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 "MSBP", 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.