollar volume of these sales/purchases does not exceed five percent (5%) of that pharmacy's total annual prescription drug sales.

G. "Wholesaler" means a person who buys or otherwise acquires prescription drugs or prescription devices for resale or distribution or for repackaging for resale or distribution to persons other than consumers.

H. "Wholesale Distributor" means any person engaged in wholesale distribution of prescription drugs or prescription devices, including but not limited to, manufacturers; repackagers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions.

I. "Deliver" or "Delivery" means the actual constructive or attempted transfer of a drug or device from one person to another, whether or not for a consideration.

J. "Distribute" means the delivery of a drug or device other than by administering or dispensing to persons other than the ultimate consumer.

K. "Repackager" means a person registered by the Federal Food and Drug Administration as a repackager who removes a prescription drug product from its marketed container and places it into another, usually of smaller size, to be distributed to persons other than the consumer.

L. "Board of Pharmacy", "Pharmacy Board", "Board", or "MSBP" shall mean the Mississippi Board of Pharmacy.

M. "Person" shall mean an individual, corporation, partnership, association, or any other legal entity.

ARTICLE XXXIII HOME HEALTH/HOSPICE PERMITS

1. Every home health agency, hospice organization or business/location in this state subject to regulation by the Mississippi Board of Pharmacy where certain prescription drugs as approved by the Board are bought, maintained, administered or provided directly to consumers, without the services of a pharmacist being required, shall obtain a permit as a home health/hospice from the Mississippi Board of Pharmacy.

2. To obtain a permit or renew a permit for a home health/hospice, the applicant shall:
   A. Submit a written application on a form prescribed by the Board;
   B. Submit the required fees as follows:
      Fifty dollars ($50.00) for the registration period January 1, 2012, through December 31, 2013, and each biennial registration period thereafter.

   Any home health/hospice permit renewal application postmarked after December 31 of the renewal period shall be returned and a fifty dollar ($50.00) late renewal fee shall be assessed prior to renewal.

3. Every business issued a home health/hospice permit by the Board shall renew this permit biennially. Newly issued permits which do not coincide with the registration period shall be valid for the following periods of time: If the permit is issued in the first half of the registration period, it must be renewed at the end of the registration period. If the permit is issued in the second half of the registration period, it must be renewed at the end of the next registration period.

4. The person who signs the application for a home health/hospice permit or the renewal of a home health/hospice permit shall be the permit holder for that facility and shall be responsible for all activities in the permitted facility which are subject to regulation by the Board. Once issued, a permit cannot be amended, transferred or assigned to another person.

5. If the employment of a permit holder is terminated or if for any other reason he/she wishes to be relieved of the responsibilities of the permit holder, he/she must return the home health/hospice permit to the Mississippi Board of Pharmacy with written notice that he/she is no longer the permit holder for that facility. When a permit is thus returned, application for a new permit for that facility must be made to the Mississippi Board of Pharmacy within ten (10) days.

6. If a permitted facility is permanently closed or has a change of ownership, the permit holder for that facility shall give notice to the Board of the effective date of closure or change in ownership at least ten (10) days prior to the closure or change of ownership.

7. If a permitted facility has a change in name or location, a new permit must be obtained.

Application for this new permit must be made to the Board at least ten (10) days prior to the change.

8. All home health/hospices permitted by the Mississippi Board of Pharmacy shall comply with the following:

   A. Prescription drugs that are bought or maintained, in a home health/hospice or provided to a consumer from a home health/hospice shall be limited to those items authorized by the Board. A list of the authorized prescription drugs shall be published by the Board at least annually.
   Items may be added to or deleted from the list by the Board at any regularly called meeting. At any time a change in the list of authorized drugs is made, the Board shall provide the changed list to all persons registered with a home health/hospice permit.
   B. A home health/hospice shall not buy, maintain or provide to a consumer any prescription drug not authorized by the Board of Pharmacy unless such prescription drug was obtained pursuant to the valid prescription or order of a practitioner.
   C. Delivery of any prescription drug to a consumer shall be pursuant to a valid order of a practitioner who is authorized to prescribe the drug. These orders shall be maintained for a period of six (6) years.
   D. A facility permitted with a home health/hospice permit shall not sell or distribute a prescription drug to any person who is not permitted or otherwise authorized to purchase prescription drugs except that a facility permitted by the Board of Pharmacy with a home health/hospice permit may supply these items to other facilities under common control or ownership.
   E. Complete and accurate records of acquisition and disposition of all prescription drugs which are bought or maintained by a home health/hospice shall be maintained for a period of six (6) years. These records shall be readily retrievable and available for inspection by agents of the Mississippi Board of Pharmacy.
   F. Any prescription drug maintained in a home health/hospice or provided to a consumer from a home health/hospice shall be labeled so as to be in compliance with the labeling requirements of the Federal Food and Drug Administration and any additional labeling necessary for the safe and effective use of the product by the consumer.
   G. Each home health/hospice where prescription drugs are bought or maintained shall provide storage areas that ensure proper lighting, ventilation, temperature, sanitation, humidity, space and equipment. All prescription drugs shall be stored at appropriate temperatures per label requirements or official United States Pharmacopeia (USP) compendium requirements to ensure that the identity, strength, quality, and purity of the products are not affected. If no temperature requirements are listed, prescription drugs may be stored at room temperature as defined in the USP. A separate storage area shall be provided for prescription drugs that are deteriorated, outdated, misbranded, or otherwise adulterated.
   H. Each home health/hospice shall employ adequate personnel with the education and experience necessary to safely and lawfully engage in the preparation, administration

or delivery of prescription drugs

I. Home health/hospices shall be maintained in an orderly and sanitary fashion.

J. A permit shall not be issued for a home health/hospice located in a residence.

K. The Board of Pharmacy may refuse to issue or renew, or may suspend, revoke or restrict the permit of any home health/hospice under the applicable provisions of ARTICLE IX of these regulations.

9. For purposes of these regulations the following definitions shall apply:

A. "Home health/hospice" shall mean a business, which does not require the services of a pharmacist, where certain prescription drugs are bought, maintained or provided to consumers.

B. "Home Health Agency" shall mean a public or privately owned agency or organization or a subdivision of such agency or organization, properly authorized to conduct business in Mississippi, which is primarily engaged in providing to individuals, at the written direction of a licensed physician, in the individual's place of resident, skilled nursing services provided by or under the supervision of a registered nurse licensed to practice in Mississippi.

C. "Hospice" shall mean an autonomous, centrally administered, ~~nonprofit,~~ medically directed, nurse coordinated program providing palliative and supportive care to meet the special needs arising out of the physical, emotional, spiritual, social and economic stresses which are experienced during the final stages of illness and during dying and bereavement. This care is available twenty-four (24) hours a day, seven (7) days a week, and is provided on the basis of need regardless of inability to pay.

D. "Prescription Drug" or "Legend Drug" shall mean a drug which is required under federal law to be labeled with either of the following statements prior to being dispensed or delivered:

(1) "Caution: Federal law prohibits dispensing without prescription," or

(2) "Rx Only", or

(3) "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian"; or a drug which is required by any applicable federal or state law or regulation to be dispensed on prescription only or is restricted to use by practitioners only.

ARTICLE XXXIV PHARMACY EXTERN/INTERN REGISTRATION

1. Every person enrolled in the professional curriculum of a school of pharmacy and pursuing either a Bachelor of Science in pharmacy degree or a Doctor of Pharmacy degree must obtain an extern/intern registration from the Mississippi Board of Pharmacy prior to enrolling and participating in externship or clerkship rotations or obtaining practical experience in a pharmacy permitted by the Board. The Pharmacy extern/intern shall in no manner falsely assume, directly or by inference, to be a Pharmacist. To obtain an extern/intern registration, the applicant shall:
   A. Have submitted a written application on a form prescribed by the Board;
   B. Be of good moral character as evidenced by having undergone and successfully passed a criminal background check conducted by the Board;
   C. Show proof to the Board the applicant is enrolled in a school of pharmacy approved by the Board;
   D. Have paid fees as specified by the Board.

2. A pharmacy extern/intern registration which has been issued by the Board shall expire when:
   A. The extern/intern is expelled, suspended, withdraws or is dismissed from a school of pharmacy;
   B. The extern/intern fails to become licensed as a registered pharmacist within six (6) months of graduation from a school of pharmacy;
   C. Upon the expiration of a pharmacy extern/intern registration, the registrant may petition the Board for re-registration.

   All pharmacy interns/externs shall notify the Board immediately upon change of employment and residence address.

   When a Pharmacy Intern desires to obtain credit for training received in a state other than this State, he/she shall abide by all the provisions of the internship rules in that state, and shall provide evidence from that state's Board of Pharmacy of the number of clock hours of experience actually participated in by the Pharmacy Intern.

3. The Board may refuse to issue or renew or may suspend, revoke or restrict the registration of any extern/intern upon one or more of the following grounds:
   A. Unprofessional conduct as defined in ARTICLE V, paragraph G., Pharmacy Practice Regulations of the Mississippi Board of Pharmacy;
   B. Violation of any regulation(s) of the Board;
   C. Violation of any provisions of the Mississippi Pharmacy Practice Act or the Mississippi Uniform Controlled Substances Act;
   D. Violation of pharmacy or drug laws of this state or any other state or rules and regulations pertaining thereto;
   E. Fraud or intentional misrepresentation by a extern/intern in securing the issuance of a pharmacy extern/intern registration or failing to report to the Board any adverse

action taken by another licensing jurisdiction, government agency, law enforcement agency, or court that would constitute grounds for action;

F. Addiction to or dependence on alcohol, controlled substances or other habit forming legend drugs or the unauthorized use, possession, or theft of controlled substances or other habit forming legend drugs;

G. Physical or mental incapacity that prevents the intern/extern from practicing pharmacy with reasonable skill and safety to the public.

H. Divulging or revealing patient confidential or protected health information to any person other than as authorized by Board regulations.

I. Failure to comply with any lawful order of the Board;

J. Obtaining practical experience in a pharmacy permitted by the Board without the direct supervision and presence of a pharmacist licensed by the Board;

K. Failure to notify the Board of expulsion, suspension, dismissal or withdrawal from a school of pharmacy;

L. Violation of any university, college or school of pharmacy policies, rules or regulations thereof.

M. Failure to report directly to the Board, losses or suspected losses of controlled substances or prescription drugs.

N. Theft from a permitted facility.

O. Theft or embezzlement of prescription drugs, controlled substances or medical devices from a permitted facility.

P. Jeopardizing, compromising, interfering or failing to cooperate with any lawful investigation conducted by the Board or any state or federal regulatory or law enforcement agency.

Q. 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.

R. 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.

S. Failing to pay costs assessed in a disciplinary hearing.

T. The unlawful disclosure of information from the Prescription Monitoring Program.

U. Using information obtained from the Prescription Monitoring Program for unlawful or unethical purposes.

4. For purposes of this ARTICLE "obtaining practical experience" shall include, but not be limited to the compounding, dispensing and labeling of drugs, interpreting and evaluating prescriptions, maintaining prescription records and any other activity included in the practice of pharmacy under the direct supervision of a pharmacist.

ARTICLE XXXV INSTITUTIONAL EMERGENCY MEDICATION KIT PERMITS

1. Institutions, under the jurisdiction of the Board, that maintain prescription drugs on the premises for emergency use by patients, shall comply with the following:
   A. Permit. Every institutional facility, except a hospital, that desires to maintain a stock of prescription drugs for emergency use by patients who are confined to the institution, shall obtain an Institutional Emergency Medication Kit (IEMK) permit from the Mississippi Board of Pharmacy. Application for the IEMK shall be on a form supplied by the Board and accompanied by a fee not to exceed fifty dollars ($50.00). A separate permit shall be required for each provider pharmacy and shall be renewed a biennially. The Administrator (if a nursing home or other long term care facility) or business manager of the institution shall make application for the (IEMK) permit. In the event of the departure of the administrator or business manager, a new permit must be obtained.

   Any IEMK permit renewal application postmarked after December 31 of the renewal period shall be returned and a twenty-five ($25.00) dollar late renewal fee shall be assessed prior to renewal.

   B. Emergency Drug Kit Inventory and Accountability. Prescription drugs selected from a drug formulary specified by the Board, may be maintained by institutions for emergency use provided that:
      (1) The contents of the IEMK (up to 42 items) are supplied by any pharmacy permitted by the Board)controlled Substance Class II narcotics are not allowed); and
      (2) The contents of the IEMK are jointly determined by the consultant pharmacist, medical director, director of nurses and the pharmacist supplying the IEMK; and
      (3) A copy of the inventory of the IEMK is signed by administrator, the medical director, director of nurses and the pharmacist supplying the IEMK and placed on file in the institution and at the provider pharmacy; and
      (4) Only limited quantities (not to exceed twelve (12) dosage units) of prepackaged medications are available from the IEMK; and
      (5) Each prepackaged drug maintained in the IEMK is assigned a "par value" and each addition to or withdrawal from the IEMK is properly documented; and
      (6) An IEMK withdrawal log is maintained at the institution and all withdrawals of medications from the IEMK are documented as follows:
         (a) name and room number of resident/patient; and
         (b) drug name, quantity and strength; and
         (c) date and time of withdrawal and/or administration; and
         (d) name of person withdrawing and/or administering the medication.

(7) The provider pharmacy is furnished a copy of the IEMK medication withdrawal log on a timely basis in order for proper replacement of medications which have been utilized by the institution; and

(8) Any additions to the Board's drug formulary must be requested by the institution and approved by the Board.

2. Use. Emergency kit medications shall be administered to patients only for emergencies and pursuant to a valid medication order or prescription. Institutional emergency medication kit drug supplies are not to be used when medications are readily available from a community or hospital pharmacy.

3. Pharmacy Records. The pharmacist provider of the IEMK shall maintain complete and accurate records regarding the date, name, strength and quantity of medications supplied to each IEMK. These records shall be maintained separately for each IEMK and be readily retrievable at the provider pharmacy.

4. Storage and Security. The IEMK shall, at all times, be maintained in a securely locked room or cabinet at the institution. Access to the IEMK and it's contents shall be limited to only those persons as designated by the director of nurses and the provider pharmacist.

5. Controlled Substances. Controlled substance drugs may be maintained in an IEMK provided that:

   A. All requirements as outlined above are met; and

   B. The institution has applied for and been issued a controlled substance registration by the Mississippi Board of Pharmacy; and

   C. Controlled substances are stored in a separate locked container; and

   D. A copy of the medication order for those drugs listed in Schedule III, IV and V is delivered to the provider pharmacist within seventy-two (72) hours; and

   E. Use of Schedule II drugs shall comply with ARTICLE XIX of these Regulations of the Board. No Schedule II drugs may be maintained in the IEMK.

ARTICLE XXXVI PHARMACEUTICAL HEALTH CARE/INITIATION AND/OR MODIFICATION OF DRUG THERAPY UNDER PROTOCOL

1. Pharmacists may provide pharmaceutical health care to patients by initiating and/or modifying prescription drug therapy after a written protocol, indicating approval by a licensed practitioner who is authorized to prescribe prescription drugs, has been placed on file at the

office of the Board. Any such protocol must define the agreement by which the practitioner delegates this authority and any such authority granted must be within the scope of the

practitioner's prescribing authority and current practice. Any modification of the agreement must be treated as a new protocol.

For purposes of this ARTICLE "written protocol" shall mean an agreement in which any practitioner authorized to prescribe drugs delegates to a pharmacist authority to conduct specific initiation and/or modification of drug therapy functions in an institutional setting. In a community pharmacy out-patient setting, a specific protocol agreement shall be signed on each patient for whom a practitioner delegates any authority to initiate or modify drug therapy.

2. Unless specifically authorized by the Board, no person shall initiate or modify drug therapy under a protocol agreement unless he/she is certified and possesses the following qualifications: and
   A. Have and maintain a license to practice pharmacy issued by the Mississippi Board of Pharmacy; and
   B. Have attended and successfully completed at least sixteen (16) hours of continuing education consisting of basic pharmaceutical care, development of patient care plans and the clinical practice of pharmacy which has been approved by the Board; and in addition
   C. Have attended and successfully completed a Board pre-approved study course consisting of not less than sixteen (16) hours of continuing education focusing on a specific disease state, patient care plans and protocol management.

   Pharmacists shall, on a biennial basis, obtain re-certification in each disease state by successfully completing a continuing education program consisting of not less than six (6) hours focusing on nationally recognized updates.

   Pharmacists who have successfully completed any study course(s) focusing on disease state management and protocols or re-certification, shall send to the Board office copies of any documents certifying such on request.

3. Protocol agreements shall meet the following requirements:
   A. Identification of the practitioner who agrees to supervise the pharmacist and the scope of the practitioner's active practice; and

B. Describe the specific responsibilities authorized by the supervising practitioner; and
C. Describe the method the pharmacist shall use to document decisions or recommendations the pharmacist makes to the supervising practitioner; and
D. Describe the patient activities the supervising practitioner requires the pharmacist to monitor; and
E. Describe the types of reports the supervising practitioner requires the pharmacist to report and the schedule by which the pharmacist is to submit these reports; and
F. Include a statement of the medication categories and the type of initiation and modification of drug therapy that the supervising practitioner authorizes the pharmacist to perform; and
G. Describe the procedures or plan that the pharmacist shall follow if the pharmacist exercises initiation and modification of drug therapy; and
H. Indicate the date the supervising practitioner's supervision ends. The duration of the protocol agreement shall not exceed one (1) year; and
I. Be dated and signed by the pharmacist(s) and the supervising practitioner, if more than one practitioner agrees to supervise the pharmacist(s), each practitioner and pharmacist(s) shall sign and date the protocol; and
J. Include a statement that stipulates that the patient has been notified by the pharmacist(s) and the supervising practitioner that a protocol agreement exists.

ARTICLE XXXVII DUTIES AND RESPONSIBILITIES OF EXECUTIVE DIRECTOR

Pursuant to Section 6. Section 73-21-79, paragraph (3), Mississippi Code of 1972, Annotated, the duties and responsibilities of the Executive Director of the Mississippi Board of Pharmacy shall be defined by rules and regulations prescribed by the Board as follows:

The Executive Director (Director) is the executive officer in charge of the office of the Mississippi Board of Pharmacy and he/she shall be appointed by the Board. The Director shall serve as the budget officer and shall make, keep and be in charge of all records, record books and any files required to be maintained by the Board. The Director shall attend to the correspondence required by the office, and shall perform such other duties as the Board may require in keeping with the office. The Director shall be provided with, supervise, and have the aid of clerical, investigative and other office staff as necessary for the fulfillment of said duties and responsibilities.

1. GENERAL DUTIES AND RESPONSIBILITIES: The Executive Director shall have, but not be limited to, the following responsibilities:
   A. Issuance of all licenses, registrations and permits to all pharmacists, businesses, facilities, pharmacies or other persons as authorized by statutes, rules or regulations;
   B. Maintaining, preserving, and releasing of any public records which are required to be kept by the Board;
   C. Administration of any examinations or tests required under statutes or regulations;
   D. Serve as the representative of the Board on any committees, boards or other organizations as necessary to carry out the Board's responsibilities;
   E. Act as the Board's agent and cause to be issued and cause to be served, all subpoenas, Orders of the Board, and any Notice of Hearing and Complaint issued to any pharmacist, permit holder, business/facility, registrant or other person under the jurisdiction of the Board and execute the foregoing for and on behalf of the Board;
   F. Provide initiative, leadership and input into any proposed legislation or regulations pertaining to the practice of pharmacy, the distribution of prescription drugs, pharmacy technicians and pharmacy externs/interns;
   G. Set the agenda for all meetings of the Board, act as recording secretary and be responsible for the preparation of the Minutes of all meetings of the Board;
   H. Serve as the Board's representative in the approval of all continuing education as required by Regulations of the Board;
   I. Serve as the Board's representative when interacting and/or cooperating with other state or federal agencies or law enforcement entities.

ARTICLE XXXVIII MEDICAL EQUIPMENT SUPPLIERS PERMIT

1. Permit required:

Pursuant to Mississippi Pharmacy Practice Act Section 73-21-108 no person, business or entity subject to this chapter shall sell, rent or provide or offer to sell, rent or provide directly or indirectly to consumers in this state any home medical equipment, legend devices, and/or medical gas unless such person, business or entity first obtains a Medical Equipment Suppliers Permit from the Mississippi Board of Pharmacy. Permitting procedures are as follows:

A. The permitting requirements of this section will apply to all companies, agencies and other business entities that are in the business of supplying home medical equipment to patients in residential settings and which bill the patient or the patient's insurance, Medicare, Medicaid or other third party payor for the rent or sale of that equipment.
B. The application for a permit shall be on a form supplied by the Board and accompanied by a fee of $150.00. Once issued, every permit must be renewed annually. The renewal fee shall not exceed $150.00.
C. The Board shall require a separate permit for each facility location directly or indirectly owned or operated in this state. Permits shall not be issued for facilities located in a residence.
D. The Board shall require that all facilities issued a Non-Resident Durable Medical Equipment Supplier permit obtain a permit for a facility located within the State of Mississippi.
E. All permits issued under this section shall expire annually on June 30, of each year. Application and payment for renewal must be postmarked on or before June 30 and must be accompanied by the fee as prescribed by this section. A penalty of $50.00 shall be added to all late renewals postmarked after June 30, of each renewal period. The Permit shall become null and void if the renewal application~~,~~ and renewal fee are not received by July 1 of each year.
F. The person who signs the application for a medical equipment suppliers permit or the renewal of a medical equipment suppliers permit shall be the permit holder for that facility and shall be responsible for all activities in the permitted facility which are subject to regulation by the Board. Once issued, a permit cannot be amended, transferred or assigned to another person.
G. If the employment of a permit holder is terminated or if for any other reason he/she wishes to be relieved of the responsibilities of the permit holder, he/she must return the medical equipment suppliers permit to the Mississippi Board of Pharmacy with written notice that he/she is no longer the permit holder for that facility. When a permit is thus returned, application for a new permit for that facility must be made to the Mississippi Board of Pharmacy within ten (10) days.
H. If a permitted facility is permanently closed or has a change of ownership, the permit holder for that facility shall give notice to the Board of the effective date of closure or change in ownership at least ten (10) days prior to the closure or change of

ownership.

I. If a permitted facility has a change in name or location, a new permit must be obtained. Application for this new permit must be made to the Board at least ten (10) days prior to the change.

J. The Board shall not issue any original or annual renewal medical equipment permit until the Board is satisfied that:

(1) Adequate qualified personnel have been secured by management of the facility to properly render medical equipment services in the manner prescribed by law; and
(2) Such personnel shall be maintained during the period for which the permit is issued; and
(3) Suitable facilities shall be maintained to house inventory, to allow for equipment maintenance work space and the storage and retrieval of all records required to be kept; and
(4) Each non-resident medical equipment supplier holds a permit for a medical equipment supplier facility physically located within the State of Mississippi; and
(5) A copy of these regulations shall be present in the facility at all times; and
(6) The facility is kept in a clean, orderly and sanitary condition at all times ; and
(7) The applicant's services are accessible to its customer base; and
(8) The applicant complies with all USP, FDA, DOT and OSHA requirements regarding the storage, packaging, labeling and shipping of medical equipment including medical gases; and
(9) The applicant's services are available twenty-four (24) hours, seven (7) days per week when essential to the maintenance of life or when lack of services might reasonably cause harm; and
(10) The applicant implements and maintains a written procedure at each location for handling complaints and problems, which includes a complaint file documenting complaints and problems and resolution of the complaints and problems; and
(11) The applicant complies with all local/state fire and building laws; and
(12) The facility is equipped with a functioning lavatory where hot and cold running water or hand washing appliances or waterless hand cleaner are available; and

Exemptions are as follows:

A. The permitting requirements of this section do not apply to the following unless the following have a separate business entity, company, corporation or division that is in the business of providing home medical equipment to patients at their home: home health agencies; hospitals; wholesalers and/or manufacturers; medical doctors, physical therapists, respiratory therapists, occupational therapists, speech

pathologists, optometrists, chiropractors and podiatrists who use home medical equipment and/or legend devices in their individual practices; pharmacies; hospice programs; nursing homes and or long term care facilities; veterinarians; dentists; and emergency medical services.

B. Community pharmacies, long term care facilities and hospitals although excluded from permitting requirements of this section, will be subject to the same regulations for the sale or rental of home medical equipment covered by this section.

C. It is also recognized that oxygen, liquid oxygen and/or legend devices may be used in emergencies by trained individuals.

D. Nothing in this section shall prohibit the pre-hospital emergency administration of oxygen by licensed health care providers, emergency medical technicians, first responders, fire fighters, law enforcement officers and other emergency personnel trained in the proper use of emergency oxygen.

2. Medical Equipment Advisory Committee (MEAC) to the Board:

A. A MEAC committee, composed of three (3) members selected by the Mississippi Association of Medical Equipment Suppliers and approved by the Board, shall review and make recommendations to the Board on the merit of all regulations dealing with home medical equipment, legend devices and medical gases, which are proposed by the Board and before they are adopted by the Board.
Newly appointed MEAC members shall be assigned to Post 1., Post 2. or Post 3. Subsequent terms of MEAC members shall be for a period of five (5) years and no member shall serve two consecutive terms.

B. All MEAC members shall have been actively involved in the home medical equipment business for a minimum of five (5) years and shall hold and maintain, in good standing, a permit issued by the Board pursuant to this section.

C. The MEAC members shall meet at least quarterly and review all home medical equipment suppliers' inspection reports. All complaints and reports of investigations of violation of law or regulations shall first be reviewed by the MEAC. After review, the MEAC may make recommendations to the Board's Investigations Review Committee as to further administrative action by the Board.

D. The MEAC shall keep and maintain minutes of all meetings of the MEAC and shall provide copies of said minutes to the Board on a quarterly basis.

E. The Mississippi Board of Pharmacy may remove any or all MEAC members on proof of unprofessional conduct, continued absence from the state, being found guilty of any provisions of these regulations or other regulations of the state or federal government or failure to perform the duties of his/her office. Any MEAC member who shall not attend two (2) consecutive regular meetings of the MEAC for any reason other than illness shall be subject to removal by the Mississippi Board of Pharmacy.

3. Order Required:

Home Medical Equipment Suppliers shall not provide any legend device or medical gas to

a patient without a valid order from an authorized practitioner all orders must be readily retrievable and must be produced on request by a compliance agent. All legend items, including oxygen, require a new prescription order on a yearly basis.

4. Medical gas, oxygen and respiratory equipment suppliers shall:

   A. Comply with all applicable home medical equipment laws and regulations of Mississippi; and
   B. If transporting oxygen and other medical gases in cylinder or liquid form, comply with all current Department of Transportation rules and regulations; and
   C. If transfilling medical oxygen systems, comply with Food and Drug Administration (FDA) and all state agency requirements regarding transfilling and repackaging; and
   D. Demonstrate that oxygen and other medical gases provided in cylinder or liquid form meets minimum purity standards for medical grade oxygen and medical gases; and
   E. Meet the following safety inspection requirements:
      (1) Demonstrate that each piece of oxygen/respiratory equipment has been checked, is free of defects and operates within the manufacturer's specifications; and
      (2) Refrain from modifying equipment to the extent that the modification might reasonably cause harm; and
      (3) Maintain all electrical components so that they do not present fire or shock hazard; and
      (4) Ensure that all appropriate warning labels or labeling, including tags, are present on the equipment provided.

   I. Medical gas, oxygen and respiratory related equipment suppliers shall comply with the following recall procedures:
      A. Ensure that lot numbers and expiration dates are affixed to each cylinder delivered; and
      B. Maintain a tracking system for all medical oxygen and gas delivered; and
      C. Document all equipment serial numbers and model numbers to ensure that equipment can be retrieved if a recall is initiated; and
      D. Maintain records for equipment that requires FDA tracking.

   II. Medical gas, oxygen and respiratory related equipment suppliers shall comply with the following maintenance and cleaning requirements:
      B. Maintain documentation demonstrating that a function and safety check of equipment was performed prior to set up; and
      B. Maintain an established protocol for cleaning and disinfecting equipment which addresses both aerobic and anaerobic pathogens; and
      C. Maintain a Material Safety Data Sheet (MSDS) on file for solutions and products used in cleaning and disinfecting procedures; and
      D. Maintain segregated areas on the premises and in delivery vehicles for clean, dirty, and contaminated equipment; and

E. Clean and disinfect equipment according to manufacturers' specifications; and
F. Instruct the patient on proper cleaning techniques as specified by the manufacturer; and
G. Ensure that all medical gas, oxygen and respiratory related equipment is properly identified by a tag or label as to it's current status of use, i.e. out of order or ready for use.

III. Medical gas, oxygen and respiratory related equipment suppliers shall implement a comprehensive preventative maintenance program which includes the following:
A. Procedures for problem reporting, tracking, recall, and resolution; and
B. Performance of service as specified by the manufacturer and the documentation of such performance in the service records; and
C. Routine inspection, service, and maintenance of equipment located in the patient's/customer's home according to manufacturers' specifications.

IV. Medical gas, oxygen and respiratory related equipment suppliers shall maintain repair logs to document repair and maintenance of equipment, including, but not limited to, oxygen concentrators, infant monitors, and mechanical ventilators. The following information shall be documented in the repair log:
A. type of equipment; and
B. manufacturer; and
C. model; and
D. serial number; and
E. date of repair; and
F. specific repair made; and
G. name of person or company performing the repair.

V. Medical gas, oxygen and respiratory related equipment suppliers shall maintain testing equipment to ensure accurate calibration. Testing equipment shall be appropriate for the level of service offered. Scales used to weigh liquid oxygen reservoirs shall be properly maintained to ensure accuracy.

VI. Medical gas, oxygen and respiratory related equipment suppliers shall implement a written procedure at each location for handling complaints and problems, which includes a complaint file documenting complaints and problems and resolutions of the complaints or problems.

VII. Medical gas, oxygen and respiratory related equipment suppliers shall comply with the following counseling requirements:
A. Utilize orientation checklists to review:
(1) Instructions for use of the equipment; and
(2) Safety precautions; and
(3) Cleaning procedures; and
(4) Maintenance procedures; and

(5) Return demonstrations on back up oxygen systems delivered; and

B. Instruct the patient about emergency and routine contact procedures; and

C. Deliver and review written instruction materials to ensure that the patient receives adequate information in order to properly operate the equipment.

A written plan of service shall be developed, implemented, and documented in the patient record. The plan of service shall include, but is not limited to, an assessment of the safety of the home environment, the care giver or patient ability to comply with the order, and the care giver or patient ability to operate and clean the equipment as instructed.

5. Other Medical Equipment

Persons that shall sell, rent and/or provide other medical equipment or legend devices, as defined in these regulations, shall also comply with the following:

A. Provide proper training of personnel for the safe delivery and use of any medical equipment or legend device; and

B. Ensure that all manufacturer's recommended assembly and maintenance procedures are followed; and

C. Meet the following safety inspection requirements:

(1) Demonstrate that each piece of medical equipment or legend device has been checked, is free of defect and operates within the manufacturer's specifications; and

(2) Refrain from modifying equipment to the extent that the modification might reasonably cause harm; and

(3) Maintain all electrical components so that they do not present fire or shock hazard; and

(4) Ensure that all appropriate warning labels or labeling, including tags, are present on the equipment provided.

6. Revocation, Suspension or Restriction, Penalties of Permit shall be as follows:

A. The Board may revoke, suspend, restrict, refuse to issue or renew or impose a monetary penalty, in accordance with Section 73-21-103. Mississippi Code of 1972, Annotated, if the business or holder of a permit or applicant for a permit, issued under this section, has committed or is found guilty by the Board of any of the following:

(1) Violation of any Federal, State or local law or regulation relating to medical equipment, legend devices or medical gases.

(2) Violation of any of the provisions of these regulations.

(3) Commission of an act or engaging in a course of conduct which constitutes a clear and present danger to the public health and safety.

(4) Filing a claim or assisting in the filing of a claim for reimbursement for medical equipment, medical gases, legend devices or professional services which were not provided or which were not authorized to be provided.

(5) Failure to comply with any lawful order of the Board.

(6) Conviction of a felony.

(7) Entering into any written agreements or other activities which interferes with or otherwise denies a patient the freedom to choose any willing provider of medical equipment or services.

B. Disciplinary action by the Board against a business or any person holding a permit pursuant to this section shall be in accordance with Section 73-21-99 of the Mississippi Code of 1972, Annotated.

Definitions:

For purposes of these regulations:

A. "Home Medical Equipment" means technologically sophisticated medical equipment and devices usable in a home care setting including, but not limited to:

(1) Oxygen for human consumption, oxygen concentrators, and/or oxygen delivery systems and equipment;

(2) Ventilators;

(3) Respiratory disease management devices;

(4) Electronic and computer driven wheelchairs and seating systems;

(5) Apnea monitors;

(6) Transcutaneous electrical nerve stimulator (TENS) units;

(7) Low air loss cutaneous pressure management devices;

(8) Sequential compression devices;

(9) Neonatal home phototherapy devices;

(10) Feeding pumps;

(11) And other similar equipment as defined in any regulations established

B. "Home Medical Services" means the delivery, installation, maintenance, replacement, and/or instruction in the use of home medical equipment, used by a sick or disabled individual, to allow the individual to be cared for and maintained in a home or non-institutional environment.

C. "Medical gas" means those gases and liquid oxygen intended for human consumption.

D. "Order" means an order issued by a licensed medical practitioner legally authorized to order medical gases, legend devices and/or home medical equipment.

E. The term "Home Medical Equipment" does not mean medical equipment used in the normal course of treating patients by hospitals, hospices, long term care facilities or home health agencies or medical equipment used or dispensed by health care professionals licensed by the State of Mississippi---provided that the professional is practicing within the scope of his/her professional practice. Further, that items such as upper and lower extremity prosthetics, canes, crutches, walkers, bathtub grab bars, standard wheelchairs, commode chairs and bath benches are not considered to be home medical equipment.

F. "Pharmacy Board, State Board of Pharmacy or Board" shall mean the Mississippi Board of Pharmacy.

G. The term "Legend Device" shall mean any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including any component part or accessory which is required under federal or state law to be prescribed or ordered by a physician and/or practitioner.

4. Automated pharmacy systems include, but are not limited to, mechanical systems that perform operations or activities relative to the storage, packaging, delivery, or distribution of medications, and which collects, controls and maintains all transaction information. Every pharmacy that utilizes any such automated medication delivery system shall comply with the following.

5. PERSONNEL

The pharmacist-in-charge shall have the following responsibilities:

D. Assuring that the automated pharmacy system is in good working order and accurately delivers the correct strength, dosage form and quantity of the medication prescribed while maintaining appropriate record-keeping and security safeguards; and
E. Implementing an ongoing quality assurance program that monitors performance of the automated pharmacy system, which is evidenced by written policies and procedures developed by the pharmacy; and
F. Providing the Board with prior written notice of the installation or removal of any automated pharmacy system. Such notice must include the name and address of the pharmacy, the location of the automated equipment and the identification of the responsible pharmacist.

6. PHARMACY PRACTICE

Automated pharmacy systems can be utilized in permitted pharmacies, remote locations wherein patients are receiving pharmaceutical care by the pharmacist and/or pharmacy responsible for the automated pharmacy system, and other health care facilities, provided they are under the jurisdiction of the Board. The pharmacist-in-charge shall be responsible

for the following:

A. Documentation as to type of equipment, serial numbers, content, policies and procedures and location shall be maintained onsite in the pharmacy for review by the Board. Such documentation may include, but is not limited to:
   (1) Name and address of the pharmacy and/or licensed health care facility where the automated pharmacy system(s) is being used; and
   (2) Manufacturer's name and model; and
   (3) Description of how the device is used; and
   (4) Quality assurance procedures to determine continued appropriate use of the automated device; and
   (5) Policies and procedures for system operation, safety, security, accuracy, patient confidentiality, access and malfunction.
B. Automated pharmacy systems should be used only in settings where there is a program of pharmaceutical care which provides that medication orders are reviewed by a pharmacist in accordance with established policies and procedures. The delivery

of a “first dose” or an “emergency dose” may take place without prior order review by a pharmacist, provided appropriate security and patient medication management controls are in place.

C. All policies and procedures must be maintained in the pharmacy responsible for the system. If the system is not within the facility where the pharmacy is located, policies and procedures must be maintained at the location where the system is being used.

D. Automated pharmacy systems shall have adequate security systems and procedures, evidenced by written polices and procedures, to:
   (2) Prevent unauthorized access and to comply with federal and state regulations; and
   (3) Maintain patient confidentiality.

E. Records and/or electronic data kept by automated pharmacy systems shall meet the following requirements:
   (3) All events involving the contents of the automated pharmacy system must be recorded electronically; and
   (4) Records must be maintained by the pharmacy and must be readily available to the Board. Such records shall include:
      (a) Identity of system accessed; and
      (b) Identification of the individual accessing the system; and
      (c) Type of transaction; and
      (d) Name, strength, dosage form and quantity of the drug accessed and/or removed; and
      (e) Name of the patient for whom the drug was ordered and a record in the automated pharmacy system or other readily retrievable system of the name of the prescriber; and
      (f) Such additional information as the pharmacist-in-charge may deem necessary.

F. Access to, and limits on access (e.g. security levels) to the automated pharmacy system must be defined by policy and procedures and must comply with state and federal regulations.

G. The pharmacist-in-charge shall be responsible for:
   (4) Assigning, discontinuing or changing access to the system; and
   (5) Ensuring that access to the medications comply with state and federal regulations; and
   (6) Ensuring that the automated pharmacy system is filled/stocked/replenished accurately and in accordance with established written policies and procedures.

H. The filling/stocking/replenishing of all medications in the automated pharmacy system shall be accomplished by qualified personnel under the supervision of a pharmacist licensed by the Board.

I. A record of the medications filled/stocked/replenished in an automated pharmacy system shall be maintained for a period of two (2) years and shall include identification of the persons filling/stocking/replenishing and checking for accuracy.

J. All containers of medications stored in an automated pharmacy system shall be packaged and labeled in accordance with federal and state laws and regulations.

K. The automated pharmacy system must have the capability to produce a hard copy printout of the utilization of controlled substances maintained in each automated pharmacy system. All aspects of handling controlled substances shall meet the requirements of all state and federal laws and regulations.

L. The automated pharmacy systems shall provide a mechanism for securing and accounting for medications removed from and subsequently returning to the equipment, all in accordance with existing state and federal law.

M. The automated pharmacy system shall provide a mechanism for securing and accounting for wastage of medications or discarded medications in accordance with state and federal law and/or regulations.

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 serve~~s~~ 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) 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 XLI MEDICAL GAS WHOLESALERS PERMIT

1. Every person, business or other entity where medical gas(es) are maintained, bought, sold or distributed within this state shall obtain a permit as a medical gas wholesaler from the Mississippi Board of Pharmacy.

2. To obtain a permit or renew a permit for a medical gas wholesalers permit, the applicant shall:
   A. Submit a written application on a form prescribed by the Board;
   B. Submit the required fees as follows:
      Fifty dollars ($50.00) for the registration period January 1, 2012, through December 31, 2013, and each biennial registration period thereafter.

      A penalty of $50.00 shall be added to all late renewals postmarked after January 1, of each renewal period.

3. Every business issued a medical gas wholesalers permit shall renew this permit biennially. Newly issued permits which do not coincide with the registration period shall be valid for the following periods of time: If the permit is issued in the first half of the registration period, it must be renewed at the end of the registration period. If the permit is issued in the second half of the registration period, it must be renewed at the end of the next registration period.

4. The person who signs the application for a medical gas wholesalers permit or its renewal shall be the permit holder for that facility and shall be responsible for all activities in the permitted facility which are subject to regulation by the Board. Once issued, a permit cannot be amended, transferred or assigned to another person.

5. If the employment of a permit holder is terminated or if for any other reason he/she wishes to be relieved of the responsibilities of the permit holder, he/she must return the medical gas distributors permit to the Mississippi Board of Pharmacy with written notice that he/she is no longer the permit holder for that facility. When a permit is thus returned, application for a new permit for that facility must be made to the Mississippi Board of Pharmacy within ten (10) days.

6. If a permitted facility is permanently closed or has a change of ownership, the permit holder for that facility shall give notice to the Board of the effective date of closure or change in ownership at least ten (10) days prior to the closure or change of ownership.

7. If a permitted facility has a change in name or location, a new permit must be obtained. Application for this new permit must be made to the Board at least ten (10) days prior to the change.
8. All medical gas wholesalers permitted by the Mississippi Board of Pharmacy shall comply with the following:

A. A medical gas wholesaler shall distribute medical gases only to those persons authorized by state law to purchase, maintain, administer or use these products.
B. A medical gas wholesaler shall not distribute medical gases directly to a patient.
C. A medical gas wholesaler must maintain records of all acquisition and sales of medical gases for a period of two (2) years. Normal business records are sufficient.
D. A medical gas wholesaler who wishes to transfill medical gases shall register with the Food and Drug Administration and shall comply with all regulations and standards as required by such registration. All copies of any inspections conducted by the Food and Drug Administration shall be maintained and produced for review by any agent of the Mississippi Board of Pharmacy. A copy of the transfilling registration must be maintained on file.
E. A medical gas wholesaler shall properly store and transport any medical gas in compliance with all federal, state and local laws and regulations.
F. The Board of Pharmacy may refuse to issue or renew, or may suspend, revoke or restrict the permit of any medical gas wholesaler under the applicable provisions of ARTICLE IX of these regulations.

9. For purposes of these regulations “medical gas” means a liquid or gaseous substance used for medical purposes and that is required by federal law to bear the following statement: “Caution: Federal law prohibits dispensing without a prescription.” Medical gases may include, but not be limited to liquid oxygen, compressed oxygen and nitrous oxide.

ARTICLE XLII ADMINISTRATIVE PROCEDURE RULES

4. SCOPE

The following Rules of Procedure as contained in this ARTICLE shall apply to all pharmacists licensed by the Mississippi Board of Pharmacy and all other persons under the jurisdiction of said Board. The purpose of this ARTICLE is to implement and enforce the standards of pharmacy and pharmacy practice and conduct of all other persons under the jurisdiction of the Mississippi Board of Pharmacy as provided for in all state & federal drug laws, the Mississippi Pharmacy Practice Act and the Pharmacy Practice Regulations of the Mississippi Board of Pharmacy.

5. DEFINITIONS

For purposes of this ARTICLE the following definitions shall apply:

D. The word "Board" shall mean the Mississippi Board of Pharmacy.

E. The term “Investigative Staff” shall mean duly sworn Mississippi Board of Pharmacy Compliance Agents.

F. The term “Investigations Review Committee” shall mean a committee composed of two (2) members as designated by the Board to serve on a rotating, no longer than three-consecutive-month basis along with the Board’s Executive Director and counsel for the Board.

D. The word "Respondent" shall mean a pharmacist or other person against whom a disciplinary action and proceeding has been initiated by the Mississippi Board of Pharmacy.

G. Masculine terms, when used in the following Rules of Procedure, shall also be deemed to include the feminine.

H. The term “Mississippi Pharmacy Practice Act” shall mean Sections 73-21-71, et. seq. of the Mississippi Code of 1972, Annotated.

6. COMPLAINTS/INVESTIGATIONS

An investigation of alleged violation(s) of the Mississippi Pharmacy Practice Act may be initiated by the investigative staff of the Board either:

C. In response to a written complaint or adverse information received by the Board; or

D. Based on information independently developed by the investigative staff of the Board.

Upon receipt of information indicating possible violation of the Pharmacy Practice Act, the investigative staff, with advice and consultation of members of the Investigations Review Committee, shall make an initial determination as to whether the information justifies further investigation. A case may be dismissed without further investigation based on a determination of either:

C. Lack of jurisdiction; or

D. No violation of the Mississippi Pharmacy Practice Act.

4. INITIATION OF DISCIPLINARY ACTION

Upon conclusion of an investigation, the investigative staff shall present the results of the investigation to the Investigations Review Committee for review and action. Disciplinary action by the Board shall require the following:

C. A sworn affidavit filed with the Board charging a licensee, registrant or pharmacist-in-charge with an act which is grounds for discipline as provided for in Section 73-21-97, Mississippi Code of 1972, Annotated; and

D. An order of the investigations Review Committee which shall cause the Executive Director of the Board to fix a time and place for Hearing by the Board. Such Notice of Hearing and Complaint may be served by mailing a copy thereof by certified mail, postage prepaid, to the last known residence or business address of the licensee, registrant or pharmacist-in-charge.

5. ADMINISTRATIVE HEARINGS

Policies for the granting of a continuance are as follows:

A. Hearings shall be held before the Board at the time and place designated in the "Notice of Hearing and Complaint", unless a continuance is granted for just good cause by the Board. A motion for a continuance must be filed with the Board at least fifteen (15) days prior to the scheduled hearing, or upon a showing of good cause, at any time prior to the hearing; and

B. It must be recognized that the Board consists of seven (7) practicing pharmacists representing various regions of the State. Unlike the judiciary, the Board members are not in the business of conducting hearings, therefore hearings will be held only during regularly scheduled meetings or other dates established by the Board. Attorneys representing pharmacists should take this fact into consideration. A scheduled hearing may be continued if the Respondent shows substantial, legitimate grounds for continuing the hearing, based on the balance of:

(1) The right of Respondent to a reasonable opportunity to prepare and present a defense; and

(2) The Board's responsibility to protect the public health, safety and welfare.

C. Where the counsel for Respondent has a scheduling conflict on the initial hearing date, continuances will be liberally granted. However, Respondent's Counsel must submit written proof of the scheduling conflict fifteen (15) days prior to the scheduled hearing date. Thereafter, no further continuances will be granted based solely on scheduling conflicts; and

D. So that counsel for the Respondent and Complaint Counsel shall be able to adequately prepare for hearing, any motion for a continuance filed within the time limitations as specified in Subsection A above, will be immediately considered by the Board's President, who shall have the authority to grant or deny said motion. If granted, the Director of Compliance of the Board shall reschedule hearing at the earliest open date on the Board's calendar; and

E. It is the responsibility of the Respondent to make a prompt decision as to whether to appear before the Board without counsel or to retain counsel for this purpose.

Unless due to extraordinary circumstances, the Respondent's last minute decision to retain counsel will not be considered valid grounds for continuance of the matter.

6. SUBPOENAS

Policies for the issuance of subpoenas are as follows:

A. For the purpose of disciplinary hearings, the Board acting by and through its Executive Director, may subpoena persons and papers on its own behalf and on behalf of a Respondent.

B. Prior to the Board issuing any subpoena on behalf of a Respondent, the Respondent shall:

(1) File with the Board a written request for the issuance of said subpoenas, identifying with certainty the identity and address of all individuals to be subpoenaed, along with a concise description of the records to be subpoenaed with the identity and address of the custodian of said records; and

(2) All subpoenas issued by the Board on behalf of Respondent shall be hand delivered or effected by registered mail; and

(3) All requests for issuance of subpoenas shall be filed with the Board sufficiently distant in time to allow for the preparation and mailing of said subpoenas at least ten (10) working days before the scheduled hearing date. The Board shall not be responsible for the timely receipt of subpoenas issued after the aforementioned deadline.

C. The Board shall charge a Respondent a reasonable fee, not to exceed $25.00 per subpoena, for preparation and mailing of subpoenas.

7. INFORMAL SETTLEMENT, PRE-HEARING, STIPULATIONS, CONSENT ORDERS

Policies for informal settlements and consent orders are as follows:

A. All disciplinary proceedings initiated by the Board shall be brought to a final resolution through one of three means:

(1) Disciplinary hearings before the Board; or

(2) Acceptance by the Board of a mutually agreeable Consent Order in lieu of a hearing; or

(3) Dismissal of the case.

B. As to disciplinary proceedings wherein the Respondent has been duly served with a Notice of Hearing and Complaint, said Respondent and/or Respondent's Counsel may agree that an Informal Settlement Conference be held for the purpose of possible resolution of the matter or for purposes of simplifying the issues for hearing or promoting stipulations as to facts and proposed evidentiary offerings which will not be disputed at hearing.

C. The Informal Settlement Conference shall be conducted by Respondent and/or his counsel and Board Counsel. Other parties who may attend include Compliance Agents for the Board and Board members who served on the Investigations Review Committee (IRC) that authorized that a Notice of Hearing and Complaint

be issued in the matter. Other Board members may not attend or have knowledge or input into any activities of the Conference.

D. Discovery or exchange of information may be accomplished during the Informal Settlement Conference.

E. The Informal Settlement Conference may result in:

(1) Preparation of a proposed Consent Order as a resolution of the matter;

(2) Proceeding with the scheduled hearing.

F. Any action which the Board may take following a full disciplinary hearing may be taken in lieu thereof by Consent Order, Duly executed by the Respondent. Because of the lengthy dockets before the Board, informal Settlement Conferences must be held in sufficient time to allow consummation of negotiations of a Consent Order, at least ten (10) working days prior to the scheduled hearing date. After the terms of the Consent Order have been prepared and mutually accepted by Board Counsel, the investigating Compliance Agent and the two (2) IRC Board members that originally heard the matter, all terms of the Consent Order shall be binding on the Board. Said terms of the Consent Order are not effective until Board approval. Notwithstanding, it is still the responsibility of the Respondent to personally appear before the Board on the scheduled hearing date to answer any questions which the Board may have prior to Board approval.

G. Failure of the Board to approve and/or ratify any Consent Order shall result in an administrative hearing before the Board as originally scheduled in order to resolve all matters as outlined in the Notice of Hearing and Complaint.

H. Hearings for matters in which Consent Orders are considered by the Board, shall be conducted according to the Board's Rules of Procedures for Administrative Hearings.

11. DISCOVERY

Policies for discovery are as follows:

D. Upon written request by a Respondent or his counsel, Complaint Counsel of the Board shall disclose and permit Respondent or his counsel to inspect, copy or photograph the following information and material, which is in the possession, custody, or control of the Board, or the existence of which is known to the Complaint Counsel:

(7) Names and addresses of all witnesses proposed to be called in Complaint Counsel's case in chief, together with a copy of the contents of any statement, written, recorded, or otherwise preserved, of each such witness.

(8) Copies of any written or recorded statement of Respondent and the substance of any oral statement made by the Respondent.

(9) Copies of any criminal records of a Respondent, if proposed to be used.

(10) Any written reports or statements of experts, if proposed to be offered as evidence in connection with the particular case.

(11) All records, documents, physical evidence or photographs which may be offered as evidence.

(12) Any exculpatory material concerning the Respondent. The Board shall charge a Respondent a reasonable fee, not to exceed fifty cents per copy, payable in advance of delivery of copied documents.

E. The Board may deny disclosure authorized by subsection A if it finds that there is a substantial risk to any person of physical harm, intimidation, bribery, economic reprisals, or unnecessary embarrassment, resulting from such disclosure, which outweighs any usefulness of the disclosure to Respondent or his counsel.

F. If Respondent requests discovery under this rule, Respondent shall, promptly disclose to Complaint Counsel and permit him to inspect, copy or photograph, the following information and material which is in the possession, custody, or control of Respondent of his counsel, or the existence of which is known to Respondent or his counsel:

(4) Names and addresses of all witnesses proposed to be called in Respondent's defense together with a copy of the contents of any statement, written, recorded, or otherwise preserved, of each such witness.

(5) All records, documents, physical evidence or photographs which may be offered as evidence in Respondent's defense.

(6) Any written reports or statements of the experts, if proposed to be offered as evidence in connection with the particular case.

D. No depositions shall be taken in preparation for matters to be heard before the Board.

12. POLICIES FOR ADMINISTRATIVE HEARINGS

Procedures for administrative hearings are as follows:

A. Procedures are designed to give the accused the right to be heard in a fair and impartial hearing.

B. The President or Vice-President or Senior Member of the Board present shall act as the presiding officer and shall rule on all objections and motions. All such rulings are subject to the full Board's approval.

C. The Board is not bound by strict rules of evidence but all determinations must be based upon sufficient evidence.

D. All hearings are open to the public, however, public members shall not participate nor be present during any Executive Session of the Board.

E. The Executive Director, with the advice of the Board Counsel, will subpoena all witnesses for the Board or the defendant when requested to do so.

F. All charges shall be based upon affidavits sufficiently definite to constitute an allegation or specific violation of any law or regulation that governs pharmacists and the practice of pharmacy or any other person under the jurisdiction of the Board.

G. The Respondent has the right to appear either personally, by counsel, or both; to produce witnesses, cross-examine witnesses and have subpoenas issued by the Board.

H. A definite time and place shall be set with proper notice being given and a quorum present for all proceedings.

I. Board members who served on the Investigations Review Committee and who reviewed the investigation of the complaint that led to the administrative hearing, shall recuse themselves and not participate in the disciplinary proceeding.

J. All Board decisions are made in Executive Session.

L. A copy of these Board Rules of Procedure for Administrative Hearings shall be supplied to the Respondent along with the Notice of Hearing and Complaint.

13. PROCEDURES FOR ADMINISTRATIVE HEARINGS

Procedures for the conduct of administrative hearings are as follows:

A. The Hearing is called to order by the President or presiding officer.

B. President requests that the Respondent/counsel be called.

C. When Respondent appears, introductions are made and oaths administered to the Respondent and others, as may be necessary for proper conduct of the hearing.

D. The Respondent is then asked to state his/her name, address and license number and is informed that the hearing is being recorded.

E. If Respondent is represented by counsel, counsel name and address is entered into the record.

F. The President then asks Board Counsel to present the charges and place said charges into the record as appropriate.

G. Before going into the merits of the cause, evidence should be placed into the record showing that the Respondent was properly notified of the charges.

H. The Respondent is then asked to respond to the charges.

I. The Board Counsel may have witnesses called for the Board and shall conduct the direct examination of same.

(1) At the conclusion of the examination, the Respondent or Respondent’s Counsel may cross-examine.

(2) At the conclusion of the cross-examination, the Board may question the witness.

(3) At the conclusion of the witness' testimony, the witness may be excused subject to recall.

J. The Respondent may call witnesses after the Board has rested it's case. The Respondent or Respondent’s Counsel will conduct the direct examination.

(1) Board Counsel may cross-examine Respondent witness.

(2) Board members may then question Respondent witness.

(3) The witness may be excused subject to recall.

K. The Board may then call rebuttal witnesses.

L. Respondent or Respondent’s Counsel may make closing arguments if desired.

M. After all response has been presented by both sides, the Board by majority vote, shall enter into Executive Session to consider all evidence presented and make a final decision or ruling.

N. The Board shall make findings of fact on each charge. The Board should adjudicate each charge as presented, based on the evidence submitted.

O. The Board then determines what disciplinary action, if any, should be taken in the matter.

P. Following the Executive Session, the Respondent may or may not be informed of the Board's action. However, within thirty (30) days the Board shall reduce its decision to writing and include the Proceedings, Conclusions of Law, Findings of Fact and the Final Order of the Board. The Board shall forward an attested true copy thereof to the last known residence or business address of such licensee or permit holder by way of United States first-class, certified mail, postage prepaid.

ARTICLE XLIII PRESCRIPTION MONITORING PROGRAM

1. The Board of Pharmacy shall establish and maintain, with the consultation of the Prescription Monitoring Advisory Board, an electronic system for monitoring and tracking prescriptions dispensed for controlled substances listed in Schedules II, III, IV or V that are dispensed by a pharmacy.
   The Prescription Monitoring Program shall provide information regarding the inappropriate use of controlled substances in Schedule II, III, IV and V to pharmacies, practitioners and appropriate state or federal agencies in order to prevent the improper or illegal use of such controlled substances. This program shall not infringe on the legal use of controlled substances for the management of severe or intractable pain.
   The Board of Pharmacy will report any activity it reasonably suspects may be fraudulent or illegal to the appropriate law enforcement or regulatory board and provide them with relevant information obtained for further investigation.

2. A record of all controlled substance dispensing information shall be transmitted to the Prescription Monitoring Program on a time basis determined by the program by all pharmacies dispensing controlled substances (greater than a 48 hours supply) on an out-patient basis for the purpose of tracking the dispensing of Schedules II, III, IV and V controlled substances by the Prescription Monitoring Program. Dispensers will be required to collect and transmit the following information:

   (A) The recipient's name.
   (B) The recipient's or the recipient representative's identification number.
   (C) The recipient's date of birth.
   (D) The national drug code (NDC) number of the controlled substance dispensed.
   (E) The date the controlled substance is dispensed.
   (F) The quantity of the controlled substance dispensed.
   (G) The number of days supply dispensed.
   (H) The dispenser's NABP or NCPDP registration number.
   (I) The prescriber's U. S. DEA registration number.
   (J) The method of payment of the prescription purchase.

3. Each dispenser shall submit the required information as required by the Prescription Monitoring Program.

4. (a) Except as indicated in paragraphs (b), (c), and (d) of this Section, Prescription Monitoring Information submitted to the program shall be considered Protected Health Information and not subject to public or open record laws.
   (b) The program shall review the Prescription Monitoring Information. If there is reasonable cause to believe a violation of law or of occupational standards may have occurred, the program shall notify the appropriate law enforcement and/or occupational licensing, certification, or regulatory agency or entity, and provide Prescription Monitoring

information required for an investigation.
(c) The program may provide Prescription Monitoring Information for public research, policy or education purposes, to the extent all information has been de-identified.
(d) The Board of Pharmacy and the Prescription Monitoring Program shall be immune from civil liability arising from inaccuracy of any of the information submitted to the program pursuant to this act.

5. Disciplinary action for failure to submit drug monitoring information or knowingly submitting incorrect information shall be in accordance with Section 73-21-103, paragraph (1), (d), (v) of the Pharmacy Practice Act.

ARTICLE XLIV SEVERABILITY PROVISION

If any ARTICLE, Section, Paragraph, Sentence, Clause, Phrase, or any part of the above and foregoing Rules and Regulations of the Mississippi Board of Pharmacy is declared to be unconstitutional or void or for any reason is declared to be invalid or of no effect, the remaining ARTICLES, Sections, Paragraphs, Sentences, Clauses, Phrases, shall be in no manner affected thereby but shall remain in full force and effect.

ARTICLE XLV PHARMACY BENEFIT MANAGER

In addition to all other applicable sections of the Mississippi Code of 1972, ARTICLE XXLV of the Mississippi Board of Pharmacy Regulation pertains specifically to Pharmacy Benefit Managers.

1. DEFINITIONS

M. "Board" means the State Board of Pharmacy.

N. "Commissioner" means the Mississippi Commissioner of Insurance.

O. "Day" means a calendar day, unless otherwise defined or limited.

P. "Electronic claim" means the transmission of data for purposes of payment of covered prescription drugs, other products and supplies, and pharmacist services in an electronic data format specified by a pharmacy benefit manager and approved by the department.

Q. "Electronic adjudication" means the process of electronically receiving, reviewing and accepting or rejecting an electronic claim.

R. "Enrollee" means an individual who has been enrolled in a pharmacy benefit management plan.

S. "Health insurance plan" means benefits consisting of prescription drugs, other products and supplies, and pharmacist services provided directly, through insurance or reimbursement, or otherwise and including items and services paid for as prescription drugs, other products and supplies, and pharmacist services under any hospital or medical service policy or certificate, hospital or medical service plan contract, preferred provider organization agreement, or health maintenance organization contract offered by a health insurance issuer, unless preempted as an employee benefit plan under the Employee Retirement Income Security Act of 1974. However, "health insurance coverage" shall not include benefits due under the workers compensation laws of this or any other state.

T. "Pharmacy benefit manager" means a business that administers the prescription drug/device portion of pharmacy benefit management plans or health insurance plans on behalf of plan sponsors, insurance companies, unions and health maintenance organizations. For purposes of Sections 73-21-151 through 73-21-159, a "pharmacy benefit manager" shall not include an insurance company that provides an integrated health benefit plan and that does not separately contract for pharmacy benefit management services. The pharmacy benefit manager of the Mississippi State and School Employees Health Insurance Plan or the Mississippi Division of Medicaid or its contractors when performing services for the Division of Medicaid shall not be subject

to Sections 73-21-151 through 73-21-159 because of those activities, but, if they are conducting business as a pharmacy benefit manager other than with those agencies, they shall be subject to Sections 73-21-151 through 73-21-159 for those activities only.

U. "Pharmacy benefit management plan" means an arrangement for the delivery of pharmaceutical services in which a pharmacy benefit manager undertakes to administer the payment or reimbursement of any of the costs of pharmacist's services for an enrollee on a prepaid or insured basis which (i) contains one or more incentive arrangements intended to influence the cost or level of pharmaceutical services between the plan sponsor and one or more pharmacies with respect to the delivery of pharmacist's services; and (ii) requires or creates benefit payment differential incentives for enrollees to use under contract with the pharmacy benefit manager. A pharmacy benefit management plan does not mean any employee welfare benefit plan if preempted by the Employee Retirement Income Security Act of 1974, which is self-insured or self-funded, the Mississippi State and School Employees Health Insurance Plan or the programs operated by the Mississippi Division of Medicaid.

V. "Pharmacist", "pharmacist services" and "pharmacy" or "pharmacies" shall have the same definitions as provided in Section 73-21-73.

W. "Uniform claim form" means a form prescribed by rule by the State Board of Pharmacy, provided however that, for purposes of Sections 73-21-151 through 73-21-159, the board shall adopt the same definition or rule where the State Department of Insurance has adopted a rule covering the same type of claim. The board may modify the terminology of the rule and form when necessary to comply with the provisions of Sections 73-21-151 through 73-21-159.

X. "Plan sponsors" means the employers, insurance companies, unions and health maintenance organizations that contract with a pharmacy benefit manager for delivery of prescription services.

2. LICENSE REQUIRED BEFORE CONDUCTING BUSINESS AS PHARMACY BENEFIT MANAGER; PHARMACY BENEFIT MANAGERS TO FILE CERTAIN FINANCIAL STATEMENTS WITH STATE BOARD OF PHARMACY; TIME PERIOD FOR FILING STATEMENTS

H. Before beginning to do business as a pharmacy benefit manager, a pharmacy benefit manager shall obtain a license from the board. To obtain a license, the applicant shall submit an application to the board on a form prescribed by the board.

a. Contents of Application shall include:

i. The identity of the pharmacy benefits manager and any company or organization controlling the operation of the pharmacy benefits

manager, including the name, business address, and contact person, for the pharmacy benefit manager and the controlling entity.

ii. A "Certificate of Good Standing" from the Mississippi Secretary of State and, if applicable, a Mississippi "Certificate of Existence".

iii. In the case of pharmacy benefit managers domiciled out of the State of Mississippi, a certificate that the pharmacy benefits manager, company or organization is in good standing in the state of domicile or organization.

iv. A report of the details of any suspension, sanction, penalty or other disciplinary action relating to the pharmacy benefits manager, controlling company or organization, in the State of Mississippi or any other state, territory or country.

v. The pharmacy benefit manager shall report all previous and future data security breaches and HIPAA security breaches.

vi. The name and address of the agent of record or for services of process for the pharmacy benefit manager in Mississippi.

vii. A list of the pharmacy benefit manager's principal owners.

viii. The geographical services area of the pharmacy benefit manager.

ix. A list of all entities on whose behalf the pharmacy benefit manager has contracts or agreements to provide pharmacy benefit services.

x. The number of total enrollees or lives served under all of the pharmacy benefit manager's contracts or agreements in Mississippi and nationwide.

xi. A contingency plan describing how contracted pharmacy benefit services will be provided in the event of insolvency of the pharmacy benefit manager.

xii. The most recently concluded fiscal year-end financial statements for the pharmacy benefit manager and its controlling company or organization, which statements have been audited by an independent certified public accountant (CPA) under U.S. generally accepted accounting principles (GAAP).

xiii. The names and addresses of the public accounting firm and internal accountant(s) preparing or assisting in the preparation of such financial statements.

xiv. A certificate signed by the Chief Executive Officer of the pharmacy benefit manager attesting to the accuracy of the information contained in the filing.

xv. The Pharmacy Benefit Manager license shall be an annually renewable license expiring on January 1st of each calendar year.

xvi. A non-refundable license fee of $500.00 must accompany each application for the application to be considered complete.

xvii. 'Pro rata' pharmacy benefit manager licenses are not allowed by the Board.

xviii. A completed application for renewal of a Pharmacy Benefit Manager

license must be received at the offices of the Board no later than December 31st annually.

xix. In the event that a pharmacy benefit manager license renewal is received after December 31st, a $500.00 late fee will be assessed and payment must be received by the Board before a license will be issued.

xx. A monetary penalty of $1000.00 per day may be imposed upon any Pharmacy Benefit Manager that practices or conducts business in the State of Mississippi without a license.

I. The pharmacy benefit manager, including all contracted entities, shall operate to the best interest of the patient or citizen of Mississippi, including costs related to the patient or citizen.

J. Each pharmacy benefit manager providing pharmacy management benefit plans in this state shall file a statement with the board annually by March 1 or within sixty (60) days of the end of its fiscal year if not a calendar year. The statement shall be verified by at least two (2) principal officers and shall cover the preceding calendar year or the immediately preceding fiscal year of the pharmacy benefit manager.

K. The statement shall be on forms prescribed by the board and shall include:

a. A financial statement of the organization, including its balance sheet and income statement for the preceding year; and

b. Any other information relating to the operations of the pharmacy benefit manager required by the board under this section.

However, no pharmacy benefit manager shall be required to disclose proprietary information of any kind to the board.

L. If the pharmacy benefit manager is audited annually by an independent certified public accountant, a copy of the certified audit report shall be filed annually with the board by June 30 or within thirty (30) days of the report being final.

M. The board may extend the time prescribed for any pharmacy benefit manager for filing annual statements or other reports or exhibits of any kind for good cause shown. However, the board shall not extend the time for filing annual statements beyond sixty (60) days after the time prescribed by subsection (1) of this section. The board may waive the requirements for filing financial information for the pharmacy benefit manager if an affiliate of the pharmacy benefit manager is already required to file such information under current law with the Commissioner of Insurance and allow the pharmacy benefit manager to file a copy of documents containing such information with the board in lieu of the statement required by this section.

N. The expense of administering this section shall be assessed annually by the board against all pharmacy benefit managers operating in this state.

3. FINANCIAL EXAMINATION OF PHARMACY BENFIT MANAGER

E. In lieu of or in addition to making its own financial examination of a pharmacy benefit manager, the board may accept the report of a financial examination of other persons responsible for the pharmacy benefit manager under the laws of another state certified by the applicable official of such other state.

F. The board shall coordinate financial examinations of a pharmacy benefit manager that provides pharmacy management benefit plans in this state to ensure an appropriate level of regulatory oversight and to avoid any undue duplication of effort or regulation. The pharmacy benefit manager being examined shall pay the cost of the examination. The cost of the examination shall be deposited in a special fund that shall provide all expenses for the licensing, supervision and examination of all pharmacy benefit managers subject to regulation under Sections 73-21-71 through 73-21-129 and Sections 73-21-151 through 73-21-159.

G. The board may provide a copy of the financial examination to the person or entity that provides or operates the health insurance plan or to a pharmacist or pharmacy.

H. The board is authorized to hire independent financial consultants to conduct financial examinations of a pharmacy benefit manager and to expend funds collected under this section to pay the costs of such examinations.

4. CLEAN CLAIM

Most current nationally recognized reference price to be used in calculation of reimbursement for prescription drugs and other products and supplies; updating of reference price; time period for payment of benefits; "clean claim" defined; compliance; penalties

C. Reimbursement under a contract to a pharmacist or pharmacy for prescription drugs and other products and supplies that is calculated according to a formula that uses a nationally recognized reference in the pricing calculation shall use the most current nationally recognized reference price or amount in the actual or constructive possession of the pharmacy benefit manager, its agent, or any other party responsible for reimbursement for prescription drugs and other products and supplies on the date of electronic adjudication or on the date of service shown on the nonelectronic claim.

D. Pharmacy benefit managers, their agents and other parties responsible for reimbursement for prescription drugs and other products and supplies shall be required

to update the nationally recognized reference prices or amounts used for calculation of reimbursement for prescription drugs and other products and supplies no less than every three (3) business days.

C. All benefits payable under a pharmacy benefit management plan shall be paid within fifteen (15) days after receipt of due written proof of a clean claim where claims are submitted electronically, and shall be paid within thirty-five (35) days after receipt of due written proof of a clean claim where claims are submitted in paper format. Benefits due under the plan and claims are overdue if not paid within fifteen (15) days or thirty-five (35) days, whichever is applicable, after the pharmacy benefit manager receives a clean claim containing necessary information essential for the pharmacy benefit manager to administer preexisting condition, coordination of benefits and subrogation provisions under the plan sponsor's health insurance plan. A "clean claim" means a claim received by any pharmacy benefit manager for adjudication and which requires no further information, adjustment or alteration by the pharmacist or pharmacies or the insured in order to be processed and paid by the pharmacy benefit manager. A claim is clean if it has no defect or impropriety, including any lack of substantiating documentation, or particular circumstance requiring special treatment that prevents timely payment from being made on the claim under this subsection. A clean claim includes resubmitted claims with previously identified deficiencies corrected.

VI. A clean claim does not include any of the following:

(e) A duplicate claim, which means an original claim and its duplicate when the duplicate is filed within thirty (30) days of the original claim;

(f) Claims which are submitted fraudulently or that are based upon material misrepresentations;

(g) Claims that require information essential for the pharmacy benefit manager to administer preexisting condition, coordination of benefits or subrogation provisions under the plan sponsor's health insurance plan; or

(h) Claims submitted by a pharmacist or pharmacy more than thirty (30) days after the date of service; if the pharmacist or pharmacy does not submit the claim on behalf of the insured, then a claim is not clean when submitted more than thirty (30) days after the date of billing by the pharmacist or pharmacy to the insured.

II. Not later than fifteen (15) days after the date the pharmacy benefit manager actually receives an electronic claim, the pharmacy benefit manager shall pay the appropriate benefit in full, or any portion of the claim that is clean, and notify the pharmacist or pharmacy (where the claim is owed to the pharmacist or pharmacy) of the reasons why the claim or portion thereof is not clean and will not be paid and what substantiating documentation and information is required to adjudicate the claim as clean. Not later than thirty-five (35) days after the date the pharmacy benefit manager actually receives a paper claim, the pharmacy benefit manager shall pay the appropriate benefit in full, or any portion of the claim that is clean,

and notify the pharmacist or pharmacy (where the claim is owed to the pharmacist or pharmacy) of the reasons why the claim or portion thereof is not clean and will not be paid and what substantiating documentation and information is required to adjudicate the claim as clean. Any claim or portion thereof resubmitted with the supporting documentation and information requested by the pharmacy benefit manager shall be paid within twenty (20) days after receipt.

E. If the board finds that any pharmacy benefit manager, agent or other party responsible for reimbursement for prescription drugs and other products and supplies has not paid ninety-five percent (95%) of clean claims as defined in subsection (3) of this section received from all pharmacies in a calendar quarter, he shall be subject to administrative penalty of not more than Twenty-five Thousand Dollars ($ 25,000.00) to be assessed by the State Board of Pharmacy.

J. Examinations to determine compliance with this subsection may be conducted by the board. The board may contract with qualified impartial outside sources to assist in examinations to determine compliance. The expenses of any such examinations shall be paid by the pharmacy benefit manager examined.

VII. Nothing in the provisions of this section shall require a pharmacy benefit manager to pay claims that are not covered under the terms of a contract or policy of accident and sickness insurance or prepaid coverage.

VIII. If the claim is not denied for valid and proper reasons by the end of the applicable time period prescribed in this provision, the pharmacy benefit manager must pay the pharmacy (where the claim is owed to the pharmacy) or the patient (where the claim is owed to a patient) interest on accrued benefits at the rate of one and one-half percent (1- 1/2%) per month accruing from the day after payment was due on the amount of the benefits that remain unpaid until the claim is finally settled or adjudicated. Whenever interest due pursuant to this provision is less than One Dollar ($ 1.00), such amount shall be credited to the account of the person or entity to whom such amount is owed.

IX. Any pharmacy benefit manager and a pharmacy may enter into an express written agreement containing timely claim payment provisions which differ from, but are at least as stringent as, the provisions set forth under subsection (3) of this section, and in such case, the provisions of the written agreement shall govern the timely payment of claims by the pharmacy benefit manager to the pharmacy. If the express written agreement is silent as to any interest penalty where claims are not paid in accordance with the agreement, the interest penalty provision of subsection (4)(c) of this section shall apply.

X. The State Board of Pharmacy may adopt rules and regulations necessary to ensure compliance with this subsection.

5. AUDIT

DEFINITIONS:

G. "Entity" means a pharmacy benefit manager, a managed care company, a health plan sponsor, an insurance company, a third-party payor, or any company, group or agent that represents or is engaged by those entities.

H. "Health insurance plan" means benefits consisting of prescription drugs, other products and supplies, and pharmacist services provided directly, through insurance or reimbursement, or otherwise and including items and services paid for as prescription drugs, other products and supplies, and pharmacist services under any hospital or medical service policy or certificate, hospital or medical service plan contract, preferred provider organization agreement, or health maintenance organization contract offered by a health insurance issuer.

I. "Individual prescription" means the original prescription for a drug signed by the prescriber, and excludes refills referenced on the prescription.

J. "Pharmacy benefit manager" means a business that administers the prescription drug/device portion of pharmacy benefit management plans or health insurance plans on behalf of plan sponsors, insurance companies, unions and health maintenance organizations. Pharmacy benefit managers may also provide some, all, but may not be limited to, the following services either directly or through outsourcing or contracts with other entities:

(i) Adjudicate drug claims or any portion of the transaction.
(ii) Contract with retail and mail pharmacy networks.
(iii) Establish payment levels for pharmacies.
(iv) Develop formulary or drug list of covered therapies.
(v) Provide benefit design consultation.
(vi) Manage cost and utilization trends.
(vii) Contract for manufacturer rebates.
(viii) Provide fee-based clinical services to improve member care.
(ix) Third-party administration.

K. "Pharmacy benefit management plan" means an arrangement for the delivery of pharmacist's services in which a pharmacy benefit manager undertakes to administer the payment or reimbursement of any of the costs of pharmacist's services for an enrollee on a prepaid or insured basis that (i) contains one or more incentive arrangements intended to influence the cost or level of pharmacist's services between the plan sponsor and one or more pharmacies with respect to the delivery of pharmacist's services; and (ii) requires or creates benefit payment differential incentives for enrollees to use under contract with the pharmacy benefit manager.

L. "Pharmacist," "pharmacist services" and "pharmacy" or "pharmacies" shall have the same definitions as provided in Section 73-21-73.

Sections 73-21-175 through 73-21-189 shall apply to any audit of the records of a pharmacy conducted by a managed care company, nonprofit hospital or medical service organization, insurance company, third-party payor, pharmacy benefit manager, a health program administered by a department of the state or any entity that represents those companies, groups, or department.

II. Audit procedures; written report; report requirements

B. The entity conducting an audit shall follow these procedures:

xix. The pharmacy contract must identify and describe in detail the audit procedures;

xx. The entity conducting the on-site audit must give the pharmacy written notice at least two (2) weeks before conducting the initial on-site audit for each audit cycle, and the pharmacy shall have at least fourteen (14) days to respond to any desk audit requirements;

xxi. The entity conducting the on-site or desk audit shall not interfere with the delivery of pharmacist services to a patient and shall utilize every effort to minimize inconvenience and disruption to pharmacy operations during the audit process;

xxii. Any audit that involves clinical or professional judgment must be conducted by or in consultation with a pharmacist;

xxiii. Any clerical or record-keeping error, such as a typographical error, scrivener's error, or computer error, regarding a required document or record shall not constitute fraud; however, those claims may be subject to recoupment. No such claim shall be subject to criminal penalties without proof of intent to commit fraud;

xxiv. A pharmacy may use the records of a hospital, physician, or other authorized practitioner of the healing arts for drugs or medicinal supplies written or transmitted by any means of communication for purposes of validating the pharmacy record with respect to orders or refills of a legend or narcotic drug;

xxv. A finding of an overpayment or an underpayment may be a projection based on the number of patients served having a similar diagnosis or on the number of similar orders or refills for similar drugs, except that recoupment shall be based on the actual overpayment or underpayment;

xxvi. A finding of an overpayment shall not include the dispensing fee amount unless a prescription was not dispensed;

xxvii. Each pharmacy shall be audited under the same standards and parameters as other similarly situated pharmacies audited by the entity;

xxviii. The period covered by an audit may not exceed two (2) years from the date

the claim was submitted to or adjudicated by a managed care company, nonprofit hospital or medical service organization, insurance company, third-party payor, pharmacy benefit manager, a health program administered by a department of the state or any entity that represents those companies, groups, or department;

xxix. An audit may not be initiated or scheduled during the first five (5) calendar days of any month due to the high volume of prescriptions filled in the pharmacy during that time unless otherwise consented to by the pharmacy;

xxx. Any prescription that complies with state law and rule requirements may be used to validate claims in connection with prescriptions, refills or changes in prescriptions;

xxxi. An exit interview that provides a pharmacy with an opportunity to respond to questions and comment on and clarify findings must be conducted at the end of an audit. The time of the interview must be agreed to by the pharmacy;

xxxii. Unless superseded by state or federal law, auditors shall only have access to previous audit reports on a particular pharmacy conducted by the auditing entity for the same pharmacy benefits manager, health plan or insurer. An auditing vendor contracting with multiple pharmacy benefits managers or health insurance plans shall not use audit reports or other information gained from an audit on a particular pharmacy to conduct another audit for a different pharmacy benefits manager or health insurance plan;

xxxiii. The parameters of an audit must comply with consumer-oriented parameters based on manufacturer listings or recommendations for the following:

(c) The day supply for eyedrops must be calculated so that the consumer pays only one (1) thirty-day copayment if the bottle of eyedrops is intended by the manufacturer to be a thirty-day supply;

(d) The day supply for insulin must be calculated so that the highest dose prescribed is used to determine the day supply and consumer copayment;

xxxiv. The day supply for a topical product must be determined by the judgment of the pharmacist based upon the treated area;

xxxv. (a) Where an audit is for a specifically identified problem that has been disclosed to the pharmacy, the audit shall be limited to claims that are identified by prescription number;

(b) For an audit other than described in subparagraph (a) of this paragraph , an audit shall be limited to one hundred (100) individual prescriptions that have been randomly selected;

(c) If an audit reveals the necessity for a review of additional claims, the audit shall be conducted on site;

(d) Except for audits initiated under paragraph (a) of this subsection, an entity shall not initiate an audit of a pharmacy more than one (1) time in any quarter;

xxxvi. A recoupment shall not be based on:

(c) Documentation requirements in addition to or exceeding requirements for creating or maintaining documentation prescribed by the State Board of Pharmacy; or

(d) A requirement that a pharmacy or pharmacist perform a professional duty in addition to or exceeding professional duties prescribed by the State Board of Pharmacy;

xiv. Except for Medicare claims, approval of drug, prescriber or patient eligibility upon adjudication of a claim shall not be reversed unless the pharmacy or pharmacist obtained the adjudication by fraud or misrepresentation of claim elements; and

xv. A commission or other payment to an agent or employee of the entity conducting the audit is not based, directly or indirectly, on amounts recouped.

III. The entity must provide the pharmacy with a written report of the audit and comply with the following requirements:

H. The preliminary audit report must be delivered to the pharmacy within one hundred twenty (120) days after conclusion of the audit, with a reasonable extension to be granted upon request;

I. A pharmacy shall be allowed at least thirty (30) days following receipt of the preliminary audit report in which to produce documentation to address any discrepancy found during the audit, with a reasonable extension to be granted upon request;

J. A final audit report shall be delivered to the pharmacy within one hundred eighty (180) days after receipt of the preliminary audit report or final appeal, as provided for in Section 73-21-185, whichever is later;

K. The audit report must be signed by the auditor;

L. Recoupments of any disputed funds, or repayment of funds to the entity by the pharmacy if permitted pursuant to contractual agreement, shall occur after final internal disposition of the audit, including the appeals process as set forth in Section 73-21-185. If the identified discrepancy for an individual audit exceeds Twenty-five Thousand Dollars ($ 25,000.00), future payments in excess of that amount to the pharmacy may be withheld pending finalization of the audit;

M. Interest shall not accrue during the audit period; and

N. Each entity conducting an audit shall provide a copy of the final audit report, after completion of any review process, to the plan sponsor.

IV. Appeals; dismissal of audit report; mediation of unresolved issues

D. Each entity conducting an audit shall establish a written appeals process under which a pharmacy may appeal an unfavorable preliminary audit report to the entity.

E. If, following the appeal, the entity finds that an unfavorable audit report or any portion thereof is unsubstantiated, the entity shall dismiss the audit report or that portion without the necessity of any further action.

F. If, following the appeal, any of the issues raised in the appeal are not resolved to the satisfaction of either party, that party may ask for mediation of those unresolved issues. A certified mediator shall be chosen by agreement of the parties from the Court Annexed Mediators List maintained by the Mississippi Supreme Court.

V. Use of extrapolation in calculating recoupments or penalties prohibited:

Notwithstanding any other provision in Sections 73-21-175 through 73-21-189, the entity conducting the audit shall not use the accounting practice of extrapolation in calculating recoupments or penalties for audits. An extrapolation audit means an audit of a sample of prescription drug benefit claims submitted by a pharmacy to the entity conducting the audit that is then used to estimate audit results for a larger batch or group of claims not reviewed by the auditor.

VI. Limitation of applicability of Sections 73-21-175 through 73-21-189

Sections 73-21-175 through 73-21-189 do not apply to any audit, review or investigation that involves alleged fraud, willful misrepresentation or abuse.

VII. Penalty for noncompliance:

D. The State Board of Pharmacy may impose a monetary penalty on pharmacy benefit managers for noncompliance with the provisions of the Pharmacy Audit Integrity Act, Sections 73-21-175 through 73-21-189, in amounts of not less than One Thousand Dollars ($ 1,000.00) per violation and not more than Twenty-five Thousand Dollars ($ 25,000.00) per violation. The board shall prepare a record entered upon its minutes which states the basic facts upon which the monetary penalty was imposed. Any penalty collected under this subsection (1) shall be deposited into the special fund of the board.

E. The board may assess a monetary penalty for those reasonable costs that are expended by the board in the investigation and conduct of a proceeding if the board imposes a monetary penalty under subsection (1) of this section. A monetary penalty assessed and levied under this section shall be paid to the board by the licensee, registrant or permit holder upon the expiration of the period allowed for appeal of those penalties under Section 73-21-101, or may be paid sooner if the licensee, registrant or permit holder elects. Money collected by the board under this subsection (2) shall be deposited to the credit of the special fund of the board.

F. When payment of a monetary penalty assessed and levied by the board against a licensee, registrant or permit holder in accordance with this section is not paid by the licensee, registrant or permit holder when due under this section, the board shall have the power to institute and maintain proceedings in its name for enforcement of payment in the chancery court of the county and judicial district of residence of the licensee, registrant or permit holder, or if the licensee, registrant or permit holder is a nonresident of the State of Mississippi, in the Chancery Court of the First Judicial District of Hinds County, Mississippi. When those proceedings are instituted, the board shall certify the record of its proceedings, together with all documents and evidence, to the chancery court and the matter shall be heard in due course by the court, which shall review the record and make its determination thereon in accordance with the provisions of Section 73-21-101. The hearing on the matter may, in the discretion of the chancellor, be tried in vacation.

TITLE 30: PROFESSIONS AND OCCUPATIONS

PART 3002: ADMINISTRATIVE RULES

MISSISSIPPI BOARD OF PHARMACY
ADMINISTRATIVE RULES
AS REQUIRED BY MISSISSIPPI ADMINISTRATIVE PROCEDURES LAW

III. METHOD OF OPERATION

1.Structure and Enabling Statutes

SEC. 73-21-75. State board of pharmacy; number, qualifications, appointment and terms of members; filling of vacancies; removal of members.

(1) The State Board of Pharmacy created by former Section 73-21-9 is hereby continued and reconstituted as follows: The board shall consist of seven (7) appointed members. At least one (1) appointment shall be made from each congressional district. Each appointed member of the board shall be appointed by the Governor, with the advice and consent of the Senate, from a list of five (5) names submitted by the Mississippi State Pharmaceutical Association/Mississippi Pharmacists Association. Of the members appointed, one (1) shall, at the time of appointment, have had five (5) years' experience as a pharmacist at a facility holding an institutional permit, and one (1) shall, at the time of appointment, have had five (5) years' experience as a pharmacist at a facility holding a retail permit. Any person appointed to the board shall be limited to two (2) full terms of office during any fifteen-year period, including any member serving on May 14, 1992.
(2) The members of the board appointed and serving prior to July 1, 1983, whose terms have not expired by July 1, 1983, shall serve the balance of their terms as members of the reconstituted board, and they shall be considered to be from the same congressional districts from which they were originally appointed if they still reside therein, even if the district boundaries have changed subsequent to their original appointments. The Governor shall appoint the remaining members of the reconstituted board in the manner prescribed in subsection (1) of this section on July 1, 1983. The initial members of the reconstituted board shall serve terms of office as follows:

(a) The term of the member from the First Congressional District shall expire on July 1, 1984; and from and after July 1, 1996, this appointment shall be designated as Post 1.

(b) The term of the member from the Second Congressional District shall expire on July 1, 1988; and from and after July 1, 1996, this appointment

shall be designated as Post 2.

(c)The term of the member from the Third Congressional District shall expire on July 1, 1986; and from and after July 1, 1996, this appointment shall be designated as Post 3.

(d) The term of the member from the Fourth Congressional District shall expire on July 1, 1985; and from and after July 1, 1996, this appointment shall be designated as Post 4.

(e) The term of the member from the Fifth Congressional District shall expire on July 1, 1987; and from and after July 1, 1996, this appointment shall be designated as Post 5.

(f) The term of one (1) of the members from the state at large shall expire on July 1, 1985; and from and after July 1, 1996, this appointment shall be designated as Post 6.

(g) The term of the other member from the state at large shall expire on July 1, 1988; and from and after July 1, 1996, this appointment shall be designated as Post 7.

(3) At the expiration of a term, members of the board shall be appointed in the manner prescribed in subsection (1) of this section for terms of five (5) years from the expiration date of the previous terms. Any vacancy on the board prior to the expiration of a term for any reason, including resignation, removal, disqualification, death or disability, shall be filled by appointment of the Governor in the manner prescribed in subsection (1) of this section for the balance of the unexpired term. The Mississippi State Pharmaceutical Association/Mississippi Pharmacists Association shall submit a list of nominees no more than thirty (30) days after a vacancy occurs, and the Governor shall fill such vacancies within ninety (90) days after each such vacancy occurs.

(4) To be qualified to be a member of the board, a person shall:

(a) Be an adult citizen of Mississippi for a period of at least five (5) years preceding his appointment to the board;

(b) Be a pharmacist licensed and in good standing to practice pharmacy in the State of Mississippi;

(c) Have at least five (5) years' experience as a pharmacist; and

(d) Be actively engaged full time in the practice of pharmacy in Mississippi.

(5) The Governor may remove any or all members of the board on proof of unprofessional conduct, continued absence from the state, or for failure to perform the duties of his office. Any member who shall not attend two (2) consecutive meetings of the board for any reason other than illness of such member shall be subject to removal by the Governor. The president of the board shall notify the Governor in writing when any such member has failed to attend two (2) consecutive regular meetings. No removal shall be made without first giving the accused an opportunity to be heard in refutation of the charges made against him, and he shall be entitled to receive a copy

of the charges at the time of filing.

SOURCES: Laws, 1983, ch. 414, Sec. 3; 1991, ch. 527, Sec. 3; 1992, ch. 531 Sec. 1; reenacted, 1993, ch. 416, Sec. 4; 1995, ch. 513, Sec. 2, eff from and after July 1, 1995

SEC. 73-21-77. Organization of board; oath; meetings; compensation and expenses of members.

(1) Each person appointed as a member of the board shall qualify by taking the oath prescribed by the Constitution for the state officers, and shall file certificate thereof in the office of the Secretary of State within fifteen (15) days after his appointment.
(2) There shall be a president of the board and such other officers as deemed necessary by the board elected by and from its membership.
(3) The board shall meet at least once each quarter to transact business, and may meet at such additional times as it may deem necessary. Such additional meetings may be called by the president of the board or a majority of the members of the board.
(4) The place for each meeting shall be determined prior to giving notice of such meeting and shall not be changed after such notice is given without adequate subsequent notice.
(5) A majority of the members of the board shall constitute a quorum for the conduct of the meeting and all actions of the board shall be by a majority.
(6) Each member of the board shall receive a per diem as provided in Section 25-3-69, not to exceed thirty (30) days in any one (1) period of twelve (12) months, for each day actually engaged in meetings of the board, together with necessary traveling and other expenses as provided in Section 25-3-41.

SOURCES: Laws, 1983, ch. 414, Sec. 4; reenacted without change, 1991, ch. 527, Sec. 4; 1992, ch. 531 Sec. 2; reenacted, 1993, ch. 416, Sec. 5, eff from and after passage (approved March 18, 1993).

SEC. 73-21-79. Executive director; additional employees; legal counsel.

(1) The board shall employ an executive director of the board. The executive director shall be a citizen of Mississippi and a pharmacist licensed and in good standing to practice pharmacy in the State of Mississippi, who has had five (5) years' experience as a pharmacist.
(2) The executive director shall receive a salary to be set by the board,

subject to the approval of the State Personnel Board, and shall be entitled to necessary expenses incurred in the performance of his official duties. He shall devote full time to the duties of his office and shall not be interested directly or indirectly as defined in Section 73-21-73 in the operation of a pharmacy in Mississippi or any other facility permitted by the board or engaged in any other business that will interfere with the duties of his office.
(3) The duties and responsibilities of the executive director shall be defined by rules and regulations prescribed by the board.
(4) The board may, in its discretion, employ persons in addition to the executive director in such other positions or capacities as it deems necessary to the proper conduct of board business. Any pharmacist-investigator employed by the board may have other part-time employment, provided that he shall not accept any employment that would cause a conflict of interest in his pharmacist-investigator duties. The board may employ legal counsel to assist in the conduct of its business.

SOURCES: Laws, 1983, ch. 414, Sec. 5; reenacted without change, 1991, ch. 527, Sec. 5; 1992, ch. 531 Sec. 3; 1993, ch. 416, Sec. 6, eff from and after passage (approved March 18, 1993).

SEC. 73-21-81. General powers and duties of board; enforcement of chapter; rules and regulations.

The responsibility for the enforcement of the provisions of this chapter shall be vested in the board. The board shall have all of the duties, powers and authority specifically granted by and necessary to the enforcement of this chapter. The board may make, adopt, amend and repeal such rules and regulations as may be deemed necessary by the board from time to time for the proper administration and enforcement of this chapter, in accordance with the provisions of the Mississippi Administrative Procedures Law (sections 25-43-1 et seq.).

SOURCES: Laws, 1983, ch. 414, Sec. 6; reenacted without change, 1991, ch.

527, Sec. 6; reenacted without change, 1993, ch. 416, Sec. 7, eff from and after passage (approved March 18, 1993).

SEC. 73-21-83. Board to regulate practice of pharmacy; licensing of pharmacists; fees; persons holding license on July 1, 1991.

(1) The board shall be responsible for the control and regulation of the practice of pharmacy, to include the regulation of pharmacy externs or interns and pharmacist technicians in this state, the regulation of the

wholesaler distribution of drugs and devices as defined in Section 73-21-73, and the distribution of sample drugs or devices by manufacturer's distributors as defined in Section 73-21-73 by persons other than the original manufacturer or distributor in this state.
(2) A license for the practice of pharmacy shall be obtained by all persons prior to their engaging in the practice of pharmacy. However, the provisions of this chapter shall not apply to physicians, dentists, veterinarians, osteopaths or other practitioners of the healing arts who are licensed under the laws of the State of Mississippi and are authorized to dispense and administer prescription drugs in the course of their professional practice.
(3) The initial licensure fee shall be set by the board but shall not exceed Two Hundred Dollars ($200.00).
(4) All students actively enrolled in a professional school of pharmacy accredited by the American Council on Pharmaceutical Education who are making satisfactory progress toward graduation and who act as an extern or intern under the direct supervision of a pharmacist in a location permitted by the Board of Pharmacy must obtain a pharmacy student registration prior to engaging in said activity. The student registration fee shall be set by the board but shall not exceed One Hundred Dollars ($100.00).
(5) All persons licensed to practice pharmacy prior to July 1, 1991, by the State Board of Pharmacy under Section 73-21-89 shall continue to be licensed under the provisions of Section 73-21-91.

SOURCES: Laws, 1983, ch. 414, Sec. 7; 1991, ch. 527, Sec. 7; 1993, ch. 416, Sec. 8; 1994, ch. 513, Sec. 2, eff from and after July 1, 1994; 1997, ch. 441, Sec. 1, eff July 1, 1997.

2.Public Information. The public may obtain information regarding operations and responsibilities of the Mississippi Board of Pharmacy, the Pharmacy Practice Act and Board Regulations and other pertinent information by contacting the Board office at 204 Key Drive, Suite C, Madison, Mississippi 39110, 601-605-5388. Additional information is available on the Mississippi Board of Pharmacy Website at www.mbp.state.ms.us.

IV. FORMAL AND INFORMAL PROCEEDINGS

MISSISSIPPI BOARD OF PHARMACY

RULES OF PROCEDURE

I. SCOPE

The following Rules of Procedure shall apply to all pharmacists licensed by the Mississippi Board of Pharmacy and all other persons under the jurisdiction of said Board.

II. PURPOSE

A. To implement and enforce the standards of pharmacy and pharmacy practice and conduct of all other persons under the jurisdiction of the Mississippi Board of Pharmacy as provided for in all state & federal drug laws, the Mississippi Pharmacy Practice Act and the Pharmacy Practice Regulations of the Mississippi Board of Pharmacy.

III. DEFINITIONS

A. The word "Board" shall mean the Mississippi Board of Pharmacy.

B. The word "Respondent" shall mean a pharmacist or other person against whom a disciplinary action and proceeding has been initiated by the Mississippi Board of Pharmacy.

C. Masculine terms, when used in the following Rules of Procedure, shall also be deemed to include the feminine.

IV. ADMINISTRATIVE HEARINGS

1. CONTINUANCES

A. Hearings shall be held before the Board at the time and place designated in the "Notice of Hearing and Complaint", unless a continuance is granted for just good cause by the Board. A motion for a continuance must be filed with the Board at least fifteen (15) days prior to the scheduled hearing, or upon a showing of good cause, at any time prior to the hearing.

B. It must be recognized that the Board consists of seven (7) practicing pharmacists representing various regions of the State. Unlike the judiciary, the Board members are not in the business of conducting hearings, therefore hearings will be held only during regularly scheduled meetings or other dates established by the Board. Attorneys representing pharmacists should take this fact into consideration. A scheduled hearing may be continued if the Respondent shows substantial, legitimate grounds for continuing the hearing, based on the balance of:

(1) The right of Respondent to a reasonable opportunity to prepare and present a defense; and

(2) The Board's responsibility to protect the public health, safety and welfare.

C. Where the counsel for Respondent has a scheduling conflict on the initial hearing date, continuances will be liberally granted. However, Respondent's counsel must submit written proof of the scheduling conflict fifteen (15) days prior to the scheduled hearing date. Thereafter, no further continuances will be granted based solely on scheduling conflicts.

D. So that counsel for the Respondent and Complaint Counsel shall be able to adequately prepare for hearing, any motion for a continuance filed within the time limitations as specified in Subsection A above, will be immediately considered by the Board's President, who shall have the authority to grant or deny said motion. If Granted the order will be presented to the Board at the scheduled hearing date at which time the order will be formally entered and the rescheduled hearing date set.

E. It is the responsibility of the Respondent to make a prompt decision as to whether to appear before the Board without counsel or to retain counsel for this purpose.

Unless due to extraordinary circumstances, the Board will not consider as a valid ground for continuance, the Respondent's last minute decision to retain counsel.

2. POLICIES FOR ADMINISTRATIVE HEARINGS

A. Procedures are designed to give the accused the right to be heard in a fair and impartial hearing.

B. The President or the Senior Member of the Board present is the presiding officer and he/she rules on all objections and motions, subject to the Board's approval.

C. The Board is not bound by strict rules of evidence but all determinations must be based upon sufficient evidence.

D. All hearings are open to the public, however, public members may not participate nor be present for Executive Sessions.

E. The Executive Director, with the advice of the Board Counsel, will subpoena all witnesses for the Board or the defendant when requested.

F. All charges shall be based upon affidavits sufficiently definite to constitute allegation or specific violation of the laws and regulations that govern pharmacists and the practice of pharmacy.

G. The respondent has the right to appear either personally, by counsel, or both; to produce witnesses, cross-examine witnesses and have subpoenas issued by the Board.

H. A definite time and place shall be set with proper notice being given and a quorum present for all proceedings.

I. Board members who served on the Investigations Review Committee and who reviewed the investigation of the complaint that led to the administrative hearing, shall recuse themselves and not participate in the disciplinary proceeding.

J. All Board decisions are made in Executive Session.

K. A copy of these Board Rules of Procedure for Administrative Hearings shall be supplied to the respondent along with the Notice of Hearing and Complaint.

3. PROCEDURES FOR ADMINISTRATIVE HEARINGS

A. The Hearing is called to order by the President or presiding officer.

B. President requests that the respondent/counsel be called.

C. When respondent appears, introductions are made and oaths administered to respondent and others as may be necessary for proper conduct of the hearing.

D. The respondent is then asked to state his/her name, address and license number. He/she is also informed that the hearing is being recorded.

E. If respondent is represented by counsel, counsel name and address is entered into the record.

F. The President then asks Board counsel to present the charges and place same into the record as appropriate.

G. Before going into the merits of the cause, evidence should be placed into the record showing that the respondent was properly notified of the charges.

H. The respondent is then asked to respond to the charges.

I. The Board counsel may have witnesses called for the Board and he/she shall conduct the direct examination of same.

(1) At the conclusion of the examination, the respondent or respondents counsel

may cross-examine.
(2) At the conclusion of the cross-examination, the Board may question the witness.
(3) At the conclusion of the witness' testimony, the witness may be excused subject to recall.

J. The respondent may call his/her witnesses after Board has rested its case. The respondent or respondent's counsel will conduct the direct examination.
(1) Board Counsel may cross-examine respondent witness.
(2) Board members may then question respondent witness.
(3) The witness may be excused subject to recall.

K. The Board may then call rebuttal witnesses.

L. Respondent/counsel may make closing argument if desired.

M. After all response has been presented by both sides, the Board goes into Executive Session to consider all evidence presented and make a final decision or ruling.

N. The Board shall make findings of fact on each charge. The Board should adjudicate each charge as presented, based on the evidence submitted.

O. The Board then determines what disciplinary action, if any, should be taken in the matter.

P. Following the Executive Session, the respondent may or may not be informed of the Board's action, however, the action is always reduced to writing and notification may include Proceedings, Conclusions of Law, Findings of Fact and the Order of the Board.

V. INFORMAL SETTLEMENT, PRE-HEARING, STIPULATIONS, CONSENT ORDERS

A. All disciplinary proceedings initiated by the Board shall be brought to a final resolution through one of three means:
1. Disciplinary hearings before the Board; or
2. Acceptance by the Board of a mutually agreeable Consent Order in lieu of a hearing; or
3. Dismissal of the case.

B. As to disciplinary proceedings duly served by a Notice of Hearing and Complaint, Respondent and/or Respondent's Counsel may agree that an Informal Settlement Conference be held for the purpose of possible resolution of the matter or for purposes of simplifying the issues for hearing or promoting stipulations as to facts and proposed evidentiary offerings which will not be disputed at hearing.

C. The Informal Settlement Conference shall be conducted by Respondent and/or his counsel and Board Counsel. Other parties who may attend include Compliance Agents for the Board and Board members who served on the Investigations Review Committee (IRC) that authorized that a Notice of Hearing and Complaint be issued in the matter. Other Board members may not attend or have knowledge or input into any activities of the Conference.

D. Discovery or exchange of information may be accomplished during the Informal Settlement Conference.

E. The Informal Settlement Conference may result in:
   1. Preparation of a proposed Consent Order as a resolution of the matter;
   2. Proceed with the scheduled hearing.

F. Any action which the Board may take following a full disciplinary hearing may be taken in lieu thereof by Consent Order, Duly executed by the Respondent. Because of the lengthy dockets before the Board, informal Settlement Conferences must be held in sufficient time to allow consummation of negotiations of a Consent Order, at least ten (10) working days prior to the scheduled hearing date. After the terms of the Consent Order have been prepared and mutually accepted by Board Counsel, the investigating Compliance Agent and the two (2) IRC Board members that originally heard the matter, it shall be binding on the Board, but not effective until Board approval. Notwithstanding, it is still the responsibility of the Respondent to personally appear before the Board on the scheduled hearing date to answer any questions which the Board may have prior to Board approval.

G. Failure of the Board to approve and/or ratify any Consent Order shall result in an administrative hearing before the Board as originally scheduled in order to resolve all matters as outlined in the Notice of Hearing and Complaint.

H. Hearings for matters in which Consent Orders are considered by the Board shall be conducted according to the Board's Rules of Procedures for Administrative Hearings.

VI. SUBPOENAS

A. For the purpose of disciplinary hearings, the Board acting by and through its Executive Director, may subpoena persons and papers on its own behalf and on behalf of a Respondent.

B. Before the Board shall issue on behalf of a Respondent any subpoena for person or papers, the Respondent shall;
   1. File with the Board a written request for the issuance of said subpoenas, identifying with certainty the identity and address of all individuals to be subpoenaed, along with a concise description of the records to be subpoenaed with the identity and address of the custodian of said records.
   2. All subpoenas issued by the Board on behalf of Respondent shall be affected by registered mail.
   3. All requests for issuance of subpoenas shall be filed with the Board sufficiently distant in time to allow for the preparation and mailing of said subpoenas at least ten (10) working days before the scheduled hearing date. The Board shall not be responsible for the timely receipt of subpoenas issued after the aforementioned deadline.

C. The Board shall charge a Respondent a reasonable fee, not to exceed $25.00 per subpoena, for preparation and mailing of subpoenas.

8.

9. **III. ORAL PROCEEDINGS ON PROPOSED REGULATIONS**

1.Scope. These rules set forth the Mississippi Board of Pharmacy, hereinafter "Board," rules governing the form and content of requests for all oral proceedings held for the purpose of providing the public with an opportunity to make oral presentations on proposed new regulations and amendments to regulations before the Board pursuant to §25-43-3.104.

2.When Oral Proceedings will be Scheduled on Proposed Regulations. The Board will conduct an oral proceeding on a proposed regulation or amendment if requested by a political subdivision, an agency or ten (10) persons in writing within twenty (20) days after the filing of the notice of the proposed regulation.

3. Request Format. Each request must be printed or typewritten, or must be in legible handwriting. Each request must be submitted on standard business letter-size paper (8-1/2 inches by 11 inches). Requests may be in the form of a letter addressed to the Board and signed by the requestor(s).

4. Notification of Oral Proceeding. The date, time and place of all oral proceedings shall be filed with the Secretary of State's office and mailed to each requestor. The oral proceedings will be scheduled no earlier than twenty (20) days from the filing of this information with the Secretary of State.

5. Presiding Officer. The Board President or his designee, who is familiar with the substance of the proposed regulation, shall preside at the oral proceeding on a proposed regulation.

6. Public Presentations and Participation.

(a) At an oral proceeding on a proposed regulation, persons may make oral statements and make documentary and physical submissions, which may include data, views, comments or arguments concerning the proposed regulation.

(b) Persons wishing to make oral presentations at such a proceeding shall notify the Board at least one business day prior to the proceeding and indicate the general subject of their presentations. The presiding officer in his or her discretion may allow individuals to participate that have not previously contacted the Board.

(c) At the proceeding, those who participate shall indicate their names and addresses, identify any persons or organizations they may represent, and provide any other information relating to their participation deemed appropriate by the presiding officer.

(d) The presiding officer may place time limitations on individual oral presentations when necessary to assure the orderly and expeditious conduct of the oral proceeding. To encourage joint oral presentations and to avoid repetition, additional time may be provided for persons whose presentations represent the views of other individuals as well as their own views.

(e) Persons making oral presentations are encouraged to avoid restating matters that have already been submitted in writing.

(f) There shall be no interruption of a participant who has been given the floor by the presiding officer, except that the presiding officer may in his or her discretion interrupt or end the partisan's time where the orderly conduct of the proceeding so requires.

7. Conduct of Oral Proceeding.

(a) Presiding officer. The presiding officer shall have authority to conduct the proceeding in his or her discretion for the orderly conduct of the proceeding. The presiding officer shall (i) call proceeding to order; (ii) give a brief synopsis of the proposed regulation, a statement of the statutory authority for the proposed regulation, and the reasons provided by the Board for the proposed regulation; (ii)call on those individuals who have contacted the Board about speaking on or against the proposed regulation; (iii) allow for rebuttal statements following all participant's comments; (iv) adjourn the proceeding.

(b) Questions. The presiding officer, where time permits and to facilitate the exchange of information, may open the floor to questions or general discussion. The presiding officer may question participants and permit the questioning of participants by other participants about any matter relating to that regulation-making proceeding, including any prior written submissions made by those participants in that proceeding; but no participant shall be required to answer any question.

(c) Physical and Documentary Submissions. Submissions presented by participants in an oral proceeding shall be submitted to the presiding officer. Such submissions become the property of the Board and are subject to the Board's public records request procedure.

(d) Recording. The Board may record oral proceedings by stenographic or electronic means.

V. DECLARATORY OPINIONS

1. Scope. These rules set forth the Mississippi Board of Pharmacy, hereinafter "Board," rules governing the form and content of requests for declaratory opinions, and the Board's procedures regarding the requests, as required by Mississippi Code § 25-43-2.103. These rules are intended to supplement and be read in conjunction with the provisions of the Mississippi Administrative Procedures Law, which may contain additional information regarding the issuance of declaratory opinions. In the event of any conflict between these rules and the Mississippi Administrative Procedures Law, the latter shall govern.

2. Persons Who May Request Declaratory Opinions. Any person with a substantial interest in the subject matter may request a declaratory opinion from the Board by following the specified procedures. "Substantial interest in the subject matter" means: an individual, business, group or other entity that is directly affected by the Board's administration of the laws within its primary jurisdiction. "Primary jurisdiction of the Board" means the Board has a constitutional or statutory grant of authority in the subject matter at issue.

3. Subjects Which May Be Addressed In Declaratory Opinions. The Board will issue declaratory opinions regarding the applicability to specified facts of: (1) a statute administered or enforceable by the Board or (2) a regulation promulgated by the Board. The Board will not issue

a declaratory opinion regarding a statute or regulation which is outside the primary jurisdiction of the Board.

4. Circumstances In which Declaratory Opinions Will Not Be Issued. The Board may, for good cause, refuse to issue a declaratory opinion. The circumstances in which declaratory opinions will not be issued include, but are not necessarily limited to:

(a) lack of clarity concerning the question presented;

(b) there is pending or anticipated litigation, administrative action, or other adjudication which may either answer the question presented by the request or otherwise make an answer unnecessary;

(c) the statute or regulation on which a declaratory opinion is sought is clear and not in need of interpretation to answer the question presented by the request;

(d) the facts presented in the request are not sufficient to answer the question presented;

(e) the request fails to contain information required by these rules or the requestor failed to follow the procedure set forth in these rules;

(f) the request seeks to resolve issues which have become moot, or are abstract or hypothetical such that the requestor is not substantially affected by the statute or regulation on which a declaratory opinion is sought;

(g) no controversy exists concerning the issue as the requestor is not faced with existing facts or those certain to arise which raise a question concerning the application of the statute or regulation;

(h) the question presented by the request concerns the legal validity of a statute or rule;

(i) the request is not based upon facts calculated to aid in the planning of future conduct but is, instead, based on past conduct in an effort to establish the effect of that conduct;

(j) no clear answer is determinable;

(k) the question presented by the request involves the application of a criminal statute or a sets of facts which may constitute a crime;

(l) the answer to the question presented would require the disclosure of information which is privileged or otherwise protected by law from disclosure;

(m) The question is currently the subject of an Attorney General's opinion request or has been answered by an Attorney General's opinion;

(n) A similar request is pending before this Board or any other agency or a proceeding is pending on the same subject matter before any agency, administrative or judicial tribunal, or where such a opinion would constitute the unauthorized practice of law.

(o) Where issuance of a declaratory opinion may adversely affect the interests of the State, the Board or any of their officers or employees in any litigation which is pending or may reasonably be expected to arise;

(p) The question involves eligibility for a license, permit, registration or other approval by the Board or some other agency, and there is a statutory or regulatory application process by which eligibility for said license, permit, registration or other approval would be determined.

5. Written Request Required. Each request must be printed or typewritten, or must be in legible handwriting. Each request must be submitted on standard business letter-size paper (8-1/2 inches by 11 inches). Requests may be in the form of a letter addressed to the Board.

6. Where to Send Requests. All requests must be mailed, delivered or transmitted via facsimile to the Board. The request shall clearly state that it is a request for a declaratory opinion. No oral, telephone requests or email requests will be accepted for official opinions.

7. Name, Address and Signature of Requestor. Each request must include the full name, telephone number, and mailing address of the requestor. All requests shall be signed by the person filing the request, who shall attest that the request complies with the requirements set forth in these rules, including but not limited to a full, complete, and accurate statement of relevant facts and that there are no related proceedings pending before any other administrative or judicial tribunal.

8. Question Presented. Each request shall contain the following:

(a) a clear and concise statement of all facts on which the opinion is requested;

(b) a citation to the statute or regulation at issue;

(c) the question(s) sought to be answered in the opinion, stated clearly;

(d) a suggested proposed opinion from the requestor, stating the answers desired by petitioner and a summary of the reasons in support of those answers;

(e) the identity of all other known persons involved in or impacted by the described factual situation, including their relationship to the facts, name, mailing address and telephone number; and

(f) a statement to show that the person seeking the opinion has a substantial interest in the subject matter.

10. Time for Board's Response. Within forty-five (45) days after the receipt of a request for a declaratory opinion which complies with the requirements of these rules, the Board shall, in writing:

(a) issue a declaratory opinion regarding the specified statute or regulation as applied to the specified circumstances;

(b) decline to issue a declaratory opinion, stating the reasons for its action; or

(c) agree to issue a declaratory opinion by a specified time but not later than ninety (90) days after receipt of the written request;

The forty-five (45) day period shall begin running on the first State of Mississippi business day on or after the request is received by the Board, whichever is sooner.

11. Opinion Not Final for Sixty Days. A declaratory opinion shall not become final until the expiration of sixty (60) days after the issuance of the opinion. Prior to the expiration of sixty (60) days, the Board may, in its discretion, withdraw or amend the declaratory opinion for any reason which is not arbitrary or capricious. Reasons for withdrawing or amending an opinion include, but are not limited to, a determination that the request failed to meet the requirements of these rules or that the opinion issued contains a legal or factual error.

12. Notice by Board to third parties. The Board may give notice to any person, agency or entity that a declaratory opinion has been requested and may receive and consider data, facts, arguments and opinions from other persons, agencies or other entities other than the requestor.

13. Public Availability of Requests and Declaratory Opinions. Declaratory opinions and requests for declaratory opinions shall be available for public inspection and copying in accordance with the Public Records Act and the Board's public records request procedure. All declaratory opinions and requests shall be indexed by name and subject. Declaratory opinions and requests which contain information which is confidential or exempt from disclosure under the Mississippi Public Records Act or other laws shall be exempt from this requirement and shall remain confidential.

14. Effect of a Declaratory Opinion. The Board will not pursue any civil, criminal or administrative action against a person who is issued a declaratory opinion from the Board and who, in good faith, follows the direction of the opinion and acts in accordance therewith unless a court of competent jurisdiction holds that the opinion is manifestly wrong. Any declaratory opinion rendered by the Board shall be binding only on the Board and the person to whom the opinion is issued. No declaratory opinion will be used as precedent for any other transaction or occurrence beyond that set forth by the requesting person.