TITLE 30: PROFESSIONS AND OCCUPATIONS

PART 3001: MISSISSIPPI PHARMACY PRACTICE REGULATIONS

MISSISSIPPI PHARMACY PRACTICE REGULATIONS

Mississippi Board of Pharmacy
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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 or online 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 a check or money order for an additional twenty-

five dollars.

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 (601-889-8880) immediately upon discovery;
(2) Within forty-eight hours of 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 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

When a pharmacist-in-charge is terminated or relinquishes the responsibilities of the pharmacist-in-charge, he/she must 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 with the effective date of the change and a complete inventory of controlled substances performed at the time of the change. If the outgoing pharmacist-in-charge cannot or does not properly inform the Board of the change, the responsibility of notification shall be that of the incoming 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 pursuant to DEA regulations.

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 an application on the Official Application for Transfer of Pharmacist 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 this 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;
   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 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;
   D. May at the discretion of the Board appear before the Board of Pharmacy and demonstrate adequate spoken English Language skills;
   E. Have paid all fees specified by the Board for examination;
   F. Have successfully passed an examination approved by the Board;
   G. Have completed sixteen hundred hours of extern/internship hours approved by the Board;
   H. Have paid the initial licensure fee, not to exceed two-hundred dollars ($200.00).

4. Pursuant to the Military Family Freedom Act:
   A. The Board shall issue a license to an applicant who is a member of the military, or an applicant who is married to or is a dependent of a member of the military, if, upon application, the applicant satisfies the following conditions:
      (a) Has been awarded a military occupational specialty, completed a military program of training, completed testing or equivalent training and experience, and performed in the occupational specialty of a pharmacist; or
      (b) Holds a current and valid pharmacist license in another state for at least one (1) year; and
      (c) Has not committed any act in any jurisdiction that would have constituted grounds for

refusal, suspension or revocation of a license to practice pharmacy in this state at the time the act was committed, the pharmacy board in the other state holds the applicant in good standing, and the applicant does not have a disqualifying criminal record as determined by this Board; and

(d) Did not surrender a license because of negligence or intentional misconduct related to the applicant's work as a pharmacist in another state; and

(e) Does not have a complaint, allegation or investigation pending before a pharmacy board or other board in another state that relates to unprofessional conduct or an alleged crime. If the applicant has a complaint, allegation or investigation pending, this Board shall not issue or deny a license to the applicant until the complaint, allegation or investigation is resolved, or the applicant otherwise satisfies the criteria for licensure in Mississippi to the satisfaction of this Board; and

(f) Pays all required fees and complies with the all the procedures for licensure transfer as set forth in paragraph (2) of this Article. An applicant pursuant to section (A), subsection (a) of this paragraph shall not be required to comply with section (B) of paragraph (2) of this Article.

B. The Board shall issue a license to an applicant who is a member of the military, or an applicant who is married to or is a dependent of a member of the military, upon application based on work experience in another state, if all the following apply:

(a) The applicant has worked in a state that does not use a license to regulate the practice of pharmacy;

(b) The applicant has worked for at least three (3) years as a pharmacist; and

(c) The applicant satisfies the provisions of subsections (c) through (f) of paragraph (4) section (A) of this Article.

C. The Board shall issue or deny a license to an applicant pursuant to the Military Family Freedom Act within one hundred twenty (120) days after receiving an application. If the application requires longer than two (2) weeks to process, the Board shall issue a temporary practice license within thirty (30) days after receiving the application if the applicant submits an affidavit, under penalties of perjury, affirming that he or she satisfies the provisions of the Military Family Freedom Act and pays all applicable fees as required. The applicant may practice under the temporary permit until a license is granted, or until a notice to deny the license is issued, in accordance with rules adopted by this Board. A temporary license will expire in three hundred sixty-five (365) days after its issuance if the applicant fails to pass the MPJE.

D. Appeal of Board Decisions pursuant to the Military Family Freedom Act.

(a) An applicant may appeal any of the following decisions of the Board to a court of general jurisdiction:

(i) Denial of a license;

(ii) Determination of the occupation;

(iii) Determination of the similarity of the scope of practice of the license issued; or

(iv) Other determinations under this section.

(b) The court shall determine all questions of law, including the interpretation of a constitutional or statutory provision or a rule adopted by the Board without regard to any previous determination that may have been made on the question in any action before the Board.

E. The Board shall prominently print the following on all license applications, any communication denying a license, and on the Board's website: "Pursuant to the provisions

of the Military Family Freedom Act, Mississippi shall recognize pharmacist licenses obtained from other states for military members and their families". The Board shall prepare and place on the Board's website an annual report detailing the number of applications submitted to the Board under the Military Family Freedom Act during a calendar year and the actions taken by the Board on the applications.

F. Nothing in this Article shall be construed to prohibit a military applicant, spouse or dependent from proceeding under the existing licensure requirements established by the Board.

5. 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. The examination shall consist of the North American Pharmacist Licensure Examination (NAPLEX) and the Multi-State Pharmacy Jurisprudence Examination (MPJE). 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 must make a score of at least seventy-five (75) on the NAPLEX and a score of at least seventy-five (75) on the MPJE to successfully pass the examination. A person who fails the examination may repeat the examination no more than four (4) times without permission from the Board. 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.
6. A pharmacist that surrenders his/her license is no longer eligible to practice pharmacy without petitioning the Board to re-instate his/her license.

TITLE 30, PART 3001, ARTICLE II: PHARMACY BOARD EXAMINATION REPEALED. EFFECTIVE 07/06/2021

ARTICLE III PHARMACY EXTERN/INTERN REGISTRATION AND PRACTICAL EXPERIENCE REQUIREMENT

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. Have a school of pharmacy that is approved by the Board provide proof of enrollment;
   D. Have paid fees as specified by the Board.

2. A pharmacy extern/intern registration which has been issued by the Board shall expire:
   A. If the extern/intern is expelled, suspended, withdraws or is dismissed from a school of pharmacy;

B. One (1) year after graduation from a school of pharmacy;
C. One year after being issued by the Board if the extern/intern registration is issued to an applicant for the purpose of obtaining extern/intern hours for reinstatement of a pharmacist license;

An Extern/Intern who is expelled, suspended, dismissed or withdraws from a school of pharmacy may not register as a pharmacy technician until one (1) year from the date his/her extern/intern registration expiration, unless approved by the Board pursuant to a petition.

3. A pharmacy extern/intern may petition the Board for renewal of the registration for a period not to exceed one additional year.

4. The externship/internship practical experience required for licensure is defined as a total of sixteen hundred (1,600) hours of pharmacy experience. The 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.

5. 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.

6. 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. Practical experience hours obtained in Mississippi will expire two (2) years after graduation.

7. 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. 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; and verification that these hours are currently acceptable for a license in the state where the practical 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 this Article, 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.

8. In addition to any other provisions of these regulations, the Board may impose disciplinary action upon an extern/intern for one or more of the following grounds:
   A. Fraud or intentional misrepresentation by an 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;
   B. Obtaining practical experience in a pharmacy permitted by the Board without the direct supervision and presence of a pharmacist licensed by the Board;
   C. Failure to notify the Board of expulsion, suspension, dismissal or withdrawal from a school of pharmacy;
   D. Violation of any university, college, or school of pharmacy policies, rules or regulations thereof.
   E. Knowing or suspecting that a Pharmacist or Pharmacy Intern is incapable of engaging in the 3 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.
   F. The unlawful disclosure of information from the Prescription Monitoring Program or using information obtained from the Prescription Monitoring Program for unlawful or unethical purposes.
9. An Extern/Intern shall notify the Board immediately of any change of residence or change in enrollment status including delayed progression within the program.

10. An Extern/Intern that surrenders his/her registration is no longer eligible to work as an extern/intern without petitioning the Board to re-instate his/her registration.

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:
    i. Fifteen (15) hours of continuing education is required for each licensure period.
    ii. At least two (2) hours of the continuing education received each year must be related to opioid abuse and prevention or some other drug of abuse or addiction related issue.
    iii. At least two (2) hours of the continuing education received each year must be obtained via a live seminar. Live webcasts are valid for this requirement.
    iv. A pharmacist licensed by the Mississippi Board of Pharmacy must be a registered user of the Prescription Monitoring Program.
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 1st shall be considered invalid and the pharmacist is prohibited from providing pharmacy services until the license is renewed.

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. Obtain an intern registration and 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 fifteen (15) 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 fifteen (15) 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, all continuing education hours shall be:

A. Programs which have been approved by the Accreditation Council for Pharmacy Education (A.C.P.E.); or
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 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 may 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 in-service 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. Failure of a pharmacist licensed by the Mississippi Board of Pharmacy to register as a user of the Prescription Monitoring Program.
V. Failing to submit prescription monitoring information to the Prescription Monitoring Program within the time interval prescribed.
W. The unlawful disclosure of information from the Prescription Monitoring Program or using information obtained from the Prescription Monitoring Program for unlawful or unethical purposes.
X. Failure to produce continuing educations credits within required time period set forth in these regulations.
Y. 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 PRACTICE OF 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 from the Mississippi Board of Pharmacy. Effective January 1, 2016, every location 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; or
E. Pharmacy Advisory Services.
F. Sterile Product Outsourcing

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 an institutional facility 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.
An Institutional I Pharmacy shall also include Out-Patient surgery facilities which maintain, dispense and administer medications, devices and other materials in treatment and diagnosis of injury, illness and disease.

(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;
(7) 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.

E. Pharmacy Advisory Services shall include locations where a pharmacist engages in certain professional advisory services as authorized under the definition of the Practice of Pharmacy.

Various types of Advisory Services Permits may be recognized as follows:

Professional Services 1 – Pharmacists advise and provide pharmacotherapeutic consultations concerning therapeutic values, content, hazards and uses of drugs and devices. Initiate or modify drug therapy in accordance with written guidelines or protocols previously established and approved by the Board. Order lab work in accordance with written guidelines or protocols as defined by Section 73-21-73, paragraph (jj), Mississippi Code of 1972. Such services do not apply to Medication Therapy Management (MTM) conducted under a Pharmacy Permit at the permitted location. The permit must be obtained for the location in compliance with zoning requirements of the city or municipality and may not be located in a residence. A stock of drugs or devices may not be maintained or distributed from this location.

Professional Services 2 – Pharmacists advise and provide pharmacotherapeutic consultations concerning therapeutic values, content, hazards and uses of drugs and devices. Initiate or modify drug therapy in accordance with written guidelines or protocols previously established and approved by the Board. Order lab work in accordance with written guidelines or protocols as defined by Section 73-21-73, paragraph (jj), Mississippi Code of 1972. Such services do not apply to medication therapy management conducted under a Pharmacy Permit at the permitted location. The permit must be obtained for the location in compliance with zoning requirements of the city or municipality and may not be located in a residence. A pharmacist may assist in maintaining and distribution of medications provided to the patients from a manufacturer patient assistance program that assists medically indigent persons to obtain their prescription medications only.

Professional Services Outpatient Surgery Center – A pharmacist supervises appropriate documentation of administration, wastage and disposal of medications in accordance with documented policies and procedures of the facility. The Medical Director of the facility is responsible for obtaining the Drug Enforcement Administration (DEA) registration number for the facility and compliance with applicable DEA regulations.

F. Sterile Product Outsourcing shall mean the compounding and distribution of sterile medications both in-state and out-of-state in accordance with FDA guidelines. The facility must apply for a Human Drug Compounding Outsourcing Registration from the U. S. Food and Drug Administration (FDA) and must comply with applicable FDA Current Good Manufacturing Practice requirements and other applicable guidelines. Facilities are subject to inspection by FDA on a risk-based schedule. Facilities must be in compliance with applicable U. S. Drug Enforcement Administration (DEA) regulations. On the application for Sterile Product Outsourcing, the Pharmacist-In-Charge must certify that the facility is in full compliance all applicable FDA and DEA regulations and guidelines. The facility may not hold a pharmacy permit within the same location as an Outsourcer.

3. To obtain a pharmacy permit or sterile product outsourcing permit or renew a 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 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. To obtain a Pharmacy Advisory Services permit or renew a 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:
   One hundred dollars ($100.00) for the registration period January 1, 2014 through December 31, 2015, and each biennial registration period thereafter.
   C. Any 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.

5. 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.

6. 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.

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

8. 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.

9. A pharmacy permit shall not be required for the sale or delivery of dialysate solutions or devices necessary to perform home peritoneal renal dialysis to patients with end stage renal disease, provided the following criteria are met:
   A. The dialysate solutions or devices are approved or cleared by the Food and Drug Administration (FDA), as required by federal law;
   B. The dialysate solutions or devices are lawfully held by a manufacturer or a manufacturer's agent that is properly registered with the Mississippi Board of Pharmacy as a manufacturer, wholesale drug distributor (WDD) or third-party logistics provider (3PL) under Mississippi Code Section 73-21-105;
   C. The dialysate solutions or devices are held and delivered in their original, sealed packaging from the manufacturing facility;
   D. The dialysate solutions or devices are delivered only upon a receipt of a valid prescription by a pharmacy permitted by the Mississippi Board of Pharmacy and the transmittal of an order from the pharmacy to the manufacturer or the manufacturer's agent;
   E. The manufacturer or the manufacturer's agent delivers the dialysate solutions or devices directly to:
      i) A patient with chronic kidney failure, or his/her designee, for the patient's self-administration or the dialysis therapy, or
      ii) A health care provider or institution for administration or delivery of the dialysis therapy to a patient with chronic kidney failure.

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 (unless the Board grants a waiver upon presentation of good cause) 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. Responsibilities of the Pharmacist-in-Charge:
   (1) That each individual workspace is designed to provide space and a workflow 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 shall be maintained to meet the demands of the practice site, workload and the clientele served; and
   (4) 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
   (5) 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.
   (6) A PIC shall be required to be physically onsite at the pharmacy a minimum of twenty (20) hours per work week or fifty per cent (50%) of the hours of operation of the pharmacy, whichever is less. A record of the onsite hours of the PIC shall be produced upon request by the Board or an agent of the Board. Exceptions will be recognized for practical reasons, i.e., vacation, sick time, etc...

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 shall not be issued or renewed unless the pharmacist-in-charge is 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 fifteen (15) days. Failure to submit an application for a new PIC within fifteen (15) days shall render the permit inactive and the pharmacy shall cease doing business in the state until a new permit is issued to a new PIC.

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 fifteen (15) 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 business's 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 fifteen (15) 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 or orally prescribed medication orders or 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 medications for ambulatory (or outpatients):
      (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 or computerized order entry system is used, pharmacy technicians may enter information into the database and prepare labels, but it

shall be the responsibility of the pharmacist to verify the accuracy of the information entered and the prescription information produced;

(4) When refilling a prescription, it shall be the responsibility of the pharmacist to make the determination whether or not to refill the prescription;

(5) A pharmacist shall not actively supervise more than three pharmacy technicians at one time. Externs/Interns are not included in this quota calculation;

(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 supervise 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 properly labeled and identify the responsible supervising pharmacist.

E. In the event of a loss or suspected loss of a controlled substance, it is the responsibility of the discovering pharmacist to report the loss or suspected loss directly to the Board at the time of discovery.

F. In the interest of the public health the pharmacist shall, where appropriate, counsel patients and review their medication profiles to improve patient understanding and compliance.

2. Patient Records:

A. A system for documenting medications, prescribed and dispensed, shall be maintained by all pharmacies licensed to dispense medications. The patient record system shall allow 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 displaying 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.

F. A pharmacist may refuse to fill a prescription for a variety of reasons outlined within these regulations. Additionally, a pharmacist may decline to fill or refill a prescription or provide a service when the costs of providing those products or services exceeds the reimbursement obtained from a third-party payer. If a pharmacist declines to fill a prescription or provide a service because the costs associated with suppling the product or service exceeds the reimbursement for the product or service, he/she shall provide the patient with a list of pharmacies in the area that may provide the product or service.

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 and attest that they will comply with the established policies and procedures.

All pharmacies, pharmacists, pharmacy technicians, and other pharmacy employees shall attest that they will 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 assess 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/RECORDKEEPING

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. 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 patient's choice; and
      (2) be transmitted by an authorized Practitioner or his or her designated agent
   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. Except as provided below, 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. For non-controlled maintenance medications only, a pharmacist, exercising his/her professional judgment, may dispense additional dosage units authorized by the prescriber on the original prescription including refills.
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. Orders for non-controlled medications authorized for patients in LTC facilities are recognized as prescriptions and are valid until the order is discontinued.
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

Prescription Records shall be filed in one of the following ways:

1. All paper prescriptions and prescriptions received via facsimile shall be considered hard copy prescriptions.
2. Hard copy original prescriptions for **schedule** drugs received as paper or faxed shall be maintained in a hard copy (paper) format file with Schedule II prescriptions being kept separate from all other prescriptions.
3. Upon request by an agent of the Board, any prescription not maintained in a paper file must be printed and provided to the agent immediately. Failure to print and produce the requested prescriptions may result in disciplinary action by the Board.
4. All original prescriptions, whether maintained manually or in a data processing system, shall be assigned a serial number and maintained by the pharmacy in numerical order. All prescriptions shall be maintained for at least six (6) years from the date of original dispensing.

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 noncontrolled drugs may be transferred orally by telephone or electronically (to include facsimile) at the request of the patient or authorized agent 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. If pharmacies share a common computerized system, one pharmacist may perform all required actions, but this shall be limited to once per patient prescription.

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

Partial filling of Schedule II controlled substance prescriptions shall be as follows:

1. Partial Fills: A prescription for a controlled substance in schedule II may be partially filled if:
    a. it is not prohibited by Mississippi law;
    b. the prescription is written and filled in accordance with United States Code, Title 21, Chapter 13, Subchapter 1, any regulations prescribed by the United States Attorney General, and Mississippi law;
    c. the partial fill is requested by the patient or the practitioner that wrote the prescription; and
    d. the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed.
2. Remaining portions
    a. In general, except as provided in subparagraphs b and c, the remaining portions of a partially filled prescription for a controlled substance in schedule II:
        i. May be filled; and
        ii. Shall be filled not later than thirty (30) days after the date on which the prescription is written.
    b. In emergency situations, as described in 21 U.S.C. §829 (a), the remaining portions of a partially filled prescription for a controlled substance in schedule II:
        i. May be filled; and
        ii. Shall be filled not later than seventy-two (72) hours after the prescription is issued.
    c. If the patient is terminally ill or a long term care facility patient, the remaining portions of a partially filled prescription for a controlled substance in schedule II:
        i. May be filled;

ii. Shall be filled not later than sixty (60) days after the prescription is issued; and
iii. The prescription must comply with the provisions of Title 21, Chapter 2, CFR 1306.13

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 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 fourteen (14) 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. A facility may conduct the controlled substance inventory at another date so long as the annual inventory is conducted during the same period each year. 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

Section 1. Purpose and Scope.

The Practice of Nuclear/Radiologic Pharmacy is hereby recognized as a specialty of Pharmacy practice, regulated by the State Boards of Pharmacy. As such, the following rules are included to address those areas specific or unique to this specialty practice.

Nuclear/Radiologic Pharmacy Practice refers to a patient oriented 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 Drugs.

Section 2. 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) "Internal test assessment" means, but is not limited to, conducting those tests of quality assurance necessary to ensure the integrity of the test.

(c) "Nuclear pharmacy" means a Pharmacy providing radiopharmaceutical services or, an appropriate area of any Institutional Facility. These services include but are not limited to storing, preparing, compounding, dispensing, labeling or distributing radiopharmaceuticals.

(d) "Authorized Nuclear Pharmacist" (NP) means a currently licensed pharmacist in the state of Mississippi who is licensed by the Mississippi State Department of Health, Division of Radiological Health or by a certification Board recognized by the State Board of Pharmacy, 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 or the United States Nuclear Regulatory Commission or Agreement State Agency, with emphasis in the following areas:

(i) Radiation Physics and Instrumentation;

(ii) Radiation Protection;

(iii) Mathematics of Radioactivity;

(iv) Radiation Biology;
(v) Radiopharmaceutical Chemistry.

(3) Attained a minimum of five hundred (500) hours of clinical nuclear pharmacy training under the supervision of an authorized nuclear pharmacist.

(e) "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 and animals including internal test assessment, authentication of product history and the keeping of proper records. 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 fulfills professional expectations and requirements.

(f) "Radiopharmaceutical Service" means, but shall not be limited to the procurement, storage, handling, compounding, preparing, Labeling, quality assurance testing, Dispensing, Delivery, recordkeeping, and disposal of radiopharmaceuticals and other drugs.

(g) "Radiopharmaceuticals" are radioactive drugs as defined by the Food and Drug Administration and the Mississippi State Board of Pharmacy.

(h) Practice of Nuclear Pharmacy means a patient oriented 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.

(i) Nuclear Pharmacy Technician (NPT) means a person who works under the supervision of an Authorized Nuclear Pharmacist, who is currently registered with the Mississippi Board of Pharmacy, and has successfully completed a training program affiliated with a public/private learning institution or a company sponsored Nuclear Pharmacy Technician training program.

(j) Protocol Order is an order for a prescription diagnostic radiopharmaceutical that an Authorized User Physician has instituted at his/her institution or clinic via a written order/protocol for specific drug products for diagnostic use. This type of protocol order is analogous to a refill order, and therefore can be taken by a nuclear pharmacy technician. Therapeutic agents do not qualify as medication reorders.

(k) STAT/Emergency Order means an order or protocol order that must leave the nuclear pharmacy in less than 60 minutes or as fast as reasonably achievable.

(l) Therapeutic Order means a prescription drug order that is intended to treat an illness or condition of a patient and requires pharmacist judgement and therefore should be discussed with an ANP prior to order entry. Therapeutic Orders cannot be taken by an NPT.

Section 3. General Requirements for Pharmacies Providing Radiopharmaceutical Services.

(a) Nuclear Pharmacy License. A license to operate a pharmacy providing radiopharmaceutical services shall only be issued to an Authorized Nuclear Pharmacist. All personnel performing tasks in the preparation and distribution of radioactive Drugs

shall be under the direct supervision of an Authorized Nuclear Pharmacist. An Authorized Nuclear Pharmacist shall be responsible for all operations of the Pharmacy and shall be in personal attendance at all times that the Pharmacy is open for business. In the event an ANP has to leave the pharmacy while the Pharmacy is open for business, the restricted area and all prescription products have to be secured from unauthorized access

(b) Nuclear pharmacies shall have adequate space and equipment, commensurate with the scope of services required and provided, meeting minimal space requirements established for all pharmacies in the State or as otherwise defined by the Mississippi State Board of Pharmacy.

(c) The Nuclear Pharmacy area shall be secured from unauthorized personnel.

(d) Nuclear pharmacies shall maintain 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. Detailed floor plans shall be submitted to the State Board of Pharmacy and the Mississippi State Department of Health, Division of Radiological Health before approval of the license.

(f) Radiopharmaceuticals are to be Dispensed only upon receipt of a Prescription Drug Order or protocol order, from an Authorized User 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.

(g) 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 and are exempt from the electronic ordering clause.

(h) All prescriptions/orders shall be readily retrievable if requested by any governing agency.

(i) The permit to operate a Nuclear Pharmacy is conditioned upon an approved State Radiation Control Agency (RCA) or NRC license. Copies of the RCA or NRC inspection reports shall be made available upon request for Board inspection.

(j) Labeling

(1) No radiopharmaceutical may be Dispensed unless a label is affixed to the immediate container bearing the following information:

(i) the standard radiation symbol;

(ii) the words “Caution—Radioactive Material”;

(iii) for all therapeutic and blood-products, the patient name/identifier;

(iv) the patient name or “per physician order”

(v) the prescription number.

(2) No radiopharmaceutical may be Dispensed unless a label is affixed to the outer or Delivery container bearing the following information;

(i) the standard radiation symbol;

(ii) the words “Caution—Radioactive Material”;

(iii) for all therapeutic and blood-products, the patient name/identifier;

(iv) the radionuclide and chemical form;

(v) the radioactivity and date and time of calibration;
(vi) the volume or number of units dispensed (e.g., 2 capsules), as applicable;
(vii) product expiration or BUD, as applicable, and any special storage and handling instructions for non-immediate use (e.g., refrigeration resuspension);
(viii) the prescription number;
(ix) the patient name provided by the entity ordering the drug. If no patient name is given then the words, "per physician order" shall appear on the prescription.
(x) the name and address of the nuclear Pharmacy;
(xi) the name of the Practitioner; and
(xii) the lot number of the prescription.

Section 4. Other requirements

(a) All Nuclear/Radiologic Pharmacies shall also adhere to the principles outlined in the Rules for Pharmacist Care as these pertain to the practice of Nuclear Pharmacy.
(b) Radiopharmaceuticals shall only be handled in conformity with the standards of USP General Chapter <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging unless stated otherwise in this ARTICLE.
(c) 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.
(d) A pharmacy exclusively handling radiopharmaceuticals may be exempt from the general requirements of conventional pharmacies as regards to equipment and inventory.
(e) Written procedure 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 MATERIALS 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.

ARTICLE XXVIII REGULATIONS FOR PREPARATION OF STERILE PHARMACEUTICALS

REPEALED Effective 08/30/2018

ARTICLE XXIX REGULATIONS GOVERNING INSTITUTIONAL PHARMACY

1. APPLICABILITY: The following rules and regulations are applicable to all pharmacies classified and authorized by permit to operate as institutional pharmacies. All rules, regulations and laws which pertain to the practice of pharmacy in the retail setting shall be applied to those aspects of institutional practice which handle, prepare and dispense medications for use outside the confines of the institution, except that none shall be construed to prohibit the extension of a formulary system to outpatient dispensing.

2. REGISTRATION: No institutional pharmacy shall be operated before it has been registered with the Mississippi Board of Pharmacy and received an Institutional Permit in conformity with the requirements of ARTICLE VI of the regulations of the Mississippi Board of Pharmacy.

3. PERSONNEL:
   A. Director. The Director of Pharmacy shall be responsible for the safe and efficient distribution, control, and accountability for drugs. The responsibilities of the director shall include being responsible for and developing policies and procedures for the following:
      (1) Preparation of sterile medications prepared within the institutional facility;
      (2) Admixture of parenteral products;
      (3) Compounding of drugs, solutions, ointments, lotions, etc.;
      (4) To assure that no legend medication shall be stored in patient care areas except upon the approval of the Director of Pharmacy;
      (5) Establishment of specifications for procurement of all materials, including drugs, chemicals and biologicals, subject to approval of the appropriate committee of the institutional facility;
      (6) Participation in the development of a formulary for the institutional facility where applicable;
      (7) Dispensing of all drugs dispensed within the institutional facility;
      (8) Filling and labeling of all containers from which drugs are to be administered;
      (9) Maintenance of a sufficient inventory of antidotes and other emergency drugs, both in the Pharmacy and in-patient care areas, together with current antidote information, telephone numbers of regional poison control centers and other emergency assistance organizations, and such other materials and information as may be deemed necessary by the appropriate committee of the institutional facility, if any;
      (10) Maintenance of records of all transactions of the institutional pharmacy as may be required by applicable law, state and federal, and as may be necessary to maintain accurate control and accountability for all

pharmaceutical materials;

(11) Be responsible for "controlled substances" within the institution from the time of purchase until they have been administered to the patient; although individual pharmacists involved in handling controlled substances share responsibility for control of these drugs;

(12) Assure that all drugs shall be stored in areas within the institutional pharmacy and satellite storage areas to provide proper sanitation, temperature, light, ventilation, moisture control, segregation and security; that alcohol and flammables shall be stored in areas separate and apart from areas used for storage, compounding or dispensing; that disinfectants and drugs for external use are stored separately and apart from drugs for internal use or ingestion; that outdated or other unusable drugs are identified and stored in a manner that will prevent their distribution or administration prior to disposition; that emergency drugs are in adequate and proper supply at designated locations;

(13) Assure that all areas occupied by the institutional pharmacy shall be capable of being locked to prevent unauthorized access, and that all areas where drugs are stored or dispensed shall be locked in the absence of pharmacy personnel;

(14) An institutional pharmacy shall have sufficient floor space allocated to it to assure that drugs are prepared in sanitary, well-lit and enclosed places;

(15) All drugs dispensed by an institutional pharmacy intended for in-patient use shall be dispensed in appropriate containers and shall be adequately labeled so as to identify, at a minimum, brand or generic name, strength, acceptable route(s) of administration (only if other than oral). The institution will maintain a system with control numbers that will allow for recall of medication products. When a formulary is maintained, a system shall be implemented to cross reference brand name and generic products, and parenteral products that contain added drugs shall be labeled with a distinctive supplementary label indicating the name and amount of the drug added, expiration time, and name of person responsible for compounding the admixture, and all drugs dispensed by an institutional pharmacy for out-patient consumption shall comply with ARTICLE XIV;

(16) Insure that discontinued and outdated drugs are returned to the pharmacy for proper disposition together with containers with worn, illegible or missing labels. The director or his designee shall properly dispose of such drugs;

(17) Drugs shall be dispensed from the institutional pharmacy only upon receipt of a written or oral order or a direct copy thereof. These may be in the form of carbon, NCR or electronically transmitted orders (facsimile or computer generated). Orders shall be reviewed by a pharmacist before the medication is initially dispensed except in emergencies or when a pharmacist is unavailable. Medication orders must be reviewed by a pharmacist within 24 hours or as soon thereafter as possible. This regulation shall not be construed to prevent the distribution of drugs for floor stock. Medication orders shall contain: patient name and room number, drug name, strength, dosage,

directions for use, date and the signature of the practitioner or an authorized representative;

(18) Ensure that all requirements of the Controlled Substances Act of 1970 and the requirements set forth in the regulations of the Mississippi Board of Pharmacy in the purchasing, storing, distribution, dispensing, record keeping and disposal of controlled substances are met throughout the institution. The director or his designee shall establish policies and procedures for the control of these drugs at all times, including those instances when drugs are stored in surgery departments, nursing stations, ambulatory clinics, diagnostic laboratories, etc. Periodic (at least monthly) inspections of the proper storage of these drugs in other areas of the institution is required and deficiencies must be corrected.

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

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

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

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

4. ABSENCE OF PHARMACIST

A. General. During such times as an institutional pharmacy may be unattended by a pharmacist, arrangements shall be made in advance by the director for provision of drugs to the medical staff and other authorized personnel of the institutional facility.

The pharmacist shall provide on-call services at all times.

B. Access to Drugs. In the absence of a pharmacist, access shall be by locked cabinet(s) or other enclosure(s) constructed and located outside of the pharmacy area, to which only specifically authorized personnel may obtain access and which is sufficiently secure to deny access to unauthorized persons. The director shall develop inventory listings of those drugs to be included in such area(s) and shall assure that:
   (1) Such drugs are available therein, properly stored and labeled;
   (2) Only pre-packaged drugs are available therein, in amounts sufficient for immediate therapeutic requirements;
   (3) Each pre-packaged drug stored outside of the pharmacy area shall be assigned a "par value" and each addition or withdrawal by authorized persons shall be properly documented. Pharmacy personnel shall audit these areas on a regular basis no less than once per month;
   (4) Written policies and procedures are established to implement the requirements of this Subsection B.

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

   Nurses allowed access to the pharmacy shall receive thorough education and training in the proper methods of access, removal of drugs and records and procedures by the Director of Pharmacy, who shall require at a minimum, the following:
   (1) In the absence of a pharmacist, nursing staff may withdraw a single dose of medication at a time for administration to a patient.
   (2) Removal of any drug from the pharmacy by an authorized nurse must be recorded on a suitable form showing patient name and room number, name, strength and amount of drug, date, time and signature of nurse;
   (3) The completed form and a copy of the practitioner's order shall be placed conspicuously so they will be found by a pharmacist and verified promptly;
   (4) The director or his pharmacist designee shall check and initial the order.

D. Emergency Medication Supplies.
   (1) Pharmacy. All emergency medication supplies shall be maintained by a pharmacist;
   (2) Drugs Included. The pharmacist and the appropriate committee of the institutional facility shall jointly determine the drugs, by identity and quantity, to be included in emergency medication supplies.
   (3) Storage. Emergency medication supplies shall be stored in areas suitable to prevent unauthorized access and to assure a proper environment for preservation of the drugs within them. All emergency medication supplies shall be sealed with a mechanism that must be broken if the container is opened and that will thereby reveal any unauthorized or undocumented

access to emergency supplies. All emergency kit drugs shall be provided and sealed by a pharmacist;

(4) Labeling - Exterior. The exterior of the emergency medication supplies shall be labeled so as to clearly indicate that it is an emergency medication supply and it is for use in emergencies only; and in addition, the exterior shall indicate the expiration date of the supply, which shall be no later than the earliest expiration date of any drug contained therein, and in facilities operating with a part-time director, the name, address and telephone number of each supplying pharmacy or pharmacist. Upon the occurrence of an expiration date, the supplying pharmacist shall open the supply and replace expired drugs with current dated drugs and reseal it;

(5) Labeling - Interior. All drugs contained in emergency medication supplies shall be listed and properly labeled with any additional information as may be required by the medical staff of the institutional facility to prevent misunderstanding or risk of harm to the patients of the facility;

(6) Notifications. Whenever an emergency medication supply is opened, the supplying pharmacist shall be notified and the pharmacist shall restock and reseal the supply within a reasonable time so as to prevent risk of harm to patients. In the event the supply is opened in an unauthorized manner, the pharmacist and other appropriate personnel of the facility shall be notified;

(7) Inspection. Emergency medication supplies shall be routinely inspected. Procedures for the inspection shall assure that the medications are available, in date, properly stored and secured against pilferage or tampering;

(8) Procedures. The supplying pharmacist shall, in conjunction with the medical staff of the institutional facility, develop and implement written policies and procedures to assure compliance with the provisions of this subsection.

5. DRUGS FROM OUTSIDE SOURCES

A. Outside Pharmacies. If drugs and/or pharmaceutical services are not available within the institution, they may be obtained from a pharmacist outside the institution provided arrangements shall be made to assure that such outside pharmacists provide services of sufficient quality to protect the safety of the patients and serve the needs of the facility. The pharmacist who develops procedures for these services shall act in the capacity of a (part-time) director (paragraph 4. A. above) and therefore shall make provisions at a minimum for:

(1) On-call services at all times;

(2) Adequate storage facilities for drugs;

(3) Labeling of drugs that will assure that recall can be effected and proper control and supervision of such drugs may be exercised;

(4) Written reports to the institution's administrator and/or the medical director as required by law, regulations or institutional policies and procedures.

B. Patients. Whenever patients bring drugs into an institutional facility such drugs shall not be administered unless authorized by the attending practitioner and unless they

can be accurately identified and their quality reasonably assessed. Identification of such drugs from outside sources must be conducted by a pharmacist. The director shall have policy and procedure for the return of patient medication brought into the facility. Drugs not returned to the patient or the patient's family may be disposed of within a reasonable number of days following discharge or death.

6. INVESTIGATIONAL DRUGS

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

7. UNIT DOSE DISPENSING SYSTEMS

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

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

8. PHARMACY TECHNICIANS

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

A. Prohibited Acts. The following functions require the professional judgment of a pharmacist and may not be performed by pharmacy technicians:
    (1) Acceptance of oral prescriptions;
    (2) Certification of filled/finished prescription or drug orders;
    (3) Weighing or measuring active drug ingredients without a mechanism of verification;
    (4) Reconstitution of prefabricated medication without a mechanism of

verification;

(5) Verification of the constituents of final IV admixtures for accuracy, efficacy and patient utilization;

(6) Entry of orders on patient medication profiles without verification by a pharmacist;

(7) Provision of drug information that has not been prepared or approved by a pharmacist.

B. Job Descriptions and Procedure Manuals. For each pharmacy technician a job description and procedures manual shall be prepared by the director or his designee. Activities to be specifically addressed shall include the role of the pharmacy technician in bulk compounding or reconstitution, pre-packaging and labeling of multi-dose and unit dose medication; distribution and administration of medication.

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

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

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

9. PROCEDURE MANUAL

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

10. INITIATION OR MODIFICATION OF DRUG THERAPY

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

A. Protocols shall include the following:

(1) Identification of the practitioner and the scope of the practitioner's active practice;

(2) Specifications of the type of prescriptive authority to be exercised which

shall include a description of the types of medical conditions, drugs or drug categories, together with any special condition;

(3) Mechanism for communication or feedback to the authorizing practitioner;

(4) Documentation of the prescriptive activities performed;

(5) Specification of the duration of the protocol agreement not to exceed two years;

(6) Protocols must be signed by the authorizing practitioner.

11. PATIENT PROFILE

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

12. PHARMACEUTICAL CARE

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

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

A. Systems for monitoring and detecting drug interactions, contraindications, incompatibilities and allergic reactions; and

B. Systems for monitoring dosages and serum blood levels of drugs for correct ranges where appropriate; and

C. Systems for monitoring, detecting and reporting adverse drug reactions; and

D. Systems for monitoring and evaluating therapeutic duplications; and

E. Provision of drug therapeutic consultations and drug information by a pharmacist(s) to patients and health care providers.

ARTICLE XXX: LONG-TERM CARE FACILITIES (LTCF)

1. CONSULTING PHARMACISTS TO NURSING HOMES

A. Unless specifically authorized by the Board, no person shall serve as a consultant pharmacist or act or purport to act in this capacity to any nursing home unless he/she possesses the following qualifications:

(1) Have and maintain a license to practice pharmacy within the State of Mississippi;

(2) Have attended within the last two years a training course of not less than eight (8) hours in LTC or geriatric related pharmacy services that has been approved by the Board of

Pharmacy;

(3) In order to be approved by the Board of Pharmacy, the training course for a consultant pharmacist shall provide instruction in the areas of clinical pharmacy services, drug distribution systems and state and federal pharmacy regulations governing the practice of long-term care pharmacy.

B. 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 a LTCF, as well as the following responsibilities.

(1) 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;

(2) 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;

(3) Serving as a resource for pharmacy related educational services within the facility;

(4) Communication and discussion with the provider pharmacist regarding areas of concern and resolution thereof;

(5) Serving on appropriate committees;

(6) Supervising and assisting in the disposal of all discontinued, expired, or otherwise un-needed controlled substance medications;

(7) Reviewing records of the destruction of all medications and verification of the reasons for destruction;

(8) Ensuring that complete and accurate records of the acquisition and disposition of controlled substance medications which have been dispensed for residents of the LTCF are maintained;

(9) Attending, within the last two (2) years, a consultant pharmacist seminar which has been approved by the Board;

(10) Maintain consultant pharmacist eligibility as described in Section 1.

C. A LTCF which is permitted by the Board and where the services of a consultant pharmacist are required shall have the following responsibilities:

(1) Policy Manual. The LTCF shall develop policies and procedures regarding pharmacy services which include, but are 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 facility and is to be promulgated with the concurrence of the consultant pharmacist, nursing home administrator and the directors of medical and nursing services.

(2) Reference. Reference materials shall be readily available 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.

(3) Reporting. The facility 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.

(4) 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 (FIRST DOSE KITS) FOR LONG TERM CARE FACILITIES AND OTHER APPROVED INSTITUTIONAL FACILITIES of these Pharmacy Practice Regulations.

(5) Disposal of Patient Medication. The LTCF, 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:

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

(b) Documentation of any disposal of patient medications should include a paper trail from the time the medication was logged into the discontinued 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;

(c) Discontinued and unwanted patient medications shall be destroyed on a timely basis not to exceed sixty (60) days from the date that the medication was discontinued. Any such destruction shall be performed by two licensed personnel and documented by their signatures. The consultant pharmacist is valid personnel to participate in this activity.

D. A consultant pharmacist shall document communication of the findings of his/her reviews to the attending physician and director of nursing along with their responses 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.

2. UNIT DOSE DISPENSING FOR LTCF

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

(1) "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.

(2) "Provider Pharmacy" means any pharmacy permitted by the Board where medications are dispensed to residents of a LTCF located in this state.

(3) "Unit dose package" is a package, which contains one dose of a medication for administration to a patient. A unit dose package may contain one or more individual units or fractions of units of a distinct medication.

(4) "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.

(5) "Multi-dose strip packaging" (MDS) is a medication package issued by a provider pharmacy which provides multiple distinct medications to be administered at the same time.

B. Packaging for all non-sterile medications stored and dispensed in single unit dose, unit dose, unit of issue or MDS packages for use in a LTCF shall:

(1) Preserve and protect the identity and integrity of the drug medication from the point of packaging to the point of patient administration;

(2) When packaged by the manufacturer or distributor, be in compliance with Federal Food and Drug Administration guidelines;

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

(4) Utilize containers, which are classified according to USP Standard 671 as being Class A or Class B for oral solid dosage forms or tight containers for liquid dosage forms.

C. Labeling for unit dose packaging or multi-dose strip packaging shall comply with the following;

(1) When packaged by the manufacturer or distributor shall be properly labeled according to Federal Food and Drug Administration requirements;

(2) Unit doses or multi-dose strip packaging packaged by the provider pharmacy shall be properly labeled according to ARTICLE XXIX. If needed, the provider pharmacy may utilize an external container to provide required labeling elements. The name of the patient, drug, dosage strength and form must be on the primary packaging.

(3) Labeling for unit of issue packages shall contain the following information: Name and facility specific patient identifier (e.g., 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 utilized for patients in an LTCF setting.

D. 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.

E. 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:

(1) Not exceed the manufacturer's original expiration date;

(2) Have an expiration date assigned based on the unit dose container manufacturer's recommendations;

(3) 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;

(4) Drugs or dosage forms having known stability problems or that are not packaged as defined in Article XXX are assigned an expiration date of less than ninety (90) days.
(5) The shortest time span of any of the listed conditions shall be the expiration date assigned to the medication.

3. RETURN OF MEDICATIONS FROM A LTCF TO THE PROVIDER PHARMACY

A. Medication that has been dispensed for a patient residing in a LTCF facility may be returned to the provider pharmacy provided that the medication has an approved reason for return as follows:
(1) Medication was discontinued prior to delivery;
(2) Patient no longer a patient or expired prior to medication being delivered;
(3) Medication dosage changed prior to delivery;
(4) Medication is considered to be dispensed when it leaves the dispensing pharmacy and is delivered to the LTCF.

B. Any medication subject to return must be intact with no doses removed from blister package (unit dose) and must not have had contact with other medications. 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.

C. 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

Every pharmacy permitted by the Mississippi Board of Pharmacy engaged in the compounding of pharmaceuticals that is not a licensed 503B pharmacy following good manufacturing practices (GMP) shall comply with USP 795, USP 797, and USP 800 when compounding in the scope of those chapters. The designated facility USP representative must be a pharmacist licensed in the State of Mississippi.

1. GENERAL PROVISIONS

A. Prior to engaging in the compounding of pharmaceuticals, a pharmacy shall obtain a compounding certificate from the Mississippi Board of Pharmacy.
i. To obtain a compounding certificate, an applicant must complete a compounding certificate application.
ii. A compounding certificate will expire when the pharmacy permit expires and can be renewed at the time a pharmacy permit is renewed.
iii. Compounding, without obtaining the compounding certificate, shall be grounds for disciplinary action.
iv. Every pharmacy that engages in compounding shall submit a compounding statistical report to the Board on or about January 31st of each year on a form prescribed by the Board.
v. Failure to submit the report as required by this regulation shall be grounds for disciplinary action.
vi. A compounding certificate shall become inactive if a pharmacy fails to compound any

prescriptions in a calendar year. A pharmacy may not compound prescriptions with an inactive compounding certificate. A pharmacy may petition the Board to activate a compounding certificate that is inactive.

vii. Any pharmacy with an active compounding certificate is subject to a compounding inspection by the Board.

B. 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, a pharmacy may compound, for an individual patient, medications that are not commercially available in the marketplace. Compounding and manufacturing, as defined within the regulations, are not permitted in the same facility. A pharmacy may not compound a drug that appears on the FDA List of Drugs withdrawn or removed from the market for safety reasons or on the FDA List of Drug products that present demonstrable difficulties in compounding.

C. For the purpose of this Article, flavoring is not considered compounding. In addition, the combining of commercially manufactured, ready- to-use products shall be exempt from USP 795 compounding standards under the following conditions:

i. No more than four (4) commercially manufactured ready-to-use products (that have

not been manipulated) are used;
ii. Compounding is not done in anticipation of medication orders;
iii. Must follow USP 795 beyond use dates (BUDs);
iv. A valid prescription shall serve as the compounding record;
v. The prescription label shall comply with all related USP chapter requirements as well as the labeling requirements as set forth in Article XIV of these regulations.

D. A pharmacy 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.

E. Pharmacies shall not offer compounded human drug products to practitioners or to other pharmacies for resale or dispensing. However, patient specific medications may be prepared on behalf of a pharmacy permitted as an Institutional I, Hospital, 3.1 pharmacy for an inpatient at that facility. Pharmacies may compound patient specific medications for office administration by a practitioner.

F. Compounding pharmacies 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. RECORDS

A. The pharmacy shall keep records of all compounded products 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.

B. Drug Orders: The pharmacist must receive a written, electronic or verbal order from an authorized prescriber before dispensing any compounded product.
i. If the drug order is for an inpatient at an institutional facility, a copy of the patient's medication order may serve as an order for the preparation and dispensing of the compounded product. This and the medication administration record may be maintained as the permanent record in medical records at the facility.
ii. 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 medication and strength;
(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.

C. Prescriptions for compounded products shall be filed in accordance with the prescription recordkeeping provisions of these regulations. Patient medication order sheets used as authorization for the dispensing of drugs shall be filed in an easily retrievable manner.

3. COMPOUNDING WHEN COMMERCIAL PRODUCTS ARE NOT AVAILABLE

A. A pharmacy may prepare a copy of a commercial product when that commercial product is not available as evidenced by either of the following:
   i. Products that appear as unresolved status on the FDA drug shortage list in effect under section 506E of the FD&C Act; or
   ii. Products discontinued and no longer marketed by the manufacturer.

4. COMPOUNDING FOR VETERINARY USE

A. All compounding for non-human medications must follow USP 795/797/800 compounding standards.
B. A pharmacy may compound a preparation intended for administration to an animal patient:
   i. Pursuant to a patient specific prescription; or
   ii. Pursuant to a non-patient specific order from a veterinarian.
C. The label for non-patient specific compounded preparations shall contain, at a minimum, the following:
   i. Pharmacy's name, address and telephone number;
   ii. Veterinarian's name;
   iii. Name of preparation;
   iv. Strength and concentration;
   v. Lot number;
   vi. Beyond use date (BUD);
   vii. Special storage requirements, if applicable;
   viii. Name or initials of the pharmacist responsible for final check of the preparation.

ARTICLE XXXII PHARMACEUTICAL DRUG FACILITY PERMITS

1. For purposes of this Article the following definitions shall apply:

A. "Wholesale Distribution" means distribution of prescription drugs or devices, to include active pharmaceutical ingredients (API's), to a person other than a consumer or patient, but does not include:
   (l) The sale, purchase, or trade of a specified drug or device or an offer to sell, purchase, or

trade a specified drug or device for an immediate emergency medical reason including a public health emergency declaration pursuant to section 319 of the Public Service Act. Routine or temporary shortages do not constitute an immediate emergency medical reason;

(2) The sale, purchase, or trade of a drug or device, an offer to sell, purchase, or trade a drug or device, or the dispensing of a drug or a device pursuant to a patient specific prescription;

(3) The lawful distribution of drug samples by manufacturers' representatives or distributors' representatives;

(4) The sale, purchase, or trade of a drug or device or an offer to sell, purchase, or trade a drug or device among pharmacies 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. Common ownership transactions shall not include any upcharges or fees;

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

(6) The sale/purchase of a prescription drug or device by a 503a pharmacy 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 sales. In office use is defined as occurring in locations that are not serviced by a pharmacy permit;

(7) Medication transfer from facilities/businesses to meet an immediate need for a specific patient in a quantity no greater than the prescribed amount;

(8) Distribution of drugs or devices for research purposes in humans under an IND to an investigator.

2. Every facility/business that engages in the wholesale distribution of prescription drugs, API's, or devices as defined in § 73-21-71, to include without limitation, manufacturing in this state, distribution into this state, or selling or offering to sell in or into this state, or distribution from or within this state, shall register annually with the Mississippi Board of Pharmacy by applying for a permit via the licensing portal. Every facility/business that engages in the distribution of prescription drugs or devices into this state to an affiliated or related company under common ownership and control must register annually with the Board. Pharmaceutical Facility Permits issued by the Board may include, but are not limited to, the following pharmaceutical facilities/businesses:
   A. Manufacturer
   B. Virtual Manufacturer
   C. Wholesaler
   D. Virtual Wholesaler
   E. Third Party Logistics (3PL)
   F. Repackager
   G. Reverse Distributor
   H. Private Label Distributor

I. Veterinary Wholesaler

The Board may declare a pharmaceutical facility/business permit inactive due to the lack of legitimate business activity for sixty (60) consecutive days. Any permit declared inactive by the Board must petition the Board to be re-instated.

3. To obtain or renew a pharmaceutical facility/business permit, the applicant shall:
   A. Complete an application via the licensing portal which shall include, but not be limited to the following:
      (1) Name and address of the facility/business, including all trade or business names;
      (2) Detailed photo(s) of physical location that clearly display related signage and conveys business activity when requested;
      (3) Ownership information;
         (a) If a corporation: the State of incorporation and the name, telephone number, and address of all officers and directors;
         (b) If a partnership: the name, telephone number, and address of all partners;
         (c) If a sole proprietorship: the name, telephone number, and address of the sole proprietor.
      (4) Type of activities conducted by the facility/business;
      (5) Name, address, telephone number and signature of a designated representative;
      (6) Initial applications will be valid for up to 180 days from the date of filing within the application portal. A renewal application will remain active for no more than 120 days from the date of filing within the application portal. Renewal applications will be considered filed timely if they are received prior to 30 days of expiration of the permit and contain all of the requested documents necessary for permitting. If a renewal application is not approved prior to the expiration of the permit, the drug facility must cease all Mississippi focused operations until application approval is obtained
   B. Provide evidence of a surety bond in the amount of $100,000 (or $25,000 for a facility/business whose annual gross receipts total $10,000,000 or less for the previous tax year) or other equivalent means of security acceptable to the State.
   C. Complete a criminal background check for the designated representative, including fingerprinting.
   D. Provide the most recent inspection report for the physical facilities including facilities maintaining oversight of product label codes. Inspection reports may be required for contracted partners providing services for the permitted location. All facilities/businesses must provide a recent, detailed inspection (within the last 3 years) whether their home state licensing authority conducts inspections or not. If deficiencies are noted in the inspection, the Board reserves the right to require a follow-up inspection. The most recent FDA inspection is not subject to time limitations.
   E. Provide a copy of each state license/permit held by the applicant.
   F. All Pharmaceutical Facility permit applicants including Third Party Logistics Providers and Virtual Entities must provide a list of all trading partners.
   G. A permit granted by the Board to a pharmaceutical facility will be based on its stated and actual business activity(s). Such activity may take precedence over licensure type in home state. A pharmaceutical facility with multiple permitted business activities at a single location must have

separate business operations and records.

H. A fee of five hundred dollars ($500.00) will be required to be submitted by the applicant for the initial registration and each annual license renewal period as noted by the online system. Newly issued permits which do not coincide with the normal annual registration period shall be valid from the date issued until the end of the current registration period only.
I. Pharmaceutical facility permits shall not be issued for the same location occupied by a Pharmacy Permit. One exception is that a manufacturer may be co-located with a 503b Outsourcer. However, separate business records shall be maintained by each permit.

4. Each pharmaceutical facility that maintains or distributes controlled substances in or into Mississippi 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 applicantshall:
   A. Submit an application via the licensing portal.
   B. Submit a fee of Fifty dollars ($50.00) for each registration period 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.

5. 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, API's, or devices:
   A. Any convictions of the applicant, principal owners, officers, directors and/or partners under any federal, state, or local laws relating to drug samples, wholesale or retail drug or device distribution, or distribution of controlled substances;
   B. Any felony convictions of the applicant under federal, state or local laws;
   C. The past experience of the applicant, principal owners, officers, directors and/or partners in the distribution of prescription drugs or devices,including controlled substances;
   D. The furnishing by the applicant of false or fraudulent information in any application made in connection with drug or device 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 or devices,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 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.

6. The Designated Representative shall attest to the permit application or the permit renewaland 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.

7. The Designated Representative shall be required to be physically onsite at the facility a minimum of twenty (20) hours per work week or fifty per cent (50%) of the hours of operation of the facility, whichever is less. A record of the onsite hours of the designated representative shall be produced upon request by the Board or an agent of the Board. Exceptions will be recognized for practical reasons, i.e., vacation, sick time, etc.

8. If the employment of a designated representative is terminated, or if for any other reason he/she wishes to be relieved of the responsibilities of the permit holder,he/she must notify the MS Board of Pharmacy via the online portal. Application for a new designated representative must be made by within fifteen (15) days.

9. Any facility/business licensed by the State of Mississippi shall notify the Board of Pharmacy within fifteen (15) days, via the license portal, of any changes that might affect permitting status. This includes a closing, change of name, location, ownership, or legal matters involving the facility/business or its leadership.
   A. If a permitted facility has a change in ownership, a new online application must be made to the board within fifteen (15) days.
   B. If a permitted facility has a change in name or location, a facility amendment must occur within 15 days of the change.

10. All pharmaceutical supply chain facilities 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, chemicals, or devices shall be stored at appropriate temperatures and under appropriate conditions 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/National 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 at least daily.
       (2) A separate storage section shall be provided for legend drugs or devices that are deteriorated, outdated, misbranded, or otherwise adulterated.
       (3) Controlled substances should be isolated from non-controlled substances and stored in a secure area in accordance with Drug Enforcement Administration security requirements and standards.
    B. Labeling:

(1) All Federal labeling requirements must be met to include but not limited to:
   (a) Changes to product labeling must be submitted to the FDA annually.
   (b) Labels must include product identifiers in a 2-dimensional data matrix barcode both on the package and homogeneous case, unless it is a product required to have a standardized numerical id.
   (c) Distributors and 3PLs shall only accept products with proper labeling.

(2) Facilities/businesses shall have systems in place to verify productat the package level, including standard numerical identifiers and must be in full compliance with the Drug Supply Chain & Security Act (DSCSA).

C. 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 or devices that are outdated, damaged, deteriorated, non-compliant with DSCSA requirements, misbranded, or adulterated, or that are in immediate or sealed outer or sealed secondary container that have been opened. All suspect products should be quarantined until investigation is complete.

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

D. Security:

(1) All facilities shall be equipped with an electronic security system that will provide suitable protection against theft and diversion and meets all applicable federal, state, and local standards. 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) All facilities 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) All facilities/businesses 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.

E. Recordkeeping:

(1) All facilities/businesses shall establish and maintain inventories and other records of all transactions regarding the receipt, distribution, and disposition of legend drugs or devices including the name and principal 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 six (6) years following disposition of the drugs and must be compliant with all aspects of DSCSA. These records shall be made available for inspection and copying by 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 within two (2) working days of a written request by the Mississippi Board of Pharmacy or other authorized federal, state, or local law enforcement agency officials.

(3) Upon request by the Board, facilities/businesses that are permitted by the Board and who distribute prescription drugs or devices shall make available to the Board the following:
   (a) A complete Mississippi customer roster;
   (b) Transaction records of all distribution and sales for any period during the past six (6) years listing all sales or distribution of prescription drugs or devices to authorized persons upon request by the Board. This request shall be made in writing by the Board. The transaction records shall be supplied to the Board within two (2) working days and shall consist of the following:
      (i) Name and address of the purchaser;
      (ii) Name and address of the distributor;
      (iii) Drug name, strength and dosage form, and quantity, including number of containers distributed
      (iv) The invoice number;
      (v) The lot number of the product if required by DSCSA;
      (vi) Date of transaction and shipment;
      (vii) All records of returns or credits;
      (viii) Must also include product identifiers at package level by applicable DSCSA deadline.

(4) Transaction records must also accompany products whenever prescription drug or devices products change hands (unless the product is being returned to the manufacturer asunsalable).
   (a) These records should be in a single electronic document as required by DSCSA.
   (b) Products should be verified by their identifiers upon sale/return. Any product that does not correspond with transaction records shall be treated as suspect.
   (c) Product shall not be accepted without transaction records, except when returned to the manufacturer as unsalable.
   (d) Transaction records are considered confidential and may only be provided to appropriate government officials and authorized trading partners with whom a written agreement is established.

(5) Transaction records shall be exchanged in a secure, interoperable, electronic manner, adhering to all regulations (compliance required by applicable DSCSA deadline).

(6) Systems and processes should be in place for accepting salable returns by associating products with transaction records (compliance required by applicable DSCSA deadline).

F. Written Policies and Procedures:

Facilities/businesses shall establish, maintain, and adhere to written policies and procedures which allow and demonstrate oversight of legend product based on their scope of service. Specifically, wholesale drug or device 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 or devices, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Written policies and procedures shall include:

(1) A procedure to assure that the facility/business 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 or device product is distributed first. The procedure may permit deviation from this requirement if such deviation is temporary and appropriate.
(3) A procedure to assure that any outdated stock, or any stock with an expiration date that does not allow sufficient time for 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 outdated prescription drugs. This documentation shall be maintained for a period of six (6) years after the disposition of the outdated drugs or devices.
(4) A procedure to assure the facility/business exercises control over the shipping and receiving of all stock within the operation, including the following practices:
(a) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or devices or prescription drugs or devices 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 or devices and to ensure that there is no delivery of prescription drugs or devices that have been damaged in storage or held under improper conditions.
(c) The recordkeeping requirements in paragraph (E.) of this section shall be followed for all incoming and outgoing prescription drugs or devices.

G. Returned, Damaged and Outdated Prescription Drugs:
(1) Prescription drugs or devices that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs or devices until they are destroyed or returned to their supplier.
(2) Any prescription drug or device 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 or device has been returned cast doubt on the safety, identity, strength, quality, or purity, then the drug or device shall be destroyed, or returned to the supplier, unless examination, testing or other investigation proves that appropriate standards of safety, identity, strength, quality, and purity are met. In determining whether the conditions under which a product has been returned cast doubt on the drug's or device’s safety, identity, strength, quality, or purity, the wholesale drug distributor shall consider, among other things, the conditions under which the drug or device 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 E. of this section shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs or devices. Written policies and procedures shall be maintained at the permitted facility to implement the

above requirements.

H. Handling Recalls:
   (1) A facility/business shall provide support for manufacturer recalls and withdrawals of prescription drugs or devices.
   (2) 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 or devices 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.
      (c) Replacement of existing merchandise with an improved product or new package design.

I. Due Diligence To Identify Suspect/Illegitimate Products:
   (1) A facility/business in the drug supply chain shall cooperate in efforts to identify, isolate, investigate suspect products, and determine if such products are illegitimate.
   (2) A facility/business should establish processes for identifying trading partners and transactions that require heightened vigilance in preventing the receipt of suspect product. Heightened vigilance includes the examination of required records (ie. invoices, shipping documents, transaction history) for suspicious business practices and physical examination of product for factors that increase the risk of a product being suspect, such as:
      (a) A trading partner that has been involved in business transactions where they sold or delivered illegitimate product;
      (b) A trading partner that has a history of problematic or potentially false transaction histories or pedigrees, such as those that contain misspelled words or incomplete information;
      (c) A Trading Partner that is reluctant to provide a Transaction History associated with the Product being purchased or does not do so in a timely manner;
      (d) A Trading Partner that provides Transaction Information, a Transaction Statement, and/or Transaction History that appears to be incomplete or suspicious;
      (e) The trading partner providing wholesale operations but is co-located with a pharmacy.
      (f) The product offered for sale was previously owned by a dispenser;
      (g) The price of a product is suspicious;
      (h) The product has been previously or is currently the subject of a drug shortage;
      (i) A product that is in higher demand because of its potential or perceived relationship to a public health or other emergency;
      (j) The appearance of the package is suspicious; or
      (k) The package exhibits unusual or excessive adhesive residue.
   (3) Suspect products shall be quarantined, and an investigation opened into the product legitimacy. The FDA and all trading partners shall be notified of any product determined to be illegitimate within 24 hours of such determination. Records of investigations shall be kept for a minimum of 6 years regardless of the outcome.
   (4) Products deemed illegitimate shall be disposed of after a sample is taken for physical exam/laboratory analysis.

J. Due Diligence for Controlled Substance Ordering and Dispensing
   (1) Facility/business that perform customer visits as part of customer diligence reviews to resolve

red flags regarding ordering or dispensing practices of controlled substances shall share with the Board all reports and determinations within three (3) business days of receiving reports from customer.

(2) Facility/business that make the determination to suspend controlled substance ordering ability for customers must notify and provide related detailed rationale to the Board within one business day of suspension of ordering abilities.

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

(1) Each facility/business 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 from another regulatory or inspecting body which the Board determines to be comparable to that made by the Federal Food and Drug Administration or the Board. Upon request, the facility shall furnish to the Board a copy of any and all reports of inspections conducted by the Federal Food and Drug Administration or any other inspecting entity.

(3) Any facilities/businesses that possess, transport or store controlled substances in or into MS shall obtain a controlled substance registration from the MS Board of Pharmacy in addition to a registration number from the Federal Drug Enforcement Administration and shall comply with all applicable state and federal DEA regulations.

(4) The Board or its representatives may enter to inspect, during reasonable hours, a facility which has obtained or applied for a permit with the Board. Failure to allow an inspection is cause to deny a permit or result in disciplinary action upon a permit.

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

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

L. Personnel

(1) Each facility/business shall employ adequate personnel with the education and experience necessary to safely and lawfully engage in the sale and wholesale distribution of prescription drugs or devices.

(2) Each facility/business 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) Each facility/business 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.

M. Salvaging and Reprocessing:

(1) All facilities/businesses 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 Title 21, Chapter 1, Subchapter C, Parts 207, 210 and 211 of the Code of Federal Regulations. Any reverse distributor that receives saleable product for reintroduction into the

supply chain will also need to be permitted as a wholesale distributor.

N. Repackaging:
   (1) Every repackager shall register with the Federal Food and Drug Administration and shall be in compliance with all laws, rules, regulations, and FDA issued guidance 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) Repackagers shall maintain all products in the manufacturer's original container except as allowed by federal laws, rules, and regulations regarding prescription drug repackaging. Once distributed, repackaged products which are returned to the repackager shall be immediately quarantined and either destroyed or returned to the original manufacturer.

11. Prohibited Acts
   A. No facility/business may engage in wholesale distribution of a prescription drug, API's, or device in or into Mississippi unless the facility/business is licensed/permitted:
      (1) By the state from which the drug, API, or device is distributed, or if the State from which the drug, API, or device is distributed has not established a licensure requirement, is licensed by the Federal Drug Administration; and
      (2) By the state into which the drug, API, or device is distributed.
   B. No facility/business engaged in wholesale distribution is allowed to acquire prescription drugs, API's, or devices from a dispenser for resale within the State of Mississippi. The return by a dispenser of prescription drugs, API's, or devices originally purchased from that facility/business is exempt from this requirement.
   C. Any facility/business permitted by the Mississippi Board of Pharmacy shall not sell or distribute a prescription drug, API, or device to any individual or business unless the individual or business is licensed or permitted to prescribe, dispense, or possess prescription drugs, API's, or devices by an agency of the state in which the individual or business is located.
   D. Any facility/business permitted by the Board shall not distribute prescription drugs, API's, or devices to persons in or into this state unless such person is either a licensed physician, osteopath, podiatrist, or physician's assistant 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; or a drug supply chain facility/business permitted by the Board. An optometrist licensed by the Mississippi State Board of Optometry, may purchase prescription drugs or devices as authorized by said Board of Optometry. An advanced practice registered nurse, licensed by the Mississippi Board of Nursing may purchase prescription drugs or devices as authorized by said Board of Nursing.

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

REPEALED. Effective 8/10/2021.

ARTICLE XXXV INSTITUTIONAL EMERGENCY MEDICATION KIT PERMITS (FIRST DOSE KITS) FOR LONG TERM CARE FACILITIES AND OTHER APPROVED INSTITUTIONAL FACILITIES

1. Institutions, excluding hospitals, that desire to maintain a stock of prescription drugs provided by a supplying pharmacy 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. Emergency use is the procurement of non-patient assigned medications from a stock supply for the purpose of initiating medication therapy or supplying non-routine medications to provide for optimal patient care. Emergency kits as described in this article are not crash carts that are maintained by the institution for resuscitative care.
   A. Permit. The IEMK permit shall be classified as either a Manual IEMK or an Automated IEMK. The manual IEMK permit is required if the dispensing method is such that the release of each individual dose is not electronically integrated to the documentation required for each such release. An Automated IEMK permit shall be required if the dispensing method is such that the release of each individual dose is electronically integrated to the documentation required for each such releases. Only

one (1) type of permit, either Manual or Automated, shall be issued per facility.

B. Application for an IEMK permit shall be on a form supplied by the Board. The Application for a Manual IEMK permit shall be accompanied by a fee of One Hundred Dollars ($100.00) and the Application for an Automated IEMK permit shall be accompanied by a fee of Three Hundred Dollars ($300.00). A separate permit shall be required for each IEMK and shall be renewed 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 a change 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 Fifty Dollar ($50.00) late renewal fee shall be assessed prior to renewal.

C. IEMK Inventory and Accountability

(1) The contents of the IEMK are supplied by a pharmacy permitted by the Board. Only one supplying pharmacy may be utilized per facility;

(2) The contents of the IEMK are jointly determined by the consultant pharmacist, medical director, director of nurses and the pharmacist supplying the IEMK;

(3) The IEMK shall have a "par value" for each prepackaged product that is stored in the IEMK;

(4) A copy of the inventory of the IEMK is on file in the institution and at the provider pharmacy and a physical inventory shall be taken at least annually;

(5) A Manual IEMK permit authorizes an inventory up to sixty (60) medication items with a limit on the quantity (or par value) to no more than fifteen (15) units each of the sixty (60) medication items. A facility may choose to increase six (6) of the medication items to a maximum of thirty (30) units for those six (6) items. A maximum of ten (10) medication items may be controlled substances with a maximum limit of ten (10) units each. A facility that requiresmore than one manual IEMKbased on facility design or divergent patient populations may request consideration for an additional manual permit. Without multiple permits, manual IEMK's are globally restricted to the total quantity and drug counts for all kits combined. An Automated IEMK permit shall not have any limits on the quantity of the inventory, except controlled substances shall be limited to a maximum of twenty (20) medication items with a maximum limit of twenty (20) units each; each automated IEMK location requires an additional permit for the facility.

(6) An IEMK withdrawal log shall be maintained at the institution and all withdrawals of medications from the IEMK shall be documented as follows:

(a) name and room number of resident/patient;

(b) drug name, strength, and number of units withdrawn;

(c) date and time of withdrawal; and

(d) name of person withdrawing the medication.

2. Use. Emergency kit medications shall be administered to patients only for emergencies and when medications are otherwise unavailable pursuant to a valid medication order or prescription. Providing a patient starting dose(s) of a new medication regimen would be considered a valid emergency. Controlled substances may only be administered by licensed healthcare professionals.

3. Storage and Security. The IEMK shall be maintained in a securely locked room or cabinet at the institution. Access to the contents of the IEMK shall be limited to those licensed personnel designated by the director of nurses and the provider pharmacist.

4. Controlled Substances. An IEMK that contains controlled substances as allowed per 45 FR24128

(Schedule II, III, IV and V) shall be subject to the following:

A. The institution has been issued a controlled substance registration by the Mississippi Board of Pharmacy;
B. Controlled substances are stored in a separate locked container; and
C. The withdrawal of controlled substances shall comply with the Mississippi Pharmacy Practice Regulations and the Drug Enforcement Administration Regulations which includes a signed prescription by the provider.

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, discontinuing or modifying prescription drug therapy upon entering into an active protocol agreement with a licensed prescribing practitioner. Each protocol must define the parameters 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. A copy of the written protocol shall be made available upon request of the Board or an agent of the Board.

   For purposes of this ARTICLE, "protocol" shall mean a written agreement with a practitioner authorized to prescribe drugs whereby the prescribing practitioner delegates to a pharmacist or pharmacists, authority to conduct specific initiation, discontinuation or modification of drug therapy functions for those patients common to the practitioner and pharmacist(s).

2. For a pharmacist to initiate, discontinue or modify drug therapy under protocol a pharmacist must have and maintain an unrestricted license to practice pharmacy issued by the Mississippi Board of Pharmacy and notify the Board pursuant to the Board's licensing system that he/she is operating under a protocol.

3. Protocol agreements shall include, at a minimum, the following:
   A. Identification of the practitioner and pharmacist(s) with whom the protocol is written;
   B. Specific responsibilities authorized by the practitioner;
   C. Patient data the practitioner wishes the pharmacist(s) to collect;
   D. Data reporting frequency and methods;
   E. The procedures or plan that the pharmacist shall follow upon initiation and/or modification of drug therapy; and
   F. The duration of the protocol agreement not to exceed two (2) years.

4. The prescription/drug order for any drug dispensed under a protocol shall indicate the name of the pharmacist initiating/modifying the prescription. The protocol shall be limited to non-scheduled drugs.

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. Medical Equipment Advisory Committee to the Board.
   a. A Medical Equipment Advisory Committee (MEAC), 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 regarding all regulations dealing with home medical equipment, legend devices and medical gases that are proposed by the Board and before they are adopted by the Board. MEAC shall follow all statutory requirements of Mississippi Code Annotated Section 73-21-108.
   b. The Board may remove any or all (MEAC) members on proof of unprofessional conduct, 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 Board.

2. Definitions. For the purposes of this Article:
   a. "Home medical equipment" means technologically sophisticated medical equipment and devices usable in a home care setting, including, but not limited to:
      i. Oxygen for human consumption, oxygen concentrators and/or oxygen delivery systems and equipment;
      ii. Ventilators;
      iii. Respiratory disease management devices;
      iv. Electronic and computer driven wheelchairs and seating systems;
      v. Apnea monitors;
      vi. Transcutaneous electrical nerve stimulator (TENS) units;
      vii. Low air loss cutaneous pressure management devices;
      viii. Sequential compression devices;
      ix. Neonatal home phototherapy devices; and
      x. Feeding pumps.

   The term "home medical equipment" does not include 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 if the professional is practicing within the scope of his or her professional practice. In addition, the term does not include items such as upper and lower extremity prosthetics, canes, crutches, walkers, bathtub grab bars, standard wheelchairs, commode chairs and bath benches.

   b. "Home medical equipment 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 noninstitutional environment.
   c. "Medical gas" means those gases and liquid oxygen intended for human consumption.
   d. "Order" means an order issued by a licensed practitioner legally authorized to order home medical equipment, legend devices and/or medical gases.

3. In addition to the requirements provided in Mississippi Code Annotated, Section 73-21-108(2), Medical Equipment Supplier Permits shall have the following requirements:
   a. Permits shall not be issued for facilities located in a residence.
   b. 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 until a new application is filed and a new updated/amended permit is issued by the Board.
   c. 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 remove his/her name from the medical equipment suppliers permit through the Board Licensing Gateway. When a permit holder is removed from the medical equipment suppliers permit, an application for a new permit for that facility must be made to the Board within fifteen (15) days. If a new updated/amended permit is not obtained within fifteen (15) days, the permit becomes inactive and no business may be conducted until a new permit is issued by the Board.
   d. 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 fifteen (15) days prior to the closure or change of ownership. "Change of ownership", in the case of a partnership, means the removal, addition, or substitution of a partner. In the case of a corporation, the term means the merger of the provider corporation into another corporation, or the consolidation of two or more corporations, resulting in the creation of a new corporation. The transfer of corporate stock or the merger of another corporation into the provider corporation does not constitute a change of ownership.
   e. If a permitted facility will have a change in ownership, name or location, a new updated/amended permit must be issued from the Board in order to doing business under the new name or location.
   f. The Board may declare a pharmaceutical facility/business permit inactive due to the lack of legitimate business activity for sixty (60) consecutive days. The permit holder of any permit declared inactive by the Board must petition the Board to be re-instated.

4. Exemptions.
   a. The permitting requirements of this section do not apply to the following entities or practitioners unless they have a separate business entity, company, corporation or division that is in the business of providing home medical equipment for sale or rent to patients at their places of residence:
      i. Home health agencies;
      ii. Hospitals;
      iii. Wholesalers and/or manufacturers;
      iv. 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;
      v. Pharmacies;
      vi. Hospice programs;
      vii. Nursing homes and/or long-term care facilities;

viii. Veterinarians; dentists; and emergency medical services.

b. Although community pharmacies are exempt from the permitting requirements of this section, they shall be subject to the same regulations that are applicable to permitted businesses or entities for the sale or rental of home medical equipment covered by this section.
c. Nothing in this section shall prohibit trained individuals from using oxygen, liquid oxygen and/or legend devices in emergencies.
d. Nothing in this section shall prohibit the prehospital 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.

5. Orders required.
   Home medical equipment suppliers shall not provide any home medical equipment, legend device or medical gas to a patient without a valid order from an authorized licensed practitioner. All orders must be readily retrievable and must be produced on request by the Board or an agent of the Board. All home medical equipment, legend devices and medical gases require a new prescription order on a yearly basis.

6. Policies and programs shall be implemented to include:
   a. Policies that specify minimum standards for personnel qualifications, training, experience, and continuing education requirements consistent with the specialized equipment, items, and services it provides to clients;
   b. Policies that describe job descriptions, competencies, disciplinary action measures, rules of employment and employee orientation; and
   c. Polices shall allow unrestricted access to the Mississippi Board of Pharmacy website and regulations.

7. Minimum standards for competency of employees:
   a. All employees shall be competent to perform the services of the position for which they are hired.
   b. Assessment of staff competency shall be reviewed/revised/updated at least every two (2) years.
   c. The competency policy shall outline the competency program including services and tasks performed by each designated staff member based on job function or category. This policy shall be reviewed and signed by each staff member.

8. Minimum standards for education and training of persons employed by home medical equipment suppliers:
   a. Educational topics provided must be relevant to the employee's job function and provided on an annual basis.
   b. Records of staff attendance at all educational programs shall be maintained.
   c. The educational program shall include:
      i. OSHA and safety issues to include fire safety, disaster preparedness, and office security;
      ii. HIPAA, privacy, and security;

d. Orientation and training shall be provided to each employee whose job functions require it within ninety (90) days of employment. Orientation and training of the following areas shall be documented:
    i. Use of the equipment;
    ii. Safety and cleaning precautions and procedures for equipment;
    iii. Preventative maintenance, repair, and testing program for equipment;
    iv. Return demonstrations on back up oxygen systems delivered;
    v. Emergency and routine contact procedures; and
    vi. Delivery and review of written instruction materials to the patient to ensure the patient receives adequate information in order to properly operate the equipment.

9. Minimum standards for physical location and storage of home medical equipment:
    a. Suitable facilities shall be maintained to house inventory, to allow for equipment maintenance workspace and the storage and retrieval of all records required to be kept;
    b. The facility is kept in a clean, orderly, and sanitary condition at all times;
    c. The applicant's services are accessible to its customer base;
    d. The applicant complies with all USP, FDA, DOT and OSHA requirements regarding the storage, packaging, labeling, and shipping of medical equipment including medical gases;
    e. The applicant can be contacted twenty-four (24) hours, seven (7) days per week when services needed are essential to the maintenance of life or when lack of services might reasonably cause harm;
    f. The applicant complies with all local/state fire and building laws;
    g. 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
    h. The facility is temperature controlled and regulated as required by the manufacturer.

10. Minimum standards for selection of equipment, devices, and supplies:
    a. All equipment, devices, and supplies shall be based on patient need;
    b. The permit holder shall obtain copies of features, warranties, and instructions for all items from the manufacturers;
    c. All items shall meet applicable Food and Drug Administration (FDA) regulations.

11. Minimum standards of safety and cleaning requirements for home medical equipment:
    a. Demonstrate and maintain documentation that a function and safety check was performed on each piece of equipment prior to set up, and such equipment is free of defects and operates within the manufacturer's specifications;
    b. Document that all appropriate warning labels or labeling, including tags, are present on the equipment provided.
    c. Maintain an established protocol for cleaning and disinfecting equipment which addresses both aerobic and anaerobic pathogens;
    d. Maintain a Safety Data Sheet (SDS) on file for solutions and products used in cleaning and disinfecting procedures;
    e. Maintain segregated areas on the premises and in delivery vehicles for clean, dirty, and contaminated equipment;
    f. Clean and disinfect equipment according to manufacturers' specifications;
    g. Instruct the patient on proper cleaning techniques as specified by the manufacturer; and

h. Ensure that all medical gas, oxygen, and respiratory related equipment is properly identified by a tag or label as to its current status of use, i.e. out of order or ready for use.

12. Minimum standards of comprehensive preventative maintenance, repair, and testing program for home medical equipment:
    a. Provide scheduled preventive maintenance, repairs and testing of all equipment and devices provided to clients as recommended by the equipment or device manufacturer;
    b. Establish a process to identify equipment scheduled for maintenance and provide the needed maintenance or repair of the equipment and devices according to the manufacturer's guidelines or recommendations;
    c. Provide the client with a replacement item when equipment/device in use is scheduled for maintenance or repair;
    d. Establish a process to repair equipment and devices that are reported as damaged or malfunctioning;
    e. Maintain a file of all current manufacturer's maintenance, warranties, repair, and testing instructions and recommendations for all equipment, devices, and supplies the permit provides;
    f. Only qualified staff members perform repairs or maintenance on equipment and devices according to the manufacturer's guidelines;
    g. Report and return to the manufacturer of any defective item and disposition, as appropriate; and
    h. The maintenance and repair data for each piece of equipment or device, as appropriate, includes:
        i. Equipment name, manufacturer, model, and serial number;
        ii. Date equipment went into service;
        iii. Projected dates of manufacturer recommended scheduled maintenance cleaning and calibration;
        iv. Dates maintenance performed include both the dates and reason of performed repairs and the date of disposition after maintenance or repair; and
        v. Name of person or company performing the repair.

13. Implement a written procedure at each location for handling patient complaints and problems, which includes a complaint file documenting complaints and problems and resolutions of the complaints or problems. This procedure shall be in writing, shall be available onsite, either in a hardcopy or immediately accessible electronically, and provided upon the request of an agent of the Board. All patient complaints shall be maintained for at least a three (3) year period.

14. Minimum standards for patient counseling instruction:
    a. Utilize orientation checklists to review:
        i. Instructions for use of the equipment; and
        ii. Safety precautions; and
        iii. Cleaning procedures; and
        iv. Maintenance procedures; and
        v. Return demonstrations on back up oxygen systems delivered;
    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.
d. A written plan of service shall be developed, implemented, and documented in the patient record and shall include 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.

15. Additional Regulations for medical gas, oxygen, and respiratory equipment suppliers:
    a. Oxygen and other medical gases being transported in cylinder or liquid form~~,~~ shall comply with all current State and Federal Department of Transportation rules and regulations;
    b. Transfilling medical oxygen systems~~,~~ shall comply with Food and Drug Administration (FDA) requirements regarding transfilling and repackaging;
    c. Oxygen and other medical gases provided in cylinder or liquid form shall meet minimum purity standards for medical grade oxygen and medical gases; and
    d. 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.
    e. Documentation of all testing of equipment shall be maintained and readily accessible.

16. Medical gas and oxygen suppliers must also meet the following recall procedures:
    a. Ensure that lot numbers and expiration dates are affixed to each cylinder delivered;
    b. Maintain a tracking system for all medical oxygen and gas delivered;
    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.

17. The above required policies, testing and required documentation shall be in writing and shall be available onsite or immediately accessible electronically, and provided upon the request of an agent of the Board.

18. A permit holder shall report to the Board within thirty (30) days any adverse action taken by another licensing jurisdiction, government agency, law enforcement agency, or court.

19. Failure to comply with the required policies and/or standards set forth in this Article shall be deemed a violation of the rules and regulations of the Board and may result in disciplinary action taken by the Board.

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. PHARMACY TECHNICIAN REGISTRATION.
   Every person who acts or serves as a pharmacy technician must obtain a pharmacy technician registration from the Board in compliance with Mississippi Code Annotated Section 73-21-111. In addition to the requirements of Mississippi Code Annotated Section 73-21-111, an applicant for pharmacy technician shall be at least eighteen (18) years of age and be a high school graduate or hold a GED equivalent. No pharmacist whose license has been denied, revoked, suspended, or restricted for disciplinary reasons shall be eligible to be registered as a pharmacy technician.

2. PHARMACY TECHNICIAN REGISTRATION RENEWAL.
   Each pharmacy technician shall renew his/her registration annually pursuant to Mississippi Code Annotated Section 73-21-111. A pharmacy technician registration that has not been renewed by March 31 of each year shall become inactive and the pharmacy technician shall not perform any pharmacy technician duties until the registration is renewed. Pharmacy technician registrations that are renewed after March 31 of the renewal period shall be charged a Fifty Dollar ($50) late renewal fee.

3. PHARMACY TECHNICIAN RESPONSIBILITIES AND GUIDELINES.
   A. In order to adequately protect the public health, pharmacy 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.
      b. Accept by oral communication a new prescription of any nature.
      c. Prepare a copy of a prescription or read a prescription to another person.
      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.
      e. Counsel a patient on medications or perform a drug utilization review.
      f. Perform any task that requires the professional judgment of a pharmacist.
      g. Perform any task that is in violation of any federal or state pharmacy or drug laws.

B. Persons registered with the Board as a pharmacy technician may perform approved tasks under the direct supervision of a registered pharmacist 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 judgmental 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: The pharmacy technician must follow guidelines established by the pharmacist by policy and procedures. 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.

m. Pharmacy Technicians in an institutional setting may conduct patient medication histories without the direct supervision of a pharmacist. The institution must have policies and procedures and training protocols to govern such tasks.

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

D. Each pharmacy technician registered by the Board shall be responsible to maintain current information in the Board's licensing system. Each pharmacy technician shall update any change of employment or change of residential address within ten (10) days of the change occurring. If the pharmacy technician becomes unemployed, the pharmacy technician shall update the employment status to unemployed within ten (10) days of becoming unemployed. Failure to update information changes in the Board's licensing system may result in disciplinary action by the Board.

4. RESPONSIBILITY OF SUPERVISING PHARMACIST AND PHARMACIST-IN-CHARGE.

A. It is the responsibility of the supervising pharmacist on duty to require that all pharmacy technicians under his/her supervision comply with this Article.

B. It is the responsibility of the pharmacist-in-charge to ensure that all pharmacy technicians performing pharmacy technician duties have valid pharmacy technician registrations.

C. It is the responsibility of the pharmacist-in-charge to ensure that the technician is certified, has completed an accredited training program, or provides a training program for a pharmacy technician that includes pharmacy terminology, pharmacy calculations, dispensing systems and labeling requirements, pharmacy laws and regulations, record keeping and documentation, proper handling and storage of medications, pharmaceutical diversion awareness, and medication safety.

D. A pharmacist may not supervise more than three (3) pharmacy technicians during a given time. Any pharmacist that supervises more than three (3) pharmacy technicians during a given time is subject to disciplinary action by the Board. Support personnel used solely for clerical duties such as filing prescriptions and general record keeping need not be included in the pharmacist to pharmacy technician supervision ratio.

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

The Mississippi Board of Pharmacy shall operate a Prescription Monitoring Program (PMP) as provided for in Mississippi Code Annotated Section 73-21-127.

1. In addition to the provisions of Mississippi Code Annotated Section 73-21-127, the following reporting provisions shall apply:
    a. Direct administration of a controlled substance to the body of an ultimate user (such as in an inpatient setting) is exempt from reporting.
    b. Any quantity of drug dispensed that is limited to an amount adequate to treat the ultimate user for 48 hours or less is exempt from reporting.
    c. Dispensing by a veterinarian is exempt, however prescriptions written by a veterinarian and filled by a pharmacy are required to be reported by the pharmacy.
    d. Controlled substance prescriptions dispensed for patients in nursing homes, ICFMRs, and Assisted Living facilities ARE required to be reported.
    e. Mail Order pharmacies (in Mississippi, or shipping into Mississippi) shall report

to the Mississippi Prescription Monitoring Program.

f. Pharmacies shall report controlled substance dispensing information every twenty-four (24) hours or the next business day.

2. The Board may specify a uniform electronic format for the mandatory reporting, sharing, and disclosure of PMP information. Dispensers will submit information as required by the Prescription Monitoring Program. Any reporting errors shall be corrected by the dispensers within seven (7) working days of being notified of the error. The Board may develop guidelines for the registration and use of the Prescription Monitoring Program. Failure to follow the Board approved guidelines may result in disciplinary action.
3. It is the intent of the Board that pharmacists utilize the PMP on a regular basis based on their professional judgment.
4. Prior to dispensing a prescription for a Schedule II opiate, a pharmacist **shall** review the prescription monitoring program based on any of the following circumstances:
    a. The patient is a new customer to that pharmacy; or
    b. The patient has not had an opioid prescription filled at that pharmacy within six (6) months;
5. The prescription monitoring program shall be reviewed at least once every six (6) months for any patient receiving controlled substances.

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

Pharmacy Benefit Managers must comply with all federal and state laws and regulations which include, but is not limited to:

- Mississippi Pharmacy Practice Act §§ 73-21-69 to 73-21-129
- Pharmacy Benefit Prompt Pay Act §§ 73-21-151 to 73-21-163
- Pharmacy Audit Integrity Act §§ 73-21-175 to 73-21-191
- Prescription Drugs Consumer Affordable Alternative Payment Options Act §§ 73-21-201 to 73-21-205

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. The application shall include, but not be limited to:

i. The identity of the pharmacy benefit manager and any company or organization controlling the operation of the pharmacy benefit manager, including the name, business address, and contact person and direct contact information for the pharmacy benefit manager and the controlling entity.
ii. A current "Certificate of Good Standing" from the Mississippi Secretary of State.
iii. In the case of a pharmacy benefit manager domiciled out of the State of Mississippi, a certificate that the pharmacy benefit manager, controlling 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 benefit 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 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 current 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, or equivalent administrator with the authority to speak on behalf of the company, attesting to the accuracy of the information contained in the filing.

B. A non-refundable license fee of Five Hundred Dollars ($500.00) must accompany each application for the application to be considered complete.
C. The Pharmacy Benefit Manager license shall be an annually renewable license expiring on December 31st of each calendar year. 'Pro rata' pharmacy benefit manager licenses are allowed by the Board.
D. A completed application, along with online fee payment, for an initial or a renewal of a Pharmacy Benefit Manager license must be received through the Mississippi Board of Pharmacy online licensing renewal gateway no later than 12:00 o'clock pm CDT December 31st annually. In the event that a pharmacy benefit manager license renewal is received after

December 31st, a Five Hundred Dollars ($500.00) late fee will be assessed and payment must be received by the Board before a license will be issued.

E. A monetary penalty of One Thousand Dollars ($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.

ARTICLE XLVI CHARITY PHARMACY PERMITS

1. Facilities that dispense prescription medications to poor and underprivileged persons at no charge shall obtain a charity pharmacy permit from the Mississippi Board of Pharmacy. Such medications must be dispensed pursuant to orders or prescriptions of practitioners authorized by law to prescribe such drugs. A facility permitted by the Mississippi Board of Pharmacy may dispense prescription medications to poor and underprivileged persons at no charge without a charity pharmacy permit pursuant to a charitable drug distribution program that has been approved by the Mississippi Board of Pharmacy.
2. A Charity Pharmacy may receive, maintain and dispense donated "sample" or purchased prescription medications to medically indigent residents of the State of Mississippi pursuant to a valid prescription or order. No dispensed patient specific medications may be received for re-dispensing under this permit except as allowed by these regulations. It is the responsibility of the charity pharmacy to determine eligibility of patients to receive medications at no cost. Controlled substances may not be donated, purchased by or transferred to a charity pharmacy under this regulation. Donated medications must be received, maintained and dispensed in accordance with Pharmacy Board Regulations.
3. A Charity Pharmacy may receive, maintain and dispense un-needed and unused prescription medications donated by Long Term Care (LTC) and Assisted Living Facilities (ALF) pursuant to regulations as established by the Board.
4. Long-Term Care (LTC) and Assisted Living Facilities (ALF) may apply to the Mississippi Board of Pharmacy for an Unused/Unneeded Medication Donation Permit. Such facilities must be in good standing with the Mississippi State Department of Health and must comply with guidelines established by the Board for donation of un-needed and unused prescription medications to a charity. It is the responsibility of the charity pharmacy to determine eligibility of patients to receive medications at no cost. Controlled substances may not be donated or transferred by a LTC or ALF to a charity pharmacy under this regulation.
5. The Consultant Pharmacist for the Long-Term Care/Assisted Living Facility must verify that the facility has policies and procedures to comply with the following guidelines regarding donation of un-needed and unused prescription medication to a charity pharmacy:
   A. A dispensed prescription is the property of the patient for whom it was prescribed regardless of who paid for the prescription. The patient or agent of the patient must authorize the donation of the un-needed or unused medications, unless the patient is deceased. Long Term Care/Assisted Living Facilities must maintain documentation of authorization for donation of medications for a period of two years.
   B. Quality and suitability for reuse of prescription medications may be determined by

verifying documentation of the following:

(1) That the medications have been maintained in compliance with applicable Board of Pharmacy Regulations.
(2) That prior to donation to the Charity pharmacy, the name of the patient and any identifying information must be redacted or removed.
(3) That medications are not adulterated or mutilated.
(4) That medications have identifiable expiration dates that are more than 60 days after the date the drugs are donated to the charity pharmacy.
(5) That liquid medications are not acceptable for reuse or dispensing.
(6) That expired medications are not acceptable for reuse or dispensing.
(7) That controlled substances are not acceptable for donation and dispensing.

C. Medication Donation Forms must be completed according to the following guidelines and contain the following pertinent information:

(1) Name, address, Board of Pharmacy Permit Number for the donating LTC/ALF facility and name of consultant pharmacist of the donating facility.
(2) Name, address, Pharmacy Permit Number and name of Pharmacist-In-Charge of Charity Pharmacy to whom the medications are to be donated.
(3) Name, strength, quantity, expiration date, and identification verification of medications to be donated.
(4) The consultant pharmacist or a licensed healthcare provider of the donating entity must attest that the donated medications have been maintained in compliance with procedures developed by the consulting pharmacist to product integrity of the donated medications.
(5) The Medication Donation Form must be signed and dated by the Charity Pharmacy Pharmacist Representative on receipt of donated medications.
(6) A copy of the Medication Donation Form must be maintained in chronological order by the donating entity as well as the receiving Charity Pharmacy for a period of two (2) years.

6. Eligibility of donated prescription drugs:

A. Prescription drugs for donation must be packaged in the original sealed or tamper evident packaging in unit dose or blister packs as prepared by the original packager/repackager of the medication.

B. Prior to reuse or dispensing by the Charity pharmacy, medications must be identified by a licensed Pharmacist.

C. No adulterated, misbranded, compounded or unidentified medications may be accepted and dispensed by the Charity Pharmacy.

D. The expiration date assigned by the original packager/repackager of the medication will become the expiration date of the donated medication.

E. Donated prescription medications may not be sold, resold, offered for sale, traded or transferred to any other entity.

F. Donated medications must remain in original sealed packaging until time of dispensing.

G. Unused and un-needed donated medications may not be returned to the donating facility

and must be rendered unusable and disposed of in accordance with Board of Pharmacy Regulations. Records of disposal must be maintained for a period of two (2) years and must contain the signatures of two witnesses to the destruction one of which must be a licensed pharmacist.

7. Responsibility of Charity Pharmacy Pharmacist-In-Charge regarding donated medications for dispensing:
   A. Coordinate retrieval, transportation and storage of donated unused prescription medications from authorized LTC/ALF. To insure the integrity of the donated medications, the donated medications should be transported directly from the donating facility to the charitable pharmacy.

Assure that donated medications are identified and product integrity is guaranteed.

ARTICLE XLVII PHYSICIAN DISPENSING FACILITY PERMITS

For the purposes of this Article, a "dispensing physician" means any physician who dispenses to a patient for the patient's use any controlled substance, legend drug or other medication where such medication is purchased by the physician for resale to a patient whether or not a separate charge is made.

Section 1: Application for Permit

Pursuant to Part 2640, Chapter 1, Rule 1.9 of the Mississippi Board of Medical Licensure Regulations, every dispensing physician in this State shall obtain a dispensing physician facility permit from the Mississippi Board of Pharmacy for every location where controlled substances or legend drugs are dispensed. The dispensing physician must obtain a certificate to dispense medications from the Mississippi Board of Medical Licensure prior to applying for a dispensing physician facility permit from the Mississippi Board of Pharmacy. Such permit shall be obtained by applying for a permit on a form supplied by the Mississippi Board of Pharmacy and accompanied by a fee of Three Hundred Dollars ($300.00). All physician dispensing facility permits expire on December 31 of each year and shall be renewed annually by submitting a renewal application and a renewal fee of Three Hundred Dollars ($300.00). Any renewal application postmarked after December 31st of the renewal period shall be returned and assessed a Fifty Dollar ($50.00) late fee prior to renewal. Dispensing physician facility permits are not transferable or assignable.

Any physician that utilizes an automated dispensary must obtain a separate Automated Physician Dispensing Facility Permit. Each automated dispensary shall be required to have a separate permit. An automated physician dispensing facility permit shall be obtained by applying on a form supplied by the Mississippi Board of Pharmacy and accompanied by a fee of Three Hundred Dollars ($300.00). All automated physician dispensing facility permits expire on December 31 of each year and shall be renewed annually by submitting a renewal application and a renewal fee of Three Hundred Dollars ($300.00). Any renewal application postmarked after December 31st of the renewal period shall be returned and assessed a Fifty Dollar ($50.00) late fee prior to renewal. Automated dispensing physician facility permits are not transferable or assignable.

Section 2: Record Keeping

1. Every Physician Dispensing Facility Permit issued by the Board of Pharmacy shall keep complete and accurate records of the acquisition and disposition of all controlled substances. An annual inventory shall be conducted on all controlled substances. 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 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 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 dispensing physician may use a data processing system or a manual record keeping system for the storage and retrieval of all drug order and dispensing information. All records of controlled substances in Schedule II shall be maintained separately from all other records. 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 dispensing physician utilizes a data processing system, it must provide immediate retrieval of drug dispensing information. The data processing system must have the capability of producing a hard copy printout of all dispensing information 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) hours constitutes prima facie evidence of failure to keep and maintain records as required by this Article.

4. The records of controlled substances in Schedules II, III, IV and V, which are maintained in a data processing system shall be maintained with the following information pertaining to the initial dispensing of the drug shall be entered into the data processing system:

    a. Date of initial dispensing;
    b. Name and address of patient;
    c. Dispensing physician's name and DEA registration number; and
    d. The name, strength, dosage form and quantity of the controlled substance ordered and dispensed.

5. A record of all controlled substance dispensing information shall be transmitted to the Prescription Monitoring Program every twenty-four (24) hours or within the next business day by all dispensing physicians for all controlled substances dispensed which amounts to greater than a forty-eight (48) hour supply. 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 NCPDP registration number;
i. The dispenser's DEA registration number, and
j. The method of payment of the prescription purchase.

6. A single physician dispenser may not share or otherwise allow other practitioners to utilize medications or inventory ordered under their authority. Proper transference of medications may take place pursuant to an accurate record of acquisition and disposition of the medications being transferred. Additionally, for the transference of controlled substances, all Federal Drug Enforcement Agency (DEA) regulations must be followed.

Section 3: Storage and Dispensing Conditions

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 and laws of the United States or federal regulations.

2. No physician may delegate dispensing authority to another person. Except as allowed pursuant to an automated dispensing physician facility permit, a physician must personally dispense the medication. For the purpose of this regulation, "personally dispense" means the physician must actually obtain the medication, prepare, count, place the medication into the appropriate container and affix the appropriate label to the container.

3. A physician shall not dispense out-of-date drugs and 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.

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

5. A physician 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 physician.

6. All drug products shall be maintained, stored and dispensed in such a manner as to maintain the integrity of the product.
7. Unless requested not to do so, all medication dispensed in a liquid or solid dosage form shall be dispensed in child resistant packaging.

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

9. Customized Patient Medication Packages: In lieu of dispensing two or more prescribed drug products in separate containers, a physician may, with the consent of the patient or a patient's care giver, 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 physician 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. A record of each patient med-pak shall be made and filed. Each record shall contain at a minimum:
        i. The name and address of the patient;
        ii. The unique identification number of the patient med-pak;
        iii. The drug name, manufacturer or distributor name and lot number of each drug product contained;
        iv. Any special labeling instructions;
        v. 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;
        vi. The date of preparation of the patient med-pak and the beyond-use date that was assigned; and
        vii. The name or initials of the physician responsible for preparing the med-pak.

Section 4: Labeling

The label on the dispensing container shall include:

1. The name and address of the patient to whom the medication was dispensed;
2. The date that the medication was dispensed;
3. The drug name, manufacturer or distributor name and lot number of the drug product dispensed;
4. The strength and quantity of the medication;
5. Directions for taking or administering the medication;
6. The name and address of the physician dispensing the medication, and
7. Any other information which is necessary or required.

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.

Section 5: Security

In all places where controlled substances are maintained, they shall be maintained in a manner to deter loss by theft or burglary. 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. Only the dispensing physician or person authorized by the dispensing physician shall have access to this storag5e2area.

Section 6: Inventory

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 dispensing physician 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 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 dispensing physician 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 dispensing physician 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. A facility may conduct the controlled substance inventory at another date so long as the annual inventory is conducted during the same period each year. This inventory shall be maintained with the other controlled substance records of the facility.

Section 7: Disposal of Controlled Substances

1. Any dispensing physician authorized to possess controlled substances in the course of his/her 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. A dispensing physician facility permitted 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:
        i. The name of the drug;
        ii. The amount of the drug which was administered and the amount of the drug which was destroyed;
        iii. The time and the date of destruction;
        iv. The name of the patient;
        v. The name of the person admin$_5$i$_3$stering the drug;

vi. The signature of the person (physician or nurse) making the destruction;
vii. 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, may be destroyed on premise provided the destruction is documented.

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

Section 8: Automated Dispensaries

1. Any physician utilizing an automated dispensary will be responsible for developing and implementing written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality and maintenance of the quality, potency and purity of the medications dispensed by the automated dispensary.

2. Any physician utilizing an automated dispensary will be responsible for the proper maintenance and inventory/accountability requirements as if the physician were personally dispensing the medications to the patients from his or her medication stock/inventory in their personal practice.

3. An automated dispensary may only be stocked by the inventory/stock from a single physician and may not dispense controlled substances.

4. The stocking of an automated dispensary shall be performed only by the responsible physician. This task may not be delegated.

5. All medications dispensed from the automated dispensary shall comply with the labeling requirements of Section 4 of this regulation.
6. No medication may be dispensed from an automated dispensary unless the patient has first had an initial or follow-up visit with the physician. Any refills dispensed from an automated dispensary must be accompanied by its own preceding physician visit.

7. Any automated dispensing system shall maintain an electronic record of all information related to each and every medication dispensed including, but not limited to, all label information and date and time of dispensing.

Section 9: Dispensing Compounded Products

1. Prior to engaging in compounding pharmaceuticals for dispensing, a physician dispensing facility shall obtain a compounding certificate from the Mississippi Board of Pharmacy.

    a. To obtain a compounding certificate, an applicant must complete a compounding certificate application. A compounding certificate is required for each physician dispenser. The physician dispenser shall not delegate any part of the compounding process to another person.

    b. A compounding certificate will expire w5h4en the physician dispensing permit expires and can be

renewed at the time the physician dispensing permit is renewed.

c. Compounding for dispensing, without obtaining the compounding certificate, shall be grounds for disciplinary action.

d. Every physician dispenser that engages in compounding for dispensing shall keep records of all compounded products that are dispensed to patients. Such records shall be readily available for authorized inspection for six (6) years from the date of dispensing.

e. Any dispensing physician with an active compounding certificate for dispensing is subject to a compounding inspection by the Board.

2. Every dispensing physician that is engaged in compounding pharmaceuticals for dispensing shall comply with USP 795, USP 797, and USP 800 when compounding in the scope of those chapters.

3. For the purposes of this Section, flavoring is not considered compounding. In addition, the combining of commercially manufactured, ready-to-use products shall be exempt from USP 795 compounding standards under the following conditions:

a. No more than four (4) commercially manufactured ready-to-use products (that have not been manipulated) are used;

b. Compounding is not done in anticipation of orders;

c. Must follow USP 795 beyond use dates (BUDs);

d. The prescription label complies with all related USP chapter requirements as well as the labeling requirements set forth in this regulation.

4. A physician dispenser may compound for dispensing to an individual patient, medications that

are not commercially available in the marketplace in compliance with Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act. This includes compounding a copy of a commercial product when that commercial product is not available as evidenced by either of the following:

a. Products that appear as unresolved status on the FDA drug shortage list in effect under Section 506E of the FD&C Act; or

b. Products discontinued and no longer marketed by the manufacturer.

5. A physician dispenser shall not compound for dispensing products that appear on the FDA List of Drugs withdrawn or removed from the market for safety reasons or on the FDA List of Drug products that present demonstrable difficulties in compounding.

6. A physician dispenser shall not offer compounded human drug products to other practitioners or to pharmacies for resale or dispensing. A physician dispenser may not dispense compounded product from another practitioner or that was compounded by a 503A or 503B pharmacy.

7. Nothing in this section prohibits a physician from compounding for immediate administration or requires a physician dispenser to obtain a compounding certificate from the MS Board of Pharmacy for compounding for administration.

ARTICLE XLVIII TELEPHARMACY

Section 1. Purpose and Scope

As market forces continue to adversely impact community pharmacies, some pharmacies have or will close permanently. In certain parts of the state, such closures create critical access issues for citizens in need of pharmacy services. As the pharmacy workforce continues to evolve, with changing patterns of distribution of the workforce, certain parts of the state have experienced a shortage of pharmacists, which can adversely impact access to pharmacist care. In an effort to improve access to pharmacist care and pharmacy services, the Board has determined it appropriate to establish standards for the operation and regulation of telepharmacy services.

Section 2. Definitions. For the purposes of this Article:

(a) "Supervising pharmacy" means a permitted pharmacy in Mississippi that supervises a telepharmacy dispensing site.
(b) "Still image capture" means a specific image captured electronically from a video or other image capture device.
(c) "Store and forward" means a video or still image record which is saved electronically for future review.
(d) "Telepharmacy dispensing site" means a permitted pharmacy supervised by a supervising pharmacy that offers pharmacy services using a telepharmacy system.
(e) "Telepharmacy system" means a system that monitors the dispensing of prescription drugs and provides for related drug use review and patient counseling services by an electronic method which shall include the use of the following types of technology:
    1. Audio and video;
    2. Still image capture; and
    3. Store and forward

Section 3. Telepharmacy Dispensing Site

A. General Requirements
    1. At the time of its opening, there shall be no other pharmacies licensed by the board within a fifteen (15) mile radius of the location of the telepharmacy dispensing site. The Board may grant a waiver to the mileage restriction if the Board determines there is an appropriate need for a waiver.
    2. A telepharmacy dispensing site permit shall authorize the permit holder to procure and possess prescription and non-prescription drugs and devices, and:
        a. hold such items for immediate administration directly to a patient pursuant to an order from a lawful prescriber;
        b. dispense such items to a patient for later use upon the order of a practitioner with prescriptive authority; or

c. distribute such items to another entity with lawful authority to procure and possess such items.

3. In the event the telepharmacy dispensing site intends to procure and possess any controlled substances, that pharmacy shall first obtain a Controlled Substance Registration as well as the federal registration from the U.S. Drug Enforcement Administration.
4. The telepharmacy dispensing site shall operate using a telepharmacy system under the control of its supervising pharmacy.
5. A supervising pharmacy may supervise no more than two telepharmacy dispensing sites, and the supervising pharmacy and all such telepharmacy dispensing sites must be located within the state of Mississippi.
6. The minimum staffing requirement for a telepharmacy dispensing site shall be a certified pharmacy technician with at least two years of experience as a certified pharmacy technician and with demonstrated proficiency in operating the telepharmacy system used in the telepharmacy dispensing site.
7. A pharmacist shall approve each prescription before it is taken away from the telepharmacy dispensing site.

B. Licensing Procedure

1. A person or other entity intending to operate a telepharmacy dispensing site shall obtain a Telepharmacy Dispensing Site Permit by completing an application form supplied by the board and submit it with any required attachments and the application fee to the board.
2. The board shall not process applications received by facsimile or that are incomplete or submitted with the incorrect fee.
3. A person or other entity who submits a false or fraudulent application shall be subject to disciplinary action by the board.
4. If determined appropriate by the board, the applicant may be required to meet with a committee of the board or an agent of the board prior to the issuance of the permit.
5. Regardless of the date issued, the telepharmacy dispensing site permit shall expire on December 31 of every year. No person or other entity may operate a telepharmacy dispensing site with an expired permit.
6. In the event a new community pharmacy opens at a location within a fifteen (15) mile radius of the telepharmacy dispensing site, then the board shall not renew the telepharmacy dispensing site permit. The board shall notify the supervising pharmacy responsible for the telepharmacy dispensing site of the new pharmacy operating within a fifteen (15) mile radius of the telepharmacy dispensing site and of the requirement for the telepharmacy dispensing site to close permanently on or before the expiration date of the telepharmacy dispensing site's current renewal of its permit. The closure shall be accomplished in compliance with the board's regulations. In lieu of permanent closure, the telepharmacy dispensing site may elect to apply for and complete the conversion of its permit to a community pharmacy permit prior to the expiration date of the telepharmacy dispensing site permit.
7. In the event a telepharmacy dispensing site is dispensing more than one hundred fifty (150) prescriptions per day based on a six (6) month average, the telepharmacy dispensing site shall be required to convert its permit to a community pharmacy permit prior to the expiration date of the telepharmacy dispensing site permit.

C. Maintenance of Permit
1. A telepharmacy dispensing site permit shall be valid only for the person or other entity to whom it is issued and it shall not be subject to sale, assignment or other transfer, voluntary or involuntary, nor shall the permit be valid for any premises other than the physical location for which it was issued.
2. A duplicate or replacement permit shall be issued upon the written request of the permit holder and payment of the required fee. A duplicate or replacement permit shall be marked as such and it shall not serve or be used as an additional or second permit.

D. Closure of Permit
1. When the owner of the permit intends to close the telepharmacy dispensing site permanently, the owner's managing officer and the pharmacist-in-charge shall be accountable to the board for the proper closure of the pharmacy in compliance with the board's regulations.

2. Unless approved by the board in advance, all remaining inventory and records shall be transferred to the supervising pharmacy that oversees that telepharmacy dispensing site.

E. Standards of Practice
   1. Environmental Standards
      a. The prescription department shall consist of an area at least 300 square feet in size; this space shall be restricted to authorized personnel only and not accessible to the general public.
      b. The prescription department shall contain sufficient fixtures, equipment, and supplies commensurate with the nature and scope of practice for that pharmacy.
      c. The prescription department shall include a sink with a hot and cold water supply, exclusive of restroom facilities, with approved sewage disposal.
      d. All areas where drugs and devices are stored shall be dry, well-lighted, well ventilated, and maintained at temperatures which will ensure the integrity of drugs prior to their dispensing as stipulated by the United States Pharmacopeia and/or manufacturer's or distributor's product labeling unless otherwise indicated by the board.
      e. The prescription department shall be secured by a physical barrier with suitable locks and a monitored alarm system capable of detecting unauthorized entry.
      f. Prescription and other patient healthcare information shall be maintained in a manner that protects the integrity and confidentiality of such information; and
      g. The dispensing site shall be configured and equipped to sustain optimal operation of all the technological components of the telepharmacy system.
   2. Minimum Staffing Requirements
      a. The pharmacist-in-charge of the supervising pharmacy shall also be the pharmacist-in-charge of the telepharmacy dispensing site.
      b. The telepharmacy dispensing site does not require the personal presence of a pharmacist but it is permissible for a pharmacist to practice in that site.
      c. In the absence of a pharmacist, the site shall be staffed by one – and only one – certified pharmacy technician. The technician present at the telepharmacy dispensing site shall be included with the other personnel at the supervising pharmacy when calculating the ratio of pharmacists to technicians.
      d. A pharmacy intern may not practice at a telepharmacy dispensing site.
      e. Additional clerical personnel may also be present at the site.
   3. Operational Standards
      a. The telepharmacy dispensing site shall be connected to its supervising pharmacy using the telepharmacy system.
      b. In the event of an interruption in the proper operation of the telepharmacy system, the telepharmacy dispensing site must immediately cease operations. No prescription shall be dispensed during the interruption and the staff shall post a sign at the entrance advising the public of an estimated date or time of resumption of services.

c. The dispensing of prescriptions shall be construed as completed at the supervising pharmacy; therefore, the telepharmacy dispensing site shall use the supervising pharmacy's dispensing information system.
d. The telepharmacy system shall permit prescription labels to be generated from the supervising pharmacy or the telepharmacy dispensing site.
    i. New prescriptions may be received and entered at the supervising pharmacy with a label printed at the telepharmacy dispensing site; or
    ii. New prescriptions received at the telepharmacy dispensing site may be entered by the technician with all verification, utilization review, and final check the responsibility of the pharmacist at the supervising pharmacy.
e. As part of the final check, the pharmacist shall verify the source container, prescription medication, and prescription label against the prescription form, using the technology in the telepharmacy system.
f. A pharmacist shall counsel the patient or patient's agent for all new prescriptions and refills, using the technology in the telepharmacy system.
g. The pharmacist-in-charge shall be responsible for routine inspection of the telepharmacy dispensing site. The policies and procedures shall identify the inspection criteria to be monitored. Each inspection shall be conducted no later than thirty (30) days after the previous inspection. The inspection reports detailing the findings of each inspection shall be retained for at least two (2) years and shall be readily retrievable upon request by the board or its agent.

4. Recordkeeping Requirements
    a. The dispensing information system shall be capable of recording the names or initials of the pharmacist responsible for final verification of the prescription as well as the technician assisting in the dispensing process and to print those identities on the prescription label.
    b. Prescriptions filled at the telepharmacy dispensing site shall be distinguishable on records from those filled at the supervising pharmacy.
    c. Records of activities at the telepharmacy dispensing site shall be distinguishable from the records of activities at the supervising pharmacy.
    d. Telepharmacy dispensing sites holding controlled substances shall maintain a perpetual inventory of controlled substances and drugs of concern.

ARTICLE L AMBULATORY SURGERY CENTERS AND MULTI-PROVIDER CLINICS

1. For purposes of this Article, an ambulatory surgery center (ASC) or multi-provider clinic (MPC) shall mean a facility where medical procedures or services are performed or provided by multiple practitioners for outpatients. Examples would include but would not be limited to an ambulatory surgery center, a medical doctor's office/clinic, or a dental office. An ASC/MPC consultant refers to any Mississippi licensed pharmacist who reviews processes and ensures appropriate reconciliation of controlled substances at least monthly on site in an ASC or MPC. The ASC/MPC is responsible for complying with all applicable regulations of the Mississippi Board of Pharmacy as well as other state and federal regulatory agency requirements.

2. Every ASC/MPC shall obtain an ASC/MPC permit from the Mississippi Board of Pharmacy for every location where controlled substances are administered by multiple providers/practitioners under one DEA number. This permit along with a DEA registration allows the ASC/MPC to order controlled substances for the facility to be used by multiple providers/practitioners under one clinic DEA number. Such a permit shall be obtained by applying for a permit on a form supplied by the Mississippi Board of Pharmacy and accompanied by a fee. This requirement does not apply to ASC's or clinics with only a single provider where the provider's registration is based at that location. All ASC/MPC permits will expire on December 31 of each year and shall be renewed annually by submitting a renewal application and renewal fee. Any renewal application received after December 31st of the renewal period will be assessed a $50.00 late fee prior to renewal. ASC/MPC permits are not transferable or assignable. There are two subcategories for ASC/MPC permits: outpatient surgery center/clinic pharmacy and outpatient surgery center/clinic consultant.
   A. Ambulatory Surgery Center/Multi-Provider Clinic Pharmacy Services (fee $300)
      (1) This permit should be used when a pharmacist is integrated into the daily workflows of the facility including ordering and stocking of medications and clinical support but is not an actual dispensing pharmacy. Additionally, a controlled substance permit is required.
      (2) See Institutional Pharmacy Regulations
   B. Ambulatory Surgery Center/Multi-Provider Clinic Consultant (fee $100)
      (1) Requires there to be at least a monthly arrangement with a pharmacist onsite to review processes and ensure appropriate reconciliation of controlled substances. The pharmacist reviews appropriate records for ordering, storage, and other record keeping requirements and documentation of administration, wastage, and disposal of medications in accordance with documented policies and procedures of the ASC/MPC.
      (2) This permit will serve as the controlled substance permit required by statute.

3. Consultant Pharmacist Requirement.
   A. A permit for an ASC/MPC shall not be issued or renewed unless the consultant pharmacist is licensed in this state.

B. If the license of the consultant pharmacist becomes void or inactive due to surrender, revocation, suspension, restriction or for any other reason, or if the license of the consultant pharmacist is removed from the permit of the ASC/MPC for any reason, application must be made for a new permit with another consultant pharmacist within fifteen (15) days.
C. Failure to submit an application with the new consultant pharmacist within fifteen (15) days shall render the permit inactive and the ASC/MPC shall not conduct any activities using the controlled substances that were obtained pursuant to the permit and the corresponding DEA registration until a new permit is issued to the ASC/MPC with a new consultant pharmacist on the permit.
D. The failure to obtain a new consultant pharmacist within the required fifteen (15) day time period shall be reported to DEA by the Mississippi Board of Pharmacy.

4. Record Keeping
   A. Every ASC/MPC permit issued by the Board of Pharmacy shall keep complete and accurate records of acquisition and disposition of all controlled substances. These records shall include:
      (1) Complete and accurate records of receipt of all controlled substances
      (2) Complete and accurate records of disposition of all controlled substances
   B. Records of acquisition and disposition must be maintained for a period of at least 2 years. 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 controlled substances on hand and record of disposition of controlled substances.
   C. 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.
   D. The ASC/MPC consultant pharmacist shall provide a monthly report outlining any findings from their review. This document shall be signed by the medical director or designee and dated. The facility must maintain these reports for a period of two (2) years, and a copy must be available for inspection upon request.

5. Storage
   A. All drug products shall be maintained and stored in such a manner that maintains the integrity of the product.
   B. All containers from which drugs are administered must be properly labeled.
   C. Outdated drugs shall be removed from general stock and returned to a reverse distributor licensed with the Mississippi Board of Pharmacy or destroyed onsite following DEA rules for onsite destruction and use of DEA Form 41.

6. Security
   A. In all places where controlled substances are maintained, they shall be maintained in a manner to deter loss by theft or burglary. A securely locked, substantially constructed area shall be provided for storage of all controlled substances. Controlled substances for return to a MS licensed reverse distributor or for onsite destruction as described above shall be maintained in the drug storage area of the clinic and segregated from general stock 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 authorized personnel shall have access to the drug storage area.

7. Inventory
   A. A perpetual inventory shall be maintained on all Controlled Substances, Schedule II-V.
   B. The medical director shall develop inventory listings of drugs to be included in specified areas and assure that:
      a. Such drugs are available therein, properly stored and labeled
      b. Only pre-packaged drugs are available therein, in amounts sufficient for immediate therapeutic requirements
      c. Each drug stored in these areas shall be assigned a "par value" and each addition or withdrawal by authorized persons shall be properly documented.
   C. 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 ASC/MPC staff conducting the inventory.
   D. The consultant pharmacist shall be notified within twenty-four (24) hours of discovery of any discrepancy in counts or the loss of any controlled substances. The consultant pharmacist shall notify the Board immediately upon his/her notification with a plan to investigate the loss. A written report shall be submitted to the Mississippi Board of Pharmacy within fifteen (15) days; this written report shall include a copy of the inventory required by this ARTICLE.
   E. When a facility has a change in ownership or a change in the consultant pharmacist listed on their permit (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 consultant pharmacist (pharmacist-in-charge) shall notify the Board in writing within fourteen (14) days by what means and as to whom controlled substances were transferred or disposed of.
   F. 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. A facility may conduct the controlled substance inventory at another date as long as the annual inventory is conducted during the same period each year. This inventory shall be maintained with the other controlled substance records of the facility.

ARTICLE LI CONSULTING PHARMACISTS TO AMBULATORY SURGERY CENTERS AND MULTI-PROVIDER CLINICS

1. For purposes of this article, a consultant pharmacist for an ambulatory surgery center (ASC) or multi-provider clinic (MPC) shall mean any Mississippi licensed pharmacist who is listed on an ASC/MPC permit (pharmacist-in-charge). The consultant pharmacist is on site at least monthly to conduct a review of medication related processes and to ensure appropriate reconciliation of controlled substances. The consultant pharmacist for an ASC/MPC would not need a nursing home consultant certificate. The consultant pharmacist is responsible for providing recommendations only to the ASC/MPC.

2. Responsibilities of the ASC/MPC Consultant Pharmacist
   A. A perpetual inventory shall be maintained on all Controlled Substances, Schedule II-V.
   B. The ASC/MPC Consultant Pharmacist shall be responsible for advising the ASC/MPC on all matters related to safe and efficient administration, control, and accountability for drugs and proper licensing. The responsibilities of the consultant pharmacist shall include developing policies and procedures and implementation for the following:
      (1) All medications shall be purchased from facilities registered with the Mississippi Board of Pharmacy
      (2) Preparation of sterile medications prepared within the ASC/MPC
      (3) Admixture of parenteral products
      (4) Compounding of drugs, solutions, ointments, lotions, etc.
      (5) To assure that no legend medication shall be stored in patient care areas except upon the approval of the Consultant Pharmacist
      (6) Establishment of specifications for procurement of all materials, including drugs, chemicals and biologicals, subject to approval of the appropriate committee of the ASC/MPC and compliance with DSCSA requirements
      (7) Participation in the development of a formulary for the ASC/MPC where applicable
      (8) Proper filling and labeling of all containers from which drugs are to be administered
      (9) Maintenance of records of all transactions of the ASC/MPC 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
      (10) Assure that all drugs shall be stored in areas within the ASC/MPC and satellite storage areas to provide proper sanitation, temperature, light, ventilation, moisture control, segregation and security; 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 administration prior to disposition; that emergency drugs are in adequate and proper supply at designated locations
      (11) Assure that all areas occupied by the ASC/MPC shall be capable

of being locked to prevent unauthorized access, and that all areas where drugs are stored or administered shall be locked

(12) Ensure that discontinued and outdated drugs are returned to a MS Board of Pharmacy registered reverse distributor or destroyed onsite following DEA rules for onsite destruction and use of DEA Form 41.

(13) Drugs shall be administered only upon receipt of a written or oral order. There shall be no "take home" medications dispensed under this permit. Samples are exempt from this Article.

(14) 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, administration, record keeping, and disposal of controlled substances are met. There shall be policies and procedures to ensure the control of these drugs at all times, including those instances when drugs are stored in the surgery departments, nursing stations, clinics, diagnostic laboratories, etc. Periodic (at least monthly) inspections by the consultant pharmacist of the proper storage of these drugs is required and deficiencies must be corrected.

(15) At least monthly consultant audits of records of acquisition and disposition. Monthly audits of controlled substance inventory.

(16) Assisting the medical director as applicable in developing inventory listings of drugs to be included in these areas and assure that:

(a) Such drugs are available therein, properly stored and labeled

(b) Only pre-packaged drugs are available therein, in amounts sufficient for immediate therapeutic requirements

(c) Each drug stored in these areas shall be assigned a "par value" and each addition or withdrawal by authorized persons shall be properly documented. The consultant pharmacist shall audit these areas on a regular basis but no less than once per month.

(17) The consultant pharmacist shall provide a monthly report to the ASC/MPC outlining any findings from their review. This document shall be signed by the medical director or designee and dated.

(18) A consultant pharmacist for an ASC/MPC shall report to the appropriate regulatory or licensing agency any serious deficiency or violation noted on his/her consultant report if such deficiency is not corrected or addressed by the permit holder by the date of the next monthly visit by the consultant pharmacist at the permit site