MISSISSIPPI LEGISLATURE REGULAR SESSION 2017

By: Representatives Willis, Sykes

To: Drug Policy; Public Health and Human Services

COMMITTEE SUBSTITUTE
FOR
HOUSE BILL NO. 996

AN ACT TO AMEND SECTION 41-29-319, MISSISSIPPI CODE OF 1972, TO AUTHORIZE HEALTH CARE PRACTITIONERS TO ISSUE A STANDING ORDER TO ONE OR MORE INDIVIDUAL PHARMACIES 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; TO AUGMENT THE LIST OF FIRST RESPONDERS WHO ARE AUTHORIZED TO ADMINISTER OPIOID ANTAGONISTS SUCH AS NALOXONE TO PROVIDE THAT BEFORE A PHARMACIST MAY DISPENSE AN OPIOID ANTAGONIST UNDER THE AUTHORITY OF SUCH A STANDING ORDER, THE PHARMACIST MUST COMPLETE A TRAINING PROGRAM APPROVED BY THE STATE BOARD OF PHARMACY ON OPIOID ANTAGONISTS; TO AMEND SECTION 73-21-73, MISSISSIPPI CODE OF 1972, TO PROVIDE THAT THE DEFINITION OF THE TERM "PRESCRIPTION" IN THE PHARMACY PRACTICE ACT INCLUDES STANDING ORDERS AUTHORIZED BY THE PRECEDING PROVISION; AND FOR RELATED PURPOSES.

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

SECTION 1. Section 41-29-319, Mississippi Code of 1972, is amended as follows:

41-29-319. (1) This section shall be known as the "Emergency Response and Overdose Prevention Act."

(2) As used in this section, the following terms shall be defined as provided in this subsection:

(a) "Practitioner" means a physician licensed to practice medicine in this state or any licensed health care provider who is authorized to prescribe an opioid antagonist.

(b) "Opioid antagonist" means any drug that binds to opioid receptors and blocks or inhibits the effects of opioids acting on those receptors and that is approved by the federal Food and Drug Administration for the treatment of an opioid-related overdose.

(c) "Opioid-related overdose" means an acute condition, including, but not limited to, extreme physical illness, decreased level of consciousness, respiratory depression, coma, mania or death, resulting from the consumption or use of an opioid or another substance with which an opioid was combined or that a layperson would reasonably believe to be resulting from the consumption or use of an opioid or another substance with which an opioid was combined for which medical assistance is required.

(d) "Emergency medical technician" means an individual who possesses a valid emergency medical technician's certificate issued under Section 41-59-33.

(3) (a) A practitioner acting in good faith and in compliance with the standard of care applicable to that practitioner may directly or by standing order prescribe an opioid antagonist to a person at risk of experiencing an opioid-related overdose or to a registered pain management clinic, family member,

friend or other person in a position to assist such person at risk of experiencing an opioid-related overdose.

(b) A practitioner acting in good faith and in compliance with the standard of care applicable to that practitioner may issue a standing order to one or more individual pharmacies that authorizes the pharmacy to dispense an opioid antagonist to a person at risk of experiencing an opioid-related overdose or to a family member, friend or other person in a position to assist such person at risk of experiencing an opioid-related overdose, without the person to whom the opioid antagonist is dispensed needing to have an individual prescription.

(4) A pharmacist acting in good faith and in compliance with the standard of care applicable to pharmacists may dispense opioid antagonists under a prescription or a standing order issued in accordance with subsection (3) of this section. However, before a pharmacist may dispense an opioid antagonist under the authority of subsection (3)(b) of this section, the pharmacist must complete a training program approved by the State Board of Pharmacy on opioid antagonists.

(5) A person acting in good faith and with reasonable care to another person whom he or she believes to be experiencing an opioid-related overdose may administer an opioid antagonist that was prescribed or authorized by a standing order in accordance with subsection (3) of this section.

(6) Emergency medical technicians, firefighters and law enforcement officers acting in good faith shall be authorized and permitted to administer an opioid antagonist as clinically indicated. Failure of an emergency medical technician, firefighter or law enforcement officer to act shall not expose such person to any criminal or civil liability.

(7) The following individuals are immune from any civil or criminal liability or professional licensing sanctions for the following actions authorized by this section:

(a) Any practitioner who prescribes or issues a standing order for an opioid antagonist in accordance with subsection (3) of this section;

(b) Any practitioner or pharmacist acting in good faith and in compliance with the standard of care applicable to that practitioner or pharmacist who dispenses an opioid antagonist under a prescription or standing order issued in accordance with subsection (3) of this section;

(c) Any person other than a practitioner who administers an opioid antagonist in accordance with subsection (5) of this section; and

(d) Any emergency medical technician, firefighters and law enforcement officers who administers an opioid antagonist in accordance with subsection (6) of this section.

SECTION 2. The Mississippi State Department of Health shall create and offer training for first responders that meets the following criteria:

(a) The course content must include:

(i) The signs and symptoms of an opioid overdose;

(ii) The protocols and procedures for administration of an opioid antagonist;

(iii) The signs and symptoms of an adverse reaction to an opioid antagonist;

(iv) The protocols and procedures to stabilize the patient if an adverse response occurs;

(v) The procedures for storage, transport and security of the opioid antagonist.

(b) The method of opioid antagonist administration being taught.

(c) Training will be overseen by a physician or pharmacist licensed in this state.

(d) Subject to the oversight required in paragraph (c) of this section, training may be provided by the employer of the first responder.

(e) First responders trained to possess and administer opioid antagonists must be retrained at least every three (3) years.

SECTION 3. 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 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.

(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 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) "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.

(o) "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.

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

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

(r) "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.

(s) "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.

(t) "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.

(u) "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.

(v) "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.

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

(x) "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.

(y) "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.

(z) "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.

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

(bb) "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 (ll) 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.

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

(dd) "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. <u>"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</u>

the opioid antagonist is dispensed needing to have an individual prescription, as authorized by Section 41-29-319(3).

(ee) "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.

(ff) "Product selection" means the dispensing of a generic equivalent drug product in lieu of the drug product ordered by the prescriber.

(gg) "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.

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

(ii) "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.

(jj) "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.

(kk) "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.

(ll) "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.

(mm) "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.

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

SECTION 4. This act shall take effect and be in force from and after July 1, 2017.

ST: Opioid antagonists; authorize standing orders to pharmacies to dispense to persons without individual prescriptions.