MISSISSIPPI LEGISLATURE REGULAR SESSION 2023

By: Representative Yancey

To: Drug Policy

HOUSE BILL NO. 1317

AN ACT TO AUTHORIZE A PHARMACIST TO TEST OR SCREEN FOR AND INITIATE OR ADMINISTER TREATMENT FOR MINOR, NONCHRONIC HEALTH CONDITIONS; TO DEFINE THE TERM "MINOR, NONCHRONIC HEALTH CONDITION"; TO AUTHORIZE A PHARMACIST TO DELEGATE THE ADMINISTRATIVE AND TECHNICAL TASKS OF PERFORMING CERTAIN TESTS TO AN INTERN OR PHARMACY TECHNICIAN ACTING UNDER THE SUPERVISION OF THE PHARMACIST; TO AUTHORIZE A PHARMACIST TO PROHIBIT THE DENIAL OF REIMBURSEMENT UNDER HEALTH BENEFIT PLANS FOR SERVICES AND PROCEDURES PERFORMED BY A PHARMACIST THAT ARE WITHIN THE SCOPE OF THE PHARMACIST'S LICENSE, AND WOULD BE COVERED IF THE SERVICES OR PROCEDURES WERE PERFORMED BY A PHYSICIAN, AN ADVANCED PRACTICE NURSE, OR PHYSICIAN ASSISTANT; TO AMEND SECTION 73-21-73, MISSISSIPPI CODE OF 1972, TO INCLUDE IN THE DEFINITION OF THE TERM "PRACTICE OF PHARMACY", ORDERING, PERFORMING, AND INTERPRETING CERTAIN TESTS AND INITIATING, ADMINISTERING, OR MODIFYING DRUG THERAPY; TO BRING FORWARD SECTION 83-9-36, MISSISSIPPI CODE OF 1972, WHICH RELATES TO PRESCRIBING PRACTITIONERS, STEP THERAPY OR FAIL-FIRST PROTOCOLS AND OVERRIDE PROCEDURES, FOR PURPOSES OF POSSIBLE AMENDMENT; AND FOR RELATED PURPOSES.

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

SECTION 1. (1) A pharmacist may test or screen for and initiate or administer treatment for minor, nonchronic health conditions. For purposes of this section, a "minor, nonchronic health condition" means typically a short-term health condition that is generally managed with non-controlled drug therapies,

minimal treatment, or self-care, and includes all of the following:

(a) Influenza;

(b) Streptococcus;

(c) SARS-COV-2 or other respiratory illness, condition, or disease;

(d) Lice;

(e) Urinary tract infection;

(f) Skin conditions, such as ringworm and athlete's foot;

(g) Other emerging and existing public health threats identified by the State Department of Health if permitted by an order, rule, or regulation; and

(h) Other health conditions that can be screened utilizing the waived test under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) that may be adopted by rule of the Mississippi Board of Pharmacy.

(2) A pharmacist who tests or screens for and treats health conditions under subsection (3) of this section may use any test that may guide clinical decision making which the Centers for Medicare and Medicaid Services has determined qualifies for a waiver under CLIA or the federal rules adopted thereunder, or any established screening procedures that can safely be performed by a pharmacist.

(3) A pharmacist may delegate the administrative and technical tasks of performing a CLIA-waived test to an intern or pharmacy technician acting under the supervision of the pharmacist.

(4) A pharmacist may prohibit the denial of reimbursement under health benefit plans for services and procedures performed by a pharmacist that are within the scope of the pharmacist's license and would be covered if the services or procedures were performed by a physician, an advanced practice nurse, or physician assistant.

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) "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 (1) 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; * * * ordering, performing, and interpreting tests authorized by the United States Food and Drug Administration (FDA) and waived under the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA), and initiating, administering, or modifying of drug therapy; selecting drugs; participating in drug utilization reviews; storing prescription drugs and devices; * * * 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 the practitioner's individual patients, provided that a specific protocol agreement between the practitioner and the pharmacist is signed and 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 3. Section 83-9-36, Mississippi Code of 1972, is brought forward as follows:

83-9-36. (1) When medications for the treatment of any medical condition are restricted for use by an insurer by a step therapy or fail-first protocol, the prescribing practitioner shall have access to a clear and convenient process to expeditiously request an override of that restriction from the insurer. An override of that restriction shall be expeditiously granted by the insurer under the following circumstances:

(a) The prescribing practitioner can demonstrate, based on sound clinical evidence, that the preferred treatment required under step therapy or fail-first protocol has been ineffective in the treatment of the insured's disease or medical condition; or

(b) Based on sound clinical evidence or medical and scientific evidence:

(i) The prescribing practitioner can demonstrate that the preferred treatment required under the step therapy or fail-first protocol is expected or likely to be ineffective based on the known relevant physical or mental characteristics of the insured and known characteristics of the drug regimen; or

(ii) The prescribing practitioner can demonstrate that the preferred treatment required under the step therapy or fail-first protocol will cause or will likely cause an adverse reaction or other physical harm to the insured.

(2) The duration of any step therapy or fail-first protocol shall not be longer than a period of thirty (30) days when the treatment is deemed clinically ineffective by the prescribing practitioner. When the prescribing practitioner can demonstrate, through sound clinical evidence, that the originally prescribed medication is likely to require more than thirty (30) days to provide any relief or an amelioration to the insured, the step therapy or fail-first protocol may be extended up to seven (7) additional days.

(3) As used in this section:

(a) "Insurer" means any hospital, health, or medical expense insurance policy, hospital or medical service contract, employee welfare benefit plan, contract or agreement with a health maintenance organization or a preferred provider organization, health and accident insurance policy, or any other insurance contract of this type, including a group insurance plan. However, the term "insurer" does not include a preferred provider organization that is only a network of providers and does not define health care benefits for the purpose of coverage under a health care benefits plan.

(b) "Practitioner" has the same meaning as defined in Section 73-21-73.

SECTION 4. This act shall take effect and be in force from and after July 1, 2023.