Sen. Melinda Bush

Filed: 5/12/2021

AMENDMENT TO SENATE BILL 2535

AMENDMENT NO. _____. Amend Senate Bill 2535 by replacing everything after the enacting clause with the following:

"Section 5. The Pharmacy Practice Act is amended by changing Section 19.1 as follows:

(225 ILCS 85/19.1)

(Section scheduled to be repealed on January 1, 2023)

Sec. 19.1. Dispensing opioid antagonists.

(a) Due to the recent rise in opioid-related deaths in Illinois and the existence of an opioid antagonist that can reverse the deadly effects of overdose, the General Assembly finds that in order to avoid further loss where possible, it is responsible to allow greater access of such an antagonist to those populations at risk of overdose.

(b) Notwithstanding any general or special law to the contrary, a licensed pharmacist shall ~~may~~ dispense an opioid

antagonist in accordance with written, standardized procedures or protocols developed by the Department with the Department of Public Health and the Department of Human Services and ~~if the procedures or protocols are~~ filed at the pharmacy before implementation and are available to the Department upon request.

(c) Before dispensing an opioid a pharmacist shall inform patients that opioids are addictive and offer to dispense an opioid antagonist ~~pursuant to this Section, a pharmacist shall complete a training program approved by the Department of Human Services pursuant to Section 5-23 of the Substance Use Disorder Act. The training program shall include, but not be limited to, proper documentation and quality assurance~~.

(d) For the purpose of this Section, "opioid antagonist" means a drug that binds to opioid receptors and blocks or inhibits the effect of opioids acting on those receptors, including, but not limited to, naloxone hydrochloride or any other similarly acting and equally safe drug approved by the U.S. Food and Drug Administration for the treatment of drug overdose.

(Source: P.A. 99-480, eff. 9-9-15; 99-642, eff. 7-28-16; 100-759, eff. 1-1-193.)

Section 10. The Illinois Controlled Substances Act is amended by changing Sections 312 and 313 as follows:

(720 ILCS 570/312) (from Ch. 56 1/2, par. 1312)

Sec. 312. Requirements for dispensing controlled substances.

(a) A practitioner, in good faith, may dispense a Schedule II controlled substance, which is a narcotic drug listed in Section 206 of this Act; or which contains any quantity of amphetamine or methamphetamine, their salts, optical isomers or salts of optical isomers; phenmetrazine and its salts; or pentazocine; and Schedule III, IV, or V controlled substances to any person upon a written or electronic prescription of any prescriber, dated and signed by the person prescribing (or electronically validated in compliance with Section 311.5) on the day when issued and bearing the name and address of the patient for whom, or the owner of the animal for which the controlled substance is dispensed, and the full name, address and registry number under the laws of the United States relating to controlled substances of the prescriber, if he or she is required by those laws to be registered. If the prescription is for an animal it shall state the species of animal for which it is ordered. The practitioner filling the prescription shall, unless otherwise permitted, write the date of filling and his or her own signature on the face of the written prescription or, alternatively, shall indicate such filling using a unique identifier as defined in paragraph (v) of Section 3 of the Pharmacy Practice Act. The written prescription shall be retained on file by the practitioner who

filled it or pharmacy in which the prescription was filled for a period of 2 years, so as to be readily accessible for inspection or removal by any officer or employee engaged in the enforcement of this Act. Whenever the practitioner's or pharmacy's copy of any prescription is removed by an officer or employee engaged in the enforcement of this Act, for the purpose of investigation or as evidence, such officer or employee shall give to the practitioner or pharmacy a receipt in lieu thereof. If the specific prescription is machine or computer generated and printed at the prescriber's office, the date does not need to be handwritten. A prescription for a Schedule II controlled substance shall not be issued for more than a 30 day supply, except as provided in subsection (a-5), and shall be valid for up to 90 days after the date of issuance. A written prescription for Schedule III, IV or V controlled substances shall not be filled or refilled more than 6 months after the date thereof or refilled more than 5 times unless renewed, in writing, by the prescriber. A pharmacy shall maintain a policy regarding the type of identification necessary, if any, to receive a prescription in accordance with State and federal law. The pharmacy must post such information where prescriptions are filled.

(a-5) Physicians may issue multiple prescriptions (3 sequential 30-day supplies) for the same Schedule II controlled substance, authorizing up to a 90-day supply. Before authorizing a 90-day supply of a Schedule II controlled

substance, the physician must meet the following conditions:

(1) Each separate prescription must be issued for a legitimate medical purpose by an individual physician acting in the usual course of professional practice.

(2) The individual physician must provide written instructions on each prescription (other than the first prescription, if the prescribing physician intends for the prescription to be filled immediately) indicating the earliest date on which a pharmacy may fill that prescription.

(3) The physician shall document in the medical record of a patient the medical necessity for the amount and duration of the 3 sequential 30-day prescriptions for Schedule II narcotics.

(a-10) Prescribers who issue a prescription for an opioid shall inform the patient that opioids are addictive and that opioid antagonists are available by prescription or from a pharmacy.

(b) In lieu of a written prescription required by this Section, a pharmacist, in good faith, may dispense Schedule III, IV, or V substances to any person either upon receiving a facsimile of a written, signed prescription transmitted by the prescriber or the prescriber's agent or upon a lawful oral prescription of a prescriber which oral prescription shall be reduced promptly to writing by the pharmacist and such written memorandum thereof shall be dated on the day when such oral

prescription is received by the pharmacist and shall bear the full name and address of the ultimate user for whom, or of the owner of the animal for which the controlled substance is dispensed, and the full name, address, and registry number under the law of the United States relating to controlled substances of the prescriber prescribing if he or she is required by those laws to be so registered, and the pharmacist filling such oral prescription shall write the date of filling and his or her own signature on the face of such written memorandum thereof. The facsimile copy of the prescription or written memorandum of the oral prescription shall be retained on file by the proprietor of the pharmacy in which it is filled for a period of not less than two years, so as to be readily accessible for inspection by any officer or employee engaged in the enforcement of this Act in the same manner as a written prescription. The facsimile copy of the prescription or oral prescription and the written memorandum thereof shall not be filled or refilled more than 6 months after the date thereof or be refilled more than 5 times, unless renewed, in writing, by the prescriber.

(c) Except for any non-prescription targeted methamphetamine precursor regulated by the Methamphetamine Precursor Control Act, a controlled substance included in Schedule V shall not be distributed or dispensed other than for a medical purpose and not for the purpose of evading this Act, and then:

(1) only personally by a person registered to dispense a Schedule V controlled substance and then only to his or her patients, or

(2) only personally by a pharmacist, and then only to a person over 21 years of age who has identified himself or herself to the pharmacist by means of 2 positive documents of identification.

(3) the dispenser shall record the name and address of the purchaser, the name and quantity of the product, the date and time of the sale, and the dispenser's signature.

(4) no person shall purchase or be dispensed more than 120 milliliters or more than 120 grams of any Schedule V substance which contains codeine, dihydrocodeine, or any salts thereof, or ethylmorphine, or any salts thereof, in any 96 hour period. The purchaser shall sign a form, approved by the Department of Financial and Professional Regulation, attesting that he or she has not purchased any Schedule V controlled substances within the immediately preceding 96 hours.

(5) (Blank).

(6) all records of purchases and sales shall be maintained for not less than 2 years.

(7) no person shall obtain or attempt to obtain within any consecutive 96 hour period any Schedule V substances of more than 120 milliliters or more than 120 grams containing codeine, dihydrocodeine or any of its salts, or

ethylmorphine or any of its salts. Any person obtaining any such preparations or combination of preparations in excess of this limitation shall be in unlawful possession of such controlled substance.

(8) a person qualified to dispense controlled substances under this Act and registered thereunder shall at no time maintain or keep in stock a quantity of Schedule V controlled substances in excess of 4.5 liters for each substance; a pharmacy shall at no time maintain or keep in stock a quantity of Schedule V controlled substances as defined in excess of 4.5 liters for each substance, plus the additional quantity of controlled substances necessary to fill the largest number of prescription orders filled by that pharmacy for such controlled substances in any one week in the previous year. These limitations shall not apply to Schedule V controlled substances which Federal law prohibits from being dispensed without a prescription.

(9) no person shall distribute or dispense butyl nitrite for inhalation or other introduction into the human body for euphoric or physical effect.

(d) Every practitioner shall keep a record or log of controlled substances received by him or her and a record of all such controlled substances administered, dispensed or professionally used by him or her otherwise than by prescription. It shall, however, be sufficient compliance with this paragraph if any practitioner utilizing controlled

substances listed in Schedules III, IV and V shall keep a record of all those substances dispensed and distributed by him or her other than those controlled substances which are administered by the direct application of a controlled substance, whether by injection, inhalation, ingestion, or any other means to the body of a patient or research subject. A practitioner who dispenses, other than by administering, a controlled substance in Schedule II, which is a narcotic drug listed in Section 206 of this Act, or which contains any quantity of amphetamine or methamphetamine, their salts, optical isomers or salts of optical isomers, pentazocine, or methaqualone shall do so only upon the issuance of a written prescription blank or electronic prescription issued by a prescriber.

(e) Whenever a manufacturer distributes a controlled substance in a package prepared by him or her, and whenever a wholesale distributor distributes a controlled substance in a package prepared by him or her or the manufacturer, he or she shall securely affix to each package in which that substance is contained a label showing in legible English the name and address of the manufacturer, the distributor and the quantity, kind and form of controlled substance contained therein. No person except a pharmacist and only for the purposes of filling a prescription under this Act, shall alter, deface or remove any label so affixed.

(f) Whenever a practitioner dispenses any controlled

substance except a non-prescription Schedule V product or a non-prescription targeted methamphetamine precursor regulated by the Methamphetamine Precursor Control Act, he or she shall affix to the container in which such substance is sold or dispensed, a label indicating the date of initial filling, the practitioner's name and address, the name of the patient, the name of the prescriber, the directions for use and cautionary statements, if any, contained in any prescription or required by law, the proprietary name or names or the established name of the controlled substance, and the dosage and quantity, except as otherwise authorized by regulation by the Department of Financial and Professional Regulation. No person shall alter, deface or remove any label so affixed as long as the specific medication remains in the container.

(g) A person to whom or for whose use any controlled substance has been prescribed or dispensed by a practitioner, or other persons authorized under this Act, and the owner of any animal for which such substance has been prescribed or dispensed by a veterinarian, may lawfully possess such substance only in the container in which it was delivered to him or her by the person dispensing such substance.

(h) The responsibility for the proper prescribing or dispensing of controlled substances that are under the prescriber's direct control is upon the prescriber. The responsibility for the proper filling of a prescription for controlled substance drugs rests with the pharmacist. An order

purporting to be a prescription issued to any individual, which is not in the regular course of professional treatment nor part of an authorized methadone maintenance program, nor in legitimate and authorized research instituted by any accredited hospital, educational institution, charitable foundation, or federal, state or local governmental agency, and which is intended to provide that individual with controlled substances sufficient to maintain that individual's or any other individual's physical or psychological addiction, habitual or customary use, dependence, or diversion of that controlled substance is not a prescription within the meaning and intent of this Act; and the person issuing it, shall be subject to the penalties provided for violations of the law relating to controlled substances.

(i) A prescriber shall not pre-print or cause to be pre-printed a prescription for any controlled substance; nor shall any practitioner issue, fill or cause to be issued or filled, a pre-printed prescription for any controlled substance.

(i-5) A prescriber may use a machine or electronic device to individually generate a printed prescription, but the prescriber is still required to affix his or her manual signature.

(j) No person shall manufacture, dispense, deliver, possess with intent to deliver, prescribe, or administer or cause to be administered under his or her direction any

anabolic steroid, for any use in humans other than the treatment of disease in accordance with the order of a physician licensed to practice medicine in all its branches for a valid medical purpose in the course of professional practice. The use of anabolic steroids for the purpose of hormonal manipulation that is intended to increase muscle mass, strength or weight without a medical necessity to do so, or for the intended purpose of improving physical appearance or performance in any form of exercise, sport, or game, is not a valid medical purpose or in the course of professional practice.

(k) Controlled substances may be mailed if all of the following conditions are met:

(1) The controlled substances are not outwardly dangerous and are not likely, of their own force, to cause injury to a person's life or health.

(2) The inner container of a parcel containing controlled substances must be marked and sealed as required under this Act and its rules, and be placed in a plain outer container or securely wrapped in plain paper.

(3) If the controlled substances consist of prescription medicines, the inner container must be labeled to show the name and address of the pharmacy or practitioner dispensing the prescription.

(4) The outside wrapper or container must be free of markings that would indicate the nature of the contents.

(l) Notwithstanding any other provision of this Act to the contrary, emergency medical services personnel may administer Schedule II, III, IV, or V controlled substances to a person in the scope of their employment without a written, electronic, or oral prescription of a prescriber.

(Source: P.A. 99-78, eff. 7-20-15; 99-480, eff. 9-9-15; 100-280, eff. 1-1-18.)

(720 ILCS 570/313) (from Ch. 56 1/2, par. 1313)

Sec. 313. (a) Controlled substances which are lawfully administered in hospitals or institutions licensed under the Hospital Licensing Act shall be exempt from the requirements of Sections 312 and 316, except that the prescription for the controlled substance shall be in writing on the patient's record, signed by the prescriber, and dated, and shall state the name and quantity of controlled substances ordered and the quantity actually administered. The records of such prescriptions shall be maintained for two years and shall be available for inspection by officers and employees of the Illinois State Police and the Department of Financial and Professional Regulation.

The exemption under this subsection (a) does not apply to a prescription (including an outpatient prescription from an emergency department or outpatient clinic) for more than a 72-hour supply of a discharge medication to be consumed outside of the hospital or institution.

(a-5) In a hospital or institutions licensed under the Hospital Licensing Act, all prescribers of an opioid shall inform the patient that opioids are addictive and that opioid antagonists are available by prescription or from a pharmacy. Upon discharge any patient who has overdosed on controlled substances shall be provided with an opioid antagonist. If the patient is not able to pay for the opioid antagonist, then the State of Illinois shall reimburse the hospital for the opioid antagonist from federal grant funds to address substance use disorder or other State funds for the same purpose.

(b) Controlled substances that can lawfully be administered or dispensed directly to a patient in a long-term care facility licensed by the Department of Public Health as a skilled nursing facility, intermediate care facility, or long-term care facility for residents under 22 years of age, are exempt from the requirements of Section 312 except that a prescription for a Schedule II controlled substance must be either a prescription signed by the prescriber or a prescription transmitted by the prescriber or prescriber's agent to the dispensing pharmacy by facsimile. The facsimile serves as the original prescription and must be maintained for 2 years from the date of issue in the same manner as a written prescription signed by the prescriber.

(c) A prescription that is generated for a Schedule II controlled substance to be compounded for direct administration to a patient in a private residence, long-term

care facility, or hospice program may be transmitted by facsimile by the prescriber or the prescriber's agent to the pharmacy providing the home infusion services. The facsimile serves as the original prescription for purposes of this paragraph (c) and it shall be maintained in the same manner as the original prescription.

(c-1) A prescription generated for a Schedule II controlled substance for a patient residing in a hospice certified by Medicare under Title XVIII of the Social Security Act or licensed by the State may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile or electronically as provided in Section 311.5. The practitioner or practitioner's agent must note on the prescription that the patient is a hospice patient. The facsimile or electronic record serves as the original prescription for purposes of this paragraph (c-1) and it shall be maintained in the same manner as the original prescription.

(d) Controlled substances which are lawfully administered and/or dispensed in drug abuse treatment programs licensed by the Department shall be exempt from the requirements of Sections 312 and 316, except that the prescription for such controlled substances shall be issued and authenticated on official prescription logs prepared and maintained in accordance with 77 Ill. Adm. Code 2060: Alcoholism and Substance Abuse Treatment and Intervention Licenses, and in compliance with other applicable State and federal laws. The

Department-licensed drug treatment program shall report applicable prescriptions via electronic record keeping software approved by the Department. This software must be compatible with the specifications of the Department. Drug abuse treatment programs shall report to the Department methadone prescriptions or medications dispensed through the use of Department-approved File Transfer Protocols (FTPs). Methadone prescription records must be maintained in accordance with the applicable requirements as set forth by the Department in accordance with 77 Ill. Adm. Code 2060: Alcoholism and Substance Abuse Treatment and Intervention Licenses, and in compliance with other applicable State and federal laws.

(e) Nothing in this Act shall be construed to limit the authority of a hospital pursuant to Section 65-45 of the Nurse Practice Act to grant hospital clinical privileges to an individual advanced practice registered nurse to select, order or administer medications, including controlled substances to provide services within a hospital. Nothing in this Act shall be construed to limit the authority of an ambulatory surgical treatment center pursuant to Section 65-45 of the Nurse Practice Act to grant ambulatory surgical treatment center clinical privileges to an individual advanced practice registered nurse to select, order or administer medications, including controlled substances to provide services within an ambulatory surgical treatment center.

(Source: P.A. 100-513, eff. 1-1-18.)

Section 99. Effective date. This Act takes effect January 1, 2022.".