MISSISSIPPI LEGISLATURE REGULAR SESSION 2006

By: Representative Howell

To: Public Health and Human Services

COMMITTEE SUBSTITUTE
FOR
HOUSE BILL NO. 878

AN ACT TO CREATE NEW SECTION 73-21-125, MISSISSIPPI CODE OF 1972, TO REQUIRE DRUG MANUFACTURERS THAT ARE REQUIRED TO REGISTER WITH THE STATE BOARD OF PHARMACY TO MAKE ADEQUATE PROVISION FOR THE RETURN OF OUTDATED DRUGS FROM PHARMACIES FOR UP TO SIX MONTHS AFTER THE LABELED EXPIRATION DATE FOR PROMPT CREDIT OR REPLACEMENT; TO REQUIRE DRUG WHOLESALE DISTRIBUTORS AND REVERSE DISTRIBUTORS THAT ARE REQUIRED TO REGISTER WITH THE BOARD TO IMPLEMENT AND ADMINISTER THE RETURN POLICIES ESTABLISHED BY THE MANUFACTURER; TO AMEND SECTION 73-21-73, MISSISSIPPI CODE OF 1972, TO DEFINE THE TERM "REVERSE DISTRIBUTOR"; TO AMEND SECTION 73-21-105, MISSISSIPPI CODE OF 1972, TO REQUIRE REVERSE DISTRIBUTORS LOCATED IN OR OUTSIDE OF THIS STATE THAT CONDUCT BUSINESS WITH PHARMACIES IN THIS STATE TO REGISTER WITH THE BOARD; AND FOR RELATED PURPOSES.

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

SECTION 1. The following shall be codified as Section 73-21-125, Mississippi Code of 1972:

73-21-125. Each manufacturer that is required to register with the board and have a permit under Section 73-21-105 shall make adequate provision for the return of outdated drugs from pharmacies, both full and partial containers, excluding biological, infused or intravenously injected drugs and drugs that are inhaled during surgery, for up to six (6) months after the labeled expiration date, for prompt credit or replacement. Wholesale distributors and reverse distributors that are required to register with the board and have a permit under Section 73-21-105 shall implement and administer the return policies established by the manufacturer.

SECTION 2. 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" * * * means 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" * * * means 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" * * * means 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" * * * means the actual, constructive or attempted transfer of a drug or device from one person to another, whether or not for a consideration.

(f) "Device" * * * means 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" * * * means 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" * * * means the delivery of a drug or device other than by administering or dispensing to persons other than the ultimate consumer.

(i) "Drug" * * * means:

(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" * * * means 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" * * * means 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" * * * means 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" * * * means 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" * * * means 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" * * * means having a spouse who is employed by any facility permitted or licensed by the Mississippi State Board of Pharmacy.

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

(q) "Manufacturer" * * * means 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" * * * means 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 * * * means 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" * * * means 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" * * * means 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" * * * means an individual, corporation, partnership, association or any other legal entity.

(w) "Pharmacist" * * * means 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" * * * means 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" * * * means 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" * * * means physical holding or control by a pharmacist of a controlled substance outside the usual and lawful course of employment.

(aa) "Practice of pharmacy" * * * means 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 * * *(kk) 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" * * * means a physician, dentist, veterinarian, or other health care provider authorized by law to diagnose and prescribe drugs.

(cc) "Prescription" * * * means 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" * * * means 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" * * * means 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" * * * includes a pharmacist who provides health care services within his or her scope of practice pursuant to state law and regulation.

(gg) "Registrant" * * * means 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) "Reverse distributor" means a business operator that is responsible for the receipt and appropriate disposal of unwanted, unneeded or outdated stocks of controlled or uncontrolled drugs from a pharmacy.

(jj) "Supportive personnel" or "pharmacist technician" * * * means 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.

(kk) "Written guideline or protocol" * * * means 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.

(ll) "Wholesaler" * * * means a person who buys or otherwise acquires prescription drugs or prescription devices for resale or distribution, or for repackaging for resale or distribution, to persons other than consumers.

SECTION 3. Section 73-21-105, Mississippi Code of 1972, is amended as follows:

73-21-105. (1) Every facility/business that * * * engages 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, and every reverse distributor located in or outside of this state that conducts business with pharmacies in 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.

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