MISSISSIPPI LEGISLATURE REGULAR SESSION 2006

By: Representative Holland

To: Public Health and Human Services

HOUSE BILL NO. 1117

AN ACT TO PROVIDE FOR THE LICENSURE AND REGULATION OF WHOLESALE DISTRIBUTORS OF PRESCRIPTION DRUGS BY THE STATE BOARD OF PHARMACY; TO PRESCRIBE THE MINIMUM REQUIREMENTS FOR LICENSURE OF WHOLESALE DISTRIBUTORS; TO RESTRICT CERTAIN TRANSACTIONS REGARDING PRESCRIPTION DRUGS BY WHOLESALE DISTRIBUTORS; TO REQUIRE WHOLESALE DISTRIBUTORS TO MAINTAIN RECORDS OF ALL TRANSACTIONS REGARDING RECEIPT AND DISTRIBUTION OF PRESCRIPTION DRUGS, WHICH SHALL INCLUDE PEDIGREES FOR ALL DRUGS THAT LEAVE THE NORMAL DISTRIBUTION CHANNELS; TO REQUIRE WHOLESALE DISTRIBUTORS WHO HAVE A PEDIGREE FOR A PRESCRIPTION DRUG TO AFFIRMATIVELY VERIFY BEFORE ANY FURTHER DISTRIBUTION OF THE DRUG THAT EACH TRANSACTION LISTED ON THE PEDIGREE HAS OCCURRED; TO SPECIFY THE MINIMUM CONTENTS FOR DRUG PEDIGREES; TO AUTHORIZE THE BOARD TO ISSUE ORDERS REQUIRING PERSONS TO IMMEDIATELY CEASE DISTRIBUTION OF A PRESCRIPTION DRUG WITHIN THE STATE UNDER CERTAIN CIRCUMSTANCES; TO PROHIBIT CERTAIN ACTIONS REGARDING PRESCRIPTION DRUGS; TO PROVIDE FOR CRIMINAL PENALTIES FOR VIOLATIONS OF THIS ACT; TO AMEND SECTIONS 73-21-73, 73-21-83, 73-21-103 AND 73-21-105, MISSISSIPPI CODE OF 1972, TO CONFORM TO THE PRECEDING PROVISIONS; AND FOR RELATED PURPOSES.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MISSISSIPPI:

SECTION 1. As used in this act, the following terms shall have the meanings provided in this section:

(a) "Authentication" means to affirmatively verify before any wholesale distribution of a prescription drug occurs that each transaction listed on the pedigree has occurred.

(b) "Board" means the State Board of Pharmacy.

(c) "Chain pharmacy warehouse" means a physical location for drugs and/or devices that acts as a central warehouse and performs intracompany sales or transfers of the drugs or devices to a group of chain pharmacies that have the same common ownership and control.

(d) "Facility" means a facility of a wholesale distributor where prescription drugs are stored, handled, repackaged, or offered for sale.

(e) "Normal distribution channel" means a chain of custody for a medication that goes from a manufacturer to a wholesale distributor to a pharmacy to a patient or a chain of custody for a medication that goes from a manufacturer to a wholesale distributor to a chain pharmacy warehouse to their intracompany pharmacy to a patient.

(f) "Pedigree" means a document or electronic file containing information that records each distribution of any given prescription drug within the distribution channel.

(g) "Prescription drug" means any drug (including any biological product, except for blood and blood components intended for transfusion or biological products that are also medical devices) required by federal law (including federal regulation) to be dispensed only by a prescription, including finished dosage forms and bulk drug substances subject to Section 503(b) of the Federal Food, Drug and Cosmetic Act ("FFDCA").

(h) "Repackage" means repackaging or otherwise changing the container, wrapper, or labeling to further the distribution of a prescription drug excluding that completed by the pharmacists responsible for dispensing product to the patient.

(i) "Repackager" means a person who repackages.

(j) "Wholesale distributor" means anyone engaged in the wholesale distribution of prescription drugs, including, but not limited to, repackagers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, and drug wholesalers or distributors; independent wholesale drug traders; retail pharmacies that conduct wholesale distribution; and chain pharmacy warehouses that conduct wholesale distribution.

(k) "Wholesale distribution" does not include:

(i) Intracompany sales of prescription drugs, meaning any transaction or transfer between any division,

subsidiary, parent or affiliated or related company under common ownership and control of a corporate entity;

(ii) The sale, purchase, distribution, trade, or transfer of a prescription drug or offer to sell, purchase, distribute, trade, or transfer a prescription drug for emergency medical reasons;

(iii) The distribution of prescription drug samples by manufacturers' representatives;

(iv) Drug returns, when conducted by a hospital, health care entity, or charitable institution in accordance with 21 CFR Section 203.23;

(v) The sale of minimal quantities of prescription drugs by retail pharmacies to licensed practitioners for office use;

(vi) Retail pharmacies' delivery of prescription drugs to a patient or patient's agent pursuant to the lawful order of a licensed practitioner; or

(vii) The sale, transfer, merger or consolidation of all or part of the business of a pharmacy or pharmacies from or with another pharmacy or pharmacies, whether accomplished as a purchase and sale of stock or business assets.

(l) "Wholesaler" means a person engaged in the wholesale distribution of prescription drugs.

SECTION 2. (1) Every wholesale distributor located in this state that engages in the wholesale distribution of prescription drugs in Mississippi, and every nonresident wholesale distributor that ships prescription drugs into Mississippi, must be licensed by the board in accordance with this act before engaging in the wholesale distribution of wholesale prescription drugs in Mississippi. The board shall exempt manufacturers from any licensing and other requirements of this section, to the extent not required by federal law or regulation, unless particular requirements are deemed necessary and appropriate.

(2) The board shall require the following minimum information from each wholesale distributor applying to get a license under subsection (1):

(a) The name, full business address, and telephone number of the licensee.

(b) All trade or business names used by the licensee.

(c) Addresses, telephone numbers, and the names of contact persons for all facilities used by the licensee for the storage, handling, and distribution of prescription drugs.

(d) The type of ownership or operation (i.e., partnership, corporation, or sole proprietorship).

(e) The name(s) of the owner and/or operator of the licensee, including:

(i) If a person, the name of the person;

(ii) If a partnership, the name of each partner, and the name of the partnership;

(iii) If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation; and

(iv) If a sole proprietorship, the full name of the sole proprietor and the name of the business entity.

(f) A list of all licenses and permits issued to the applicant by any other state that authorizes the applicant to purchase or possess prescription drugs.

(g) The name of the applicant’s designated representative for the facility, together with a personal information statement and fingerprints.

(h) Each person required by paragraph (g) to provide a personal information statement and fingerprints shall provide the following information to the board:

(i) The person’s places of residence for the past seven (7) years;

(ii) The person’s date and place of birth;

(iii) The person’s occupations, positions of employment, and offices held during the past seven (7) years;

(iv) The principal business and address of any business, corporation, or other organization in which each such office of the person was held or in which each such occupation or position of employment was carried on;

(v) Whether the person has been, during the past seven (7) years, the subject of any proceeding for the revocation of any license or any criminal violation and, if so, the nature of the proceeding and the disposition of the proceeding;

(vi) Whether, during the past seven (7) years, the person has been enjoined, either temporarily or permanently, by a court of competent jurisdiction from violating any federal or state law regulating the possession, control, or distribution of prescription drugs or criminal violations, together with details concerning any such event;

(vii) A description of any involvement by the person with any business, including any investments, other than the ownership of stock in a publicly traded company or mutual fund, during the past seven (7) years, which manufactured, administered, prescribed, distributed, or stored pharmaceutical products and any lawsuits in which such businesses were named as a party;

(viii) A description of any misdemeanor or felony criminal offense of which the person, as an adult, was found guilty, regardless of whether adjudication of guilt was withheld or whether the person pled guilty or nolo contendere. If the person indicates that a criminal conviction is under appeal and submits a copy of the notice of appeal of that criminal offense, the applicant must, within fifteen (15) days after the disposition of the appeal, submit to the board a copy of the final written order of disposition; and

(ix) A photograph of the person taken in the previous thirty (30) days.

(3) The information required pursuant to subsection (2) shall be provided under oath.

(4) The board shall not issue a wholesale distributor license to an applicant, unless the board:

(a) Conducts a physical inspection of the facility at the address provided by the applicant as required in Section 2(2)(a); and

(b) Determines that the designated representative meets the following qualifications:

(i) Is at least twenty-one (21) years of age;

(ii) Has been employed full time for at least three (3) years in a pharmacy or with a wholesale distributor in a capacity related to the dispensing and distribution of, and recordkeeping relating to, prescription drugs;

(iii) Has received a score of seventy-five percent (75%) or more on an examination given by the state licensing authority regarding federal and state laws governing wholesale distribution of prescription drugs;

(iv) Is employed by the applicant full time in a managerial level position;

(v) Is actively involved in and aware of the actual daily operation of the wholesale distributor;

(vi) Is physically present at the facility of the applicant during regular business hours, except when the absence of the designated representative is authorized, including, but not limited to, sick leave and vacation leave;

(vii) Is serving in the capacity of a designated representative for only one (1) applicant at a time;

(viii) Does not have any convictions under any federal, state, or local laws relating to wholesale or retail

prescription drug distribution or distribution of controlled substances; and

(ix) Does not have any felony convictions under federal, state, or local laws.

(5) The board shall submit the fingerprints provided by a person with a license application for a statewide criminal record check and for forwarding to the Federal Bureau of Investigation for a national criminal record check of the person.

(6) The board shall require every wholesale distributor applying for a license to submit a bond of at least One Hundred Thousand Dollars ($100,000.00), or other equivalent means of security acceptable to the board, such as an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to a fund established by the board pursuant to subsection (7). The purpose of the bond is to secure payment of any fines or penalties imposed by the board and any fees and costs incurred by the board regarding that license, which are authorized under state law and which the licensee fails to pay thirty (30) days after the fines, penalties, or costs become final. The board may make a claim against such bond or security until one (1) year after the licensee’s license ceases to be valid. The bond shall cover all facilities operated by the applicant in the state.

(7) The board shall establish a special fund in the State Treasury, separate from its other funds, in which to deposit the wholesale distributor bonds.

(8) If a wholesale distributor distributes prescription drugs from more than one (1) facility, the wholesale distributor shall obtain a license for each facility.

(9) Every calendar year, the board shall send to each wholesale distributor licensed under this section a form setting forth the information that the wholesale distributor provided pursuant to subsection (2) of this section. Within thirty (30) days of receiving the form, the wholesale distributor must

identify and state under oath to the board all changes or corrections to the information that was provided pursuant to subsection (2). Changes in, or corrections to, any information in subsection (2) shall be submitted to the board as required by the board. The board may suspend or revoke the license of a wholesale distributor if the board determines that the wholesale distributor no longer qualifies for the license issued under this section.

(10) The designated representative identified pursuant to subsection (2)(g) of this section must complete continuing education programs as required by the board regarding federal and state laws governing wholesale distribution of prescription drugs.

(11) Information provided under this section shall not be disclosed to any person or entity other than a state licensing authority, government board, or government agency, provided that the licensing authority, government board, or agency needs that information for licensing or monitoring purposes.

SECTION 3. (1) A wholesale distributor shall receive prescription drug returns or exchanges from a pharmacy or chain pharmacy warehouse pursuant to the terms and conditions of the agreement between the wholesale distributor and the pharmacy and/or chain pharmacy warehouse, and those returns or exchanges shall not be subject to the pedigree requirement of Section 4 of this act. Wholesale distributors shall be held accountable for policing their returns process and insuring that this is of their operations, are secure and do not permit the entry of adulterated and counterfeit product.

(2) A manufacturer or wholesale distributor shall furnish prescription drugs only to a person licensed by the board. Before furnishing prescription drugs to a person not known to the manufacturer or wholesale distributor, the manufacturer or wholesale distributor shall affirmatively verify that the person is legally authorized to receive the prescription drugs by contacting the board.

(3) Prescription drugs furnished by a manufacturer or wholesale distributor shall be delivered only to the premises listed on the license; however, the manufacturer or wholesale distributor may furnish prescription drugs to an authorized person or agent of that person at the premises of the manufacturer or wholesale distributor if:

(a) The identity and authorization of the recipient is properly established; and

(b) This method of receipt is employed only to meet the immediate needs of a particular patient of the authorized person.

(4) Prescription drugs may be furnished to a hospital pharmacy receiving area provided that a pharmacist or authorized receiving personnel signs, at the time of delivery, a receipt showing the type and quantity of the prescription drug so received. Any discrepancy between receipt and the type and quantity of the prescription drug actually received shall be reported to the delivering manufacturer or wholesale distributor by the next business day after the delivery to the pharmacy receiving area.

(5) A manufacturer or wholesale distributor shall not accept payment for, or allow the use of, a person or entity’s credit to establish an account for the purchase of prescription drugs from any person other than the owner(s) of record, the chief executive officer, or the chief financial officer listed on the license of a person or entity legally authorized to receive prescription drugs. Any account established for the purchase of prescription drugs must bear the name of the licensee.

SECTION 4. (1) Each person who is engaged in wholesale distribution of prescription drugs shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of the prescription drugs. These records shall include pedigrees for all prescription drugs that leave the normal distribution channel.

(a) A retail pharmacy or chain pharmacy warehouse shall comply with the requirements of this section only if the pharmacy or chain pharmacy warehouse engages in wholesale distribution of prescription drugs.

(b) The board shall conduct a study to be completed by January 1, 2007, which study shall include consultation with manufacturers, distributors, and pharmacies responsible for the sale and distribution of prescription drug products in the state. Based on the results of the study, the board shall determine a mandated implementation date for electronic pedigrees. The implementation date for the mandated electronic pedigree shall be no sooner than December 31, 2007.

(2) Each person who is engaged in the wholesale distribution of a prescription drug (including repackagers, but excluding the original manufacturer of the finished form of the prescription drug), who is in possession of a pedigree for a prescription drug and attempts to further distribute that prescription drug, shall affirmatively verify before any distribution of a prescription drug occurs that each transaction listed on the pedigree has occurred.

(3) The pedigree shall:

(a) Include all necessary identifying information concerning each sale in the chain of distribution of the product from the manufacturer, through acquisition and sale by any wholesale distributor or repackager, until final sale to a pharmacy or other person dispensing or administering the drug. At minimum, the necessary chain of distribution information shall include:

(i) Name, address, telephone number, and if available, the e-mail address, of each owner of the prescription drug, and each wholesale distributor of the prescription drug;

(ii) Name and address of each location from which the product was shipped, if different from the owner’s;

(iii) Transaction dates; and

(iv) Certification that each recipient has authenticated the pedigree.

(b) At minimum, also include the:

(i) Name of the prescription drug;

(ii) Dosage form and strength of the prescription drug;

(iii) Size of the container;

(iv) Number of containers;

(v) Lot number of the prescription drug; and

(vi) Name of the manufacturer of the finished dosage form.

(4) Each pedigree or electronic file shall be:

(a) Maintained by the purchaser and the wholesale distributor for three (3) years from the date of sale or transfer; and

(b) Available for inspection or use within two (2) business days upon a request of an authorized officer of the law.

(5) The board shall adopt rules and a form relating to the requirements of this section no later than October 1, 2006.

SECTION 5. (1) If the board finds that there is a reasonable probability that:

(a) A wholesale distributor, other than a manufacturer, has:

(i) Violated a provision in this act, or

(ii) Falsified a pedigree, or sold, distributed, transferred, manufactured, repackaged, handled, or held a counterfeit prescription drug intended for human use,

(b) The prescription drug at issue as a result of a violation in paragraph (a) could cause serious, adverse health consequences or death, and

(c) Other procedures would result in unreasonable delay, the board shall issue an order requiring the appropriate

person (including the distributors, or retailers of the drug) to immediately cease distribution of the drug within the state.

(2) An order under subsection (1) shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than ten (10) days after the date of the issuance of the order, on the actions required by the order. If, after providing an opportunity for such a hearing, the board determines that inadequate grounds exist to support the actions required by the order, the board shall vacate the order.

SECTION 6. It is unlawful for a person to perform or cause the performance of or aid and abet any of the following acts in this state:

(a) Failure to obtain a license in accordance with this act, or operating without a valid license when a license is required by this act;

(b) Purchasing or otherwise receiving a prescription drug from a pharmacy, unless the requirements in Section 3(1) of this act are met;

(c) The sale, distribution, or transfer of a prescription drug to a person that is not legally authorized to receive the prescription drug, in violation of Section 3(2) of this act;

(d) Failure to deliver prescription drugs to specified premises, as required by Section 3(4) of this act;

(e) Accepting payment or credit for the sale of prescription drugs in violation of Section 3(5) of this act;

(f) Failure to maintain or provide pedigrees as required by this act;

(g) Failure to obtain, pass, or authenticate a pedigree, as required by this act;

(h) Providing the board or any of its representatives or any federal official with false or fraudulent records or making

false or fraudulent statements regarding any matter within the provisions of this act;

(i) Obtaining or attempting to obtain a prescription drug by fraud, deceit, misrepresentation or engaging in misrepresentation or fraud in the distribution of a prescription drug;

(j) Except for the wholesale distribution by manufacturers of a prescription drug that has been delivered into commerce pursuant to an application approved under federal law by the Food and Drug Administration, the manufacture, repacking, sale, transfer, delivery, holding, or offering for sale any prescription drug that is adulterated, misbranded, counterfeit, suspected of being counterfeit, or has otherwise been rendered unfit for distribution;

(k) Except for the wholesale distribution by manufacturers of a prescription drug that has been delivered into commerce pursuant to an application approved under federal law by the Food and Drug Administration, the adulteration, misbranding, or counterfeiting of any prescription drug;

(l) The receipt of any prescription drug that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit, or suspected of being counterfeit, and the delivery or proffered delivery of such drug for pay or otherwise; and

(m) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of a prescription drug or the commission of any other act with respect to a prescription drug that results in the prescription drug being misbranded.

The prohibited acts in this section do not include a prescription drug manufacturer, or agent of a prescription drug manufacturer, obtaining or attempting to obtain a prescription drug for the sole purpose of testing the prescription drug for authenticity.

SECTION 7. (1) If a person engages in the wholesale distribution of prescription drugs in violation of this act, the person is guilty of a felony and, upon conviction, may be imprisoned for not more than ten (10) years, and fined not more than Fifty Thousand Dollars ($50,000.00), or both.

(2) If a person knowingly engages in wholesale distribution of prescription drugs in violation of this act, the person is guilty of a felony and, upon conviction, shall be imprisoned for not more than twenty (20) years, or fined not more than Five Hundred Thousand Dollars ($500,000.00), or both.

SECTION 8. Section 73-21-73, Mississippi Code of 1972, is amended as follows:

73-21-73. As used in this chapter, unless the context requires otherwise:

(a) "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.

(b) "Board of Pharmacy," "Pharmacy Board," "MSBP" or "board" shall mean the State Board of Pharmacy.

(c) "Compounding" means (i) the production, preparation, propagation, conversion or processing of a sterile or nonsterile 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 (ii) 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.

(d) "Continuing education unit" shall mean ten (10) clock hours of study or other such activity as may be approved by the board, including, but not limited to, all programs which have been approved by the American Council on Pharmaceutical Education.

(e) "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.

(f) "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 which is required under federal or state law to be prescribed by a practitioner and dispensed by a pharmacist.

(g) "Dispense" or "dispensing" shall mean the interpretation of a valid prescription, 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.

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

(i) "Drug" shall mean:

(i) Articles recognized as drugs in the official United States Pharmacopeia, official National Formulary, official Homeopathic Pharmacopeia, other drug compendium or any supplement to any of them;

(ii) Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals;

(iii) Articles other than food intended to affect the structure or any function of the body of man or other animals; and

(iv) Articles intended for use as a component of any articles specified in subparagraph (i), (ii) or (iii) of this paragraph.

(j) "Drugroom" shall mean a business, which does not require the services of a pharmacist, where prescription drugs or prescription devices are bought, sold, maintained or provided to consumers.

(k) "Extern" shall mean a student in the professional program of a school of pharmacy accredited by the American Council on Pharmaceutical Education who is making normal progress toward completion of a professional degree in pharmacy.

(l) "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.

(m) "Generic equivalent drug product" shall mean a drug product which (i) contains the identical active chemical ingredient of the same strength, quantity and dosage form; (ii) is of the same generic drug name as determined by the United States Adoptive Names and accepted by the United States Food and Drug Administration; and (iii) conforms to such rules and regulations as may be adopted by the board for the protection of the public to assure that such drug product is therapeutically equivalent.

(n) "Interested directly" shall mean being employed by, having full or partial ownership of, or control of, any facility permitted or licensed by the Mississippi State Board of Pharmacy.

(o) "Interested indirectly" shall mean having a spouse who is employed by any facility permitted or licensed by the Mississippi State Board of Pharmacy.

(p) "Intern" shall mean a person who has graduated from a school of pharmacy but has not yet become licensed as a pharmacist.

(q) "Manufacturer" shall mean a person, business or other entity engaged in the production, preparation, propagation, conversion or processing of a prescription drug or device, if such actions are associated with promotion and marketing of such drugs or devices.

(r) "Manufacturer's distributor" shall mean any person or business who is not an employee of a manufacturer, but who distributes sample drugs or devices, as defined under subsection (i) of this section, under contract or business arrangement for a manufacturer to practitioners.

(s) "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.

(t) "Misappropriation of a prescription drug" shall mean to illegally or unlawfully convert a drug, as defined in subsection (i) of this section, to one's own use or to the use of another.

(u) "Nonprescription drugs" shall mean nonnarcotic medicines or drugs that may be sold without a prescription and are prepackaged and labeled for use by the consumer in accordance with the requirements of the statutes and regulations of this state and the federal government.

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

(w) "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.

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

(y) "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.

(z) Unlawful or unauthorized "possession" shall mean physical holding or control by a pharmacist of a controlled substance outside the usual and lawful course of employment.

(aa) "Practice of pharmacy" shall mean a health care service that includes, but is not limited to, the compounding, dispensing, and labeling of drugs or devices; interpreting and evaluating prescriptions; administering and distributing drugs and devices; the compounding, dispensing and labeling of 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 paragraph (jj) of this section; providing pharmacotherapeutic consultations; supervising supportive personnel and such other acts, services, operations or

transactions necessary or incidental to the conduct of the foregoing.

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

(cc) "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.

(dd) "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:

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

(ii) "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.

(ee) "Product selection" shall mean the dispensing of a generic equivalent drug product in lieu of the drug product ordered by the prescriber.

(ff) "Provider" or "primary health care provider" shall include a pharmacist who provides health care services within his or her scope of practice pursuant to state law and regulation.

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

(hh) "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.

(ii) "Supportive personnel" or "pharmacist technician" shall mean those individuals utilized in pharmacies whose responsibilities are to provide nonjudgmental technical services concerned with the preparation and distribution of drugs under the direct supervision and responsibility of a pharmacist.

(jj) "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.

(kk) "Wholesaler" shall mean a person who buys or otherwise acquires prescription drugs or prescription devices for resale or distribution, or for repackaging for resale or distribution, to persons other than consumers. <u>This term includes wholesale distributors and wholesalers as defined in Section 1 of this act.</u>

SECTION 9. Section 73-21-83, Mississippi Code of 1972, is amended as follows:

73-21-83. (1) The board shall be responsible for the control and regulation of the practice of pharmacy, to include the regulation of pharmacy externs or interns and pharmacist technicians, in this state, the regulation of the wholesaler distribution of drugs and devices as defined in Section 73-21-73 <u>and wholesale distributors of prescription drugs as defined in Section 1 of this act</u>, and the distribution of sample drugs or devices by manufacturer's distributors as defined in Section 73-21-73 by persons other than the original manufacturer or distributor in this state.

(2) A license for the practice of pharmacy shall be obtained by all persons prior to their engaging in the practice of pharmacy. However, the provisions of this chapter shall not apply

to physicians, dentists, veterinarians, osteopaths or other practitioners of the healing arts who are licensed under the laws of the State of Mississippi and are authorized to dispense and administer prescription drugs in the course of their professional practice.

(3) The initial licensure fee shall be set by the board but shall not exceed Two Hundred Dollars ($200.00).

(4) All students actively enrolled in a professional school of pharmacy accredited by the American Council on Pharmaceutical Education who are making satisfactory progress toward graduation and who act as an extern or intern under the direct supervision of a pharmacist in a location permitted by the Board of Pharmacy must obtain a pharmacy student registration prior to engaging in such activity. The student registration fee shall be set by the board but shall not exceed One Hundred Dollars ($100.00).

(5) All persons licensed to practice pharmacy prior to July 1, 1991, by the State Board of Pharmacy under Section 73-21-89 shall continue to be licensed under the provisions of Section 73-21-91.

SECTION 10. Section 73-21-103, Mississippi Code of 1972, is amended as follows:

73-21-103. (1) Upon the finding of the existence of grounds for action against any permitted facility or discipline of any person holding a license, registration or permit, seeking a license, registration or permit, or seeking to renew a license or permit under the provisions of this chapter<u>, or under the provisions of Sections 1 through 7 of this act</u>, the board may impose one or more of the following penalties:

(a) Suspension of the offender's license, registration and/or permit for a term to be determined by the board;

(b) Revocation of the offender's license, registration and/or permit;

(c) Restriction of the offender's license, registration and/or permit to prohibit the offender from performing certain acts or from engaging in the practice of pharmacy in a particular manner for a term to be determined by the board;

(d) Imposition of a monetary penalty as follows:

(i) For the first violation, a monetary penalty of not less than Two Hundred Fifty Dollars ($250.00) nor more than One Thousand Dollars ($1,000.00) for each violation;

(ii) For the second violation and subsequent violations, a monetary penalty of not less than Five Hundred Dollars ($500.00) nor more than Five Thousand Dollars ($5,000.00) for each violation.

Money collected by the board under Section 73-21-103, subsection (1)(d)(i), (ii) and (iv) shall be deposited to the credit of the State General Fund of the State Treasury;

(iii) The board may assess a monetary penalty for those reasonable costs that are expended by the board in the investigation and conduct of a proceeding for licensure revocation, suspension or restriction, including, but not limited to, the cost of process service, court reporters, expert witnesses and investigators.

Money collected by the board under Section 73-21-103, subsection (1)(d)(iii), shall be deposited to the credit of the Special Fund of the Pharmacy Board;

(iv) The board may impose a monetary penalty for those facilities/businesses registered with the Pharmacy Board as wholesalers/manufacturers of not less than Three Hundred Dollars ($300.00) per violation and not more than Fifty Thousand Dollars ($50,000.00) per violation;

(e) Refusal to renew offender's license, registration and/or permit;

(f) Placement of the offender on probation and supervision by the board for a period to be determined by the board;

(g) Public or private reprimand.

Whenever the board imposes any penalty under this subsection, the board may require rehabilitation and/or additional education as the board may deem proper under the circumstances, in addition to the penalty imposed.

(2) Any person whose license, registration and/or permit has been suspended, revoked or restricted pursuant to this chapter, whether voluntarily or by action of the board, shall have the right to petition the board at reasonable intervals for reinstatement of such license, registration and/or permit. Such petition shall be made in writing and in the form prescribed by the board. Upon investigation and hearing, the board may, in its discretion, grant or deny such petition, or it may modify its original finding to reflect any circumstances which have changed sufficiently to warrant such modifications. The procedure for the reinstatement of a license, registration or permit that is suspended for being out of compliance with an order for support, as defined in Section 93-11-153, shall be governed by Section 93-11-157 or 93-11-163, as the case may be.

(3) Nothing herein shall be construed as barring criminal prosecutions for violation of this chapter where such violations are deemed as criminal offenses in other statutes of this state or of the United States.

(4) A monetary penalty assessed and levied under this section shall be paid to the board by the licensee, registrant or permit holder upon the expiration of the period allowed for appeal of such penalties under Section 73-21-101, or may be paid sooner if the licensee, registrant or permit holder elects.

(5) When payment of a monetary penalty assessed and levied by the board against a licensee, registrant or permit holder in

accordance with this section is not paid by the licensee, registrant or permit holder when due under this section, the board shall have the power to institute and maintain proceedings in its name for enforcement of payment in the chancery court of the county and judicial district of residence of the licensee, registrant or permit holder, or if the licensee, registrant or permit holder is a nonresident of the State of Mississippi, in the Chancery Court of the First Judicial District of Hinds County, Mississippi. When such proceedings are instituted, the board shall certify the record of its proceedings, together with all documents and evidence, to the chancery court and the matter shall thereupon be heard in due course by the court, which shall review the record and make its determination thereon. The hearing on the matter may, in the discretion of the chancellor, be tried in vacation.

(6) The board shall develop and implement a uniform penalty policy which shall set the minimum and maximum penalty for any given violation of board regulations and laws governing the practice of pharmacy. The board shall adhere to its uniform penalty policy except in such cases where the board specifically finds, by majority vote, that a penalty in excess of, or less than, the uniform penalty is appropriate. Such vote shall be reflected in the minutes of the board and shall not be imposed unless such appears as having been adopted by the board.

SECTION 11. Section 73-21-105, Mississippi Code of 1972, is amended as follows:

73-21-105. (1) Every facility/business that shall engage in the wholesale distribution of prescription drugs, to include without limitation, manufacturing in this state, distribution into this state, or selling or offering to sell in this state, or distribution from or within this state, shall register biennially with the Mississippi State Board of Pharmacy by applying for a permit on a form supplied by the board and accompanied by a fee as

set by subsection (4) of this section. The Pharmacy Board shall by regulation determine the classification of permit(s) that shall be required. Wholesale distributors and wholesalers as defined in Section 1 of this act shall be subject to the provisions of Section 1 through 7 of this act, in addition to the provisions of this chapter.

(2) Every business/facility/pharmacy located in this state that engages in or proposes to engage in the dispensing and delivery of prescription drugs to consumers shall register with the Mississippi State Board of Pharmacy by applying for a permit on a form supplied by the board and accompanied by a fee as set by subsection (4) of this section. The Pharmacy Board shall by regulation determine the classification of permit(s) that shall be required.

(3) The board shall establish by rule or regulation the criteria which each business shall meet to qualify for a permit in each classification. The board shall issue a permit to any applicant who meets the criteria as established. The board may issue various types of permits with varying restrictions to businesses where the board deems it necessary by reason of the type of activities conducted by the business requesting a permit.

(4) The board shall specify by rule or regulation the registration procedures to be followed, including, but not limited to, specification of forms for use in applying for such permits and times, places and fees for filing such applications. However, the biennial fee for an original or renewal permit shall not exceed Three Hundred Dollars ($300.00).

(5) Applications for permits shall include the following information about the proposed business:

(a) Ownership;

(b) Location;

(c) Identity of the responsible person or pharmacist licensed to practice in the state, who shall be the pharmacist in

charge of the pharmacy, where one is required by this chapter, and such further information as the board may deem necessary.

(6) Permits issued by the board pursuant to this section shall not be transferable or assignable.

(7) The board shall specify by rule or regulation minimum standards for the responsibility in the conduct of any business/facility and/or pharmacy that has been issued a permit. The board is specifically authorized to require that the portion of the facility located in this state to which a pharmacy permit applies be operated only under the direct supervision of no less than one (1) pharmacist licensed to practice in this state, and to provide such other special requirements as deemed necessary. Nothing in this subsection shall be construed to prevent any person from owning a pharmacy.

(8) All businesses permitted by the board shall report to the board the occurrence of any of the following changes:

(a) Permanent closing;

(b) Change of ownership, management, location or pharmacist in charge;

(c) Any and all other matters and occurrences as the board may require by rule or regulation.

(9) Disasters, accidents and emergencies which may affect the strength, purity or labeling of drugs, medications, devices or other materials used in the diagnosis or the treatment of injury, illness and disease shall be immediately reported to the board.

(10) No business that is required to obtain a permit shall be operated until a permit has been issued for such business by the board. Any person, firm or corporation violating any of the provisions of this section shall be guilty of a misdemeanor and, upon conviction thereof, shall be punished by a fine of not less than One Hundred Dollars ($100.00) nor more than One Thousand Dollars ($1,000.00), or imprisonment in the county jail for not less than thirty (30) days nor more than ninety (90) days, or by

both such fine and imprisonment. However, the provisions of this chapter shall not apply to physicians, dentists, veterinarians, osteopaths or other practitioners of the healing arts who are licensed under the laws of the State of Mississippi and are authorized to dispense and administer prescription drugs in the course of their professional practice.

SECTION 12. This act shall take effect and be in force from and after July 1, 2006.