MISSISSIPPI LEGISLATURE REGULAR SESSION 2019

By: Senator(s) Kirby, Jackson (32nd), Jackson (11th)

To: Public Health and Welfare

SENATE BILL NO. 2365

AN ACT TO AMEND SECTION 73-21-73, MISSISSIPPI CODE OF 1972, TO DEFINE THE TERMS "BIOLOGICAL PRODUCT" AND "INTERCHANGEABLE BIOLOGICAL PRODUCT" AND REVISE THE DEFINITION OF THE TERM "PRODUCT SELECTION" FOR THE PURPOSES OF THE PHARMACY PRACTICE ACT; TO AMEND SECTION 73-21-117, MISSISSIPPI CODE OF 1972, TO ALLOW PRODUCT SELECTION OF INTERCHANGEABLE BIOLOGICAL PRODUCTS BY PHARMACISTS IN THE SAME MANNER AS PRODUCT SELECTION OF GENERIC DRUG EQUIVALENTS; TO REQUIRE PHARMACISTS TO MAKE CERTAIN ELECTRONICALLY ACCESSIBLE RECORDS OF BIOLOGICAL PRODUCTS DISPENSED BY THEM AND CONVEY THAT INFORMATION TO THE PRESCRIBERS OF THOSE PRODUCTS; TO AMEND SECTION 73-21-119, MISSISSIPPI CODE OF 1972, TO REQUIRE THAT THE LABELS FOR BIOLOGICAL PRODUCTS AND INTERCHANGEABLE BIOLOGICAL PRODUCTS CONTAIN CERTAIN INFORMATION; TO AMEND SECTION 73-21-127, 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. 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) "Biological product" means the same as that term is defined in 42 USC Section 262.

(* * *c) "Board of Pharmacy," "Pharmacy Board," "MSBP" or "board" means the State Board of Pharmacy.

(* * *d) "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.

(* * *e) "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.

(* * *f) "Deliver" or "delivery" means the actual, constructive or attempted transfer in any manner of a drug or device from one person to another, whether or not for a

consideration, including, but not limited to, delivery by mailing or shipping.

(* * *g) "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.

(* * *h) "Dispense" or "dispensing" means the interpretation of a valid prescription 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.

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

(* * *j) "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.

(* * *k) "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.

(* * *l) "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.

(* * *m) "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.

(* * *n) "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.

(o) "Interchangeable biological product" or "I.B." means a biological product that the federal Food and Drug Administration:

(i) Has licensed and determined as meeting the standards for interchangeability under 42 USC Section 262(k)(4); or

(ii) Has determined is therapeutically equivalent as set forth in the latest edition of or supplement to the federal Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations.

(* * *p) "Internet" means collectively the myriad of computer and telecommunications facilities, including equipment and operating software, which comprise the interconnected worldwide network of networks that employ the Transmission Control Protocol/Internet Protocol, or any predecessor or successor protocol to such protocol, to communicate information of all kinds by wire or radio.

(* * *q) "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.

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

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

(* * *t) "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.

(* * *u) "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.

(* * *v) "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.

(* * *w) "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.

(* * *x) "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.

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

(* * *z) "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.

(* * *aa) "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.

(* * *bb) "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.

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

(* * *dd) "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 (* * *nn) 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.

(* * *ee) "Practitioner" means a physician, dentist, veterinarian, or other health care provider authorized by law to diagnose and prescribe drugs.

(* * *ff) "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. "Prescription" includes a standing order issued by a practitioner to an individual pharmacy that authorizes the pharmacy to dispense an opioid antagonist to certain persons without the person to whom the opioid antagonist is dispensed needing to have an individual prescription, as authorized by Section 41-29-319(3).

(* * *gg) "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.

(* * *hh) "Product selection" means the dispensing of a generic equivalent drug product or an interchangeable biological product in lieu of the drug product ordered by the prescriber.

(* * *ii) "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.

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

(* * *kk) "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.

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

(* * *mm) "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.

(* * *nn) "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.

(* * *oo) "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.

(* * *pp) "Pharmacy benefit manager" has the same meaning as defined in Section 73-21-153.

SECTION 2. Section 73-21-117, Mississippi Code of 1972, is amended as follows:

73-21-117. (1) A pharmacist may select a generic equivalent drug product or an interchangeable biological product only when such selection results in lower cost to the purchaser, unless product selection is expressly prohibited by the prescriber.

(2) A pharmacist shall select a generic equivalent drug product or an interchangeable biological product when:

(a) The purchaser requests the selection of a generic equivalent drug product or an interchangeable biological product; or

(b) The prescriber has not expressly prohibited product selection; and

(c) Product selection will result in lower cost to the purchaser.

Before product selection is made, the pharmacist shall advise the purchaser of his prerogatives under this subsection.

(3) When requested by the purchaser to dispense the drug product or biological product as ordered by the prescriber, a

pharmacist shall not select a generic equivalent drug product or an interchangeable biological product.

(4) Within five (5) business days following the dispensing of any biological product, the dispensing pharmacist or the pharmacist's designee shall make an entry of the specific product provided to the purchaser, including the name of the product and the manufacturer, and communicate that information to the prescriber. The communication shall be conveyed by making an entry that is electronically accessible to the prescriber through:

(a) An interoperable electronic medical records system;

(b) An electronic prescribing technology;

(c) A pharmacist benefit management system; or

(d) A pharmacy record.

(5) Entry into an electronic records system as described in subsection (4) of this section is presumed to provide notice to the prescriber. Otherwise, the pharmacist shall communicate the biological product dispensed to the prescriber using facsimile, telephone, electronic transmission, or other prevailing means, provided that communication shall not be required where:

(a) There is no federal Food and Drug Administration-approved interchangeable biological product for the product prescribed; or

(b) A refill prescription is not changed from the product dispensed on the prior filling of the prescription.

(6) The board shall maintain a link on its website to the federal Food and Drug Administration's List of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations.

SECTION 3. Section 73-21-119, Mississippi Code of 1972, is amended as follows:

73-21-119. (1) The label of the container of any drug product which is sold within the State of Mississippi for resale at retail and which requires a prescription to be dispensed at retail shall contain at a minimum the name of the manufacturer of the final dosage unit, expiration date if applicable, batch or lot number and national drug code. The label of the container of any biological product dispensed by a pharmacist shall include its nonproprietary name designated by the federal Food and Drug Administration for use and the name of the manufacturer of the product.

(2) Whenever product selection is made, the pharmacist shall indicate on the label of the dispensed container the initials "G.E." *** * *** or "I.B.," as appropriate. The label for generic equivalent drugs shall include the proprietary name of the product dispensed or the generic name of the product dispensed and its manufacturer either written in full or appropriately abbreviated, unless the prescriber indicates that the name of the drug product shall not appear on the label. The label for interchangeable biological products shall include its nonproprietary name

designated by the federal Food and Drug Administration for use and the name of the manufacturer of the product.

SECTION 4. Section 73-21-127, Mississippi Code of 1972, is amended as follows:

73-21-127. The Board of Pharmacy shall develop and implement a computerized program to track prescriptions for controlled substances and to report suspected abuse and misuse of controlled substances in compliance with the federal regulations promulgated under authority of the National All Schedules Prescription Electronic Reporting Act of 2005 and in compliance with the federal HIPAA law, under the following conditions:

(a) Submission or reporting of dispensing information shall be mandatory and required by the State Board of Pharmacy for any entity dispensing controlled substances in or into the State of Mississippi, except for the dispensing of controlled substance drugs by a veterinarian residing in the State of Mississippi.

(b) The prescriptions tracked shall be prescriptions for controlled substances listed in Schedule II, III, IV or V and specified noncontrolled substances identified by the State Board of Pharmacy that are dispensed to residents in the State of Mississippi by licensed pharmacies, nonresident pharmacies, institutions and dispensing practitioners, regardless of dispenser location.

(c) The Board of Pharmacy shall report any activity it reasonably suspects may be fraudulent or illegal to the

appropriate law enforcement agency or occupational licensing board and provide them with the relevant information obtained for further investigation.

(d) The program shall provide information regarding the potential inappropriate use of controlled substances and the specified noncontrolled substances to practitioners, pharmacists-in-charge and appropriate state agencies in order to prevent the inappropriate or illegal use of these controlled substances. The specific purposes of the program shall be to: be proactive in safeguarding public health and safety; support the legitimate use of controlled substances; facilitate and encourage the identification, intervention with and treatment of individuals addicted to controlled substances and specified noncontrolled drugs; identify and prevent drug diversion; provide assistance to those state and federal law enforcement and regulatory agencies investigating cases of drug diversion or other misuse; and inform the public and health care professionals of the use and abuse trends related to controlled substance and specified noncontrolled drugs.

(e) (i) Access to collected data shall be confidential and not subject to the provisions of the federal Freedom of Information Act or the Mississippi Public Records Act. Upon request, the State Board of Pharmacy shall provide collected information to: pharmacists or practitioners who are properly registered with the State Board of Pharmacy and are authorized to

prescribe or dispense controlled substances for the purpose of providing medical and pharmaceutical care for their patients; local, state and federal law enforcement officials engaged in the administration, investigation or enforcement of the laws governing illicit drug use; regulatory and licensing boards in this state; Division of Medicaid regarding Medicaid and Medicare Program recipients; judicial authorities under grand jury subpoena; an individual who requests the individual's own prescription monitoring information; and prescription monitoring programs in other states through mutual agreement adhering to State Board of Pharmacy policies.

(ii) The Director of the Mississippi Bureau of Narcotics, or his designee, shall have access to the Prescription Monitoring Program (PMP) database for the purpose of investigating the potential illegal acquisition, distribution, dispensing, prescribing or administering of the controlled and noncontrolled substances monitored by the program, subject to all legal restrictions on further dissemination of the information obtained.

(iii) The State Board of Pharmacy may also provide statistical data for research or educational purposes if the board determines the use of the data to be of significant benefit to public health and safety. The board maintains the right to refuse any request for PMP data.

(iv) A pharmacist licensed by the Mississippi Board of Pharmacy must be a registered user of the PMP. Failure

of a pharmacist licensed by the Mississippi Board of Pharmacy to register as a user of the PMP is grounds for disciplinary action by the board.

(v) All licensed practitioners as defined under Section 73-21-73(* * *ee) holding an active DEA number shall register as users of the PMP.

(f) The Prescription Monitoring Program through the Board of Pharmacy may:

(i) Establish the cost of administration, maintenance, and operation of the program and charge to like agencies a fee based on a formula to be determined by the board with collaboration and input from participating agencies; and

(ii) Assess charges for information and/or statistical data provided to agencies, institutions and individuals. The amounts of those fees shall be set by the Executive Director of the Board of Pharmacy based on the recommendation of the Director of the PMP.

All such fees collected shall be deposited into the special fund of the State Board of Pharmacy and used to support the operations of the PMP.

(g) A dispenser pharmacist or practitioner licensed to dispense controlled substances and specified noncontrolled substance drugs who knowingly fails to submit drug-monitoring information or knowingly submits incorrect dispensing information shall be subject to actions against the pharmacist's or

practitioner's license, registrations or permit and/or an administrative penalty as provided in Sections 73-21-97 and 73-21-103. Any misuse of the PMP is subject to penalties as provided in Sections 73-21-97 and 73-21-103.

(h) The Board of Pharmacy and the Prescription Monitoring Program shall be immune from civil liability arising from inaccuracy of any of the information submitted to the program.

(i) "Practitioner," as used in this section, shall include any person licensed, registered or otherwise permitted to distribute, dispense, prescribe or administer a controlled substance, as defined under Section 41-29-105(y), and any person defined as a "practitioner" under Section 73-21-73(* * *ee).

(j) In addition to any funds appropriated by the Legislature, the State Board of Pharmacy may apply for any available grants and accept any gifts, grants or donations to assist in future development or in maintaining the program.

SECTION 5. This act shall take effect and be in force from and after July 1, 2019.