Sen. Patricia Van Pelt

Filed: 3/13/2018

AMENDMENT TO SENATE BILL 2849

AMENDMENT NO. _____. Amend Senate Bill 2849 by replacing everything after the enacting clause with the following:

"Section 1. Short title. This Act may be cited as the Prescription Drug Repository Program Act.

Section 5. Definitions. In this Act:

"Controlled substance" means a drug, substance, or immediate precursor in Schedules I through V of 21 CFR 1308.

"Covered entity" means a long-term care facility licensed under the Nursing Home Care Act, an assisted living facility licensed under the Assisted Living and Shared Housing Act, a shared housing establishment licensed under the Assisted Living and Shared Housing Act, a pharmacy, a wholesaler, or a manufacturer, located inside or outside of the State.

"Department" means the Department of Public Health.

"Dispense" has the meaning given to that term in the

Pharmacy Practice Act.

"Pharmacist" means an individual licensed to engage in the practice of pharmacy under the Pharmacy Practice Act.

"Pharmacy" means a pharmacy registered in this State under the Pharmacy Practice Act.

"Practitioner" means a person licensed in this State to prescribe and administer drugs or licensed in another state and recognized by this State as a person authorized to prescribe and administer drugs.

"Prescription drug" means any prescribed drug that may be legally dispensed by a pharmacy. "Prescription drug" does not include drugs for the treatment of cancer that can only be dispensed to a patient registered with the drug manufacturer in accordance with federal Food and Drug Administration requirements.

"Program" means the prescription drug repository program established under this Act.

Section 10. Prescription drug repository program. The Department shall, by rule, establish and maintain a prescription drug repository program, under which a covered entity may donate a prescription drug or supplies needed to administer a prescription drug for use by an individual who meets appropriate eligibility criteria. The Department shall adopt the rules within one year after the effective date of this Act. Donations may be made on the premises of a pharmacy

that elects to participate in the program and meets appropriate requirements. The pharmacy may charge an individual who receives a prescription drug or supplies needed to administer a prescription drug under this Act a handling fee that may not exceed an appropriate amount. A pharmacy that receives a donated prescription drug or supplies needed to administer a prescription drug under this Act may distribute the prescription drug or supplies to another eligible pharmacy for use under the program.

Section 15. Priority. Uninsured and underinsured individuals shall be given priority for drugs and supplies donated under this Act over other eligible persons.

Section 20. Requirements for accepting and dispensing prescription drugs and supplies. A prescription drug or supplies needed to administer a prescription drug may be accepted and dispensed under the program only if all of the following requirements are met:

(1) The prescription drug or supplies needed to administer a prescription drug are in their original, unopened, sealed, and tamper-evident packaging or, if packaged in single-unit doses, the single-unit-dose packaging is unopened. Medicine and supplies originally packaged by a pharmacy are acceptable for donation.

(2) The prescription drug bears an expiration date that

is later than an amount of time determined by the Department after the date that the drug was donated.

(3) The prescription drug or supplies needed to administer a prescription drug are not adulterated or misbranded, as determined by a pharmacist employed by, or under contract with, the pharmacy where the drug or supplies are accepted or dispensed. The pharmacist must inspect the drug or supplies before the drug or supplies are dispensed.

(4) The prescription drug or supplies needed to administer a prescription drug are prescribed by a practitioner for use by an eligible individual.

(5) The prescription drug is not a controlled substance.

(6) Drugs that can be dispensed only to a patient registered with the drug's manufacturer in accordance with federal Food and Drug Administration requirements may not be accepted or distributed under the provisions of the program.

(7) A pharmacy shall maintain a written or electronic record of a donation under this Act consisting of the name, strength, and quantity of each accepted drug, and the name, address, and telephone number of the donor. No other record of a donation shall be required.

Section 25. Resale of donated drugs or supplies prohibited.

No prescription drug or supplies needed to administer a prescription drug that are donated for use under this Act may be resold.

Section 30. Participation in program not required. Nothing in this Act requires that a pharmacy or pharmacist participate in the prescription drug repository program.

Section 90. The Pharmacy Practice Act is amended by changing Section 4 as follows:

(225 ILCS 85/4) (from Ch. 111, par. 4124)

(Section scheduled to be repealed on January 1, 2020)

Sec. 4. Exemptions. Nothing contained in any Section of this Act shall apply to, or in any manner interfere with:

(a) the lawful practice of any physician licensed to practice medicine in all of its branches, dentist, podiatric physician, veterinarian, or therapeutically or diagnostically certified optometrist within the limits of his or her license, or prevent him or her from supplying to his or her bona fide patients such drugs, medicines, or poisons as may seem to him appropriate;

(b) the sale of compressed gases;

(c) the sale of patent or proprietary medicines and household remedies when sold in original and unbroken packages only, if such patent or proprietary medicines and

household remedies be properly and adequately labeled as to content and usage and generally considered and accepted as harmless and nonpoisonous when used according to the directions on the label, and also do not contain opium or coca leaves, or any compound, salt or derivative thereof, or any drug which, according to the latest editions of the following authoritative pharmaceutical treatises and standards, namely, The United States Pharmacopoeia/National Formulary (USP/NF), the United States Dispensatory, and the Accepted Dental Remedies of the Council of Dental Therapeutics of the American Dental Association or any or either of them, in use on the effective date of this Act, or according to the existing provisions of the Federal Food, Drug, and Cosmetic Act and Regulations of the Department of Health and Human Services, Food and Drug Administration, promulgated thereunder now in effect, is designated, described or considered as a narcotic, hypnotic, habit forming, dangerous, or poisonous drug;

(d) the sale of poultry and livestock remedies in original and unbroken packages only, labeled for poultry and livestock medication;

(e) the sale of poisonous substances or mixture of poisonous substances, in unbroken packages, for nonmedicinal use in the arts or industries or for insecticide purposes; provided, they are properly and

adequately labeled as to content and such nonmedicinal usage, in conformity with the provisions of all applicable federal, state and local laws and regulations promulgated thereunder now in effect relating thereto and governing the same, and those which are required under such applicable laws and regulations to be labeled with the word "Poison", are also labeled with the word "Poison" printed thereon in prominent type and the name of a readily obtainable antidote with directions for its administration;

(f) the delegation of limited prescriptive authority by a physician licensed to practice medicine in all its branches to a physician assistant under Section 7.5 of the Physician Assistant Practice Act of 1987. This delegated authority under Section 7.5 of the Physician Assistant Practice Act of 1987 may, but is not required to, include prescription of controlled substances, as defined in Article II of the Illinois Controlled Substances Act, in accordance with a written supervision agreement;

(g) the delegation of prescriptive authority by a physician licensed to practice medicine in all its branches or a licensed podiatric physician to an advanced practice registered nurse in accordance with a written collaborative agreement under Sections 65-35 and 65-40 of the Nurse Practice Act; ~~and~~

(g-5) the donation or acceptance, or the packaging, repackaging, or labeling, of prescription drugs to the

extent permitted or required under the Prescription Drug Repository Program Act; and

(h) the sale or distribution of dialysate or devices necessary to perform home peritoneal renal dialysis for patients with end-stage renal disease, provided that all of the following conditions are met:

(1) the dialysate, comprised of dextrose or icodextrin, or devices are approved or cleared by the federal Food and Drug Administration, as required by federal law;

(2) the dialysate or devices are lawfully held by a manufacturer or the manufacturer's agent, which is properly registered with the Board as a manufacturer or wholesaler;

(3) the dialysate or devices are held and delivered to the manufacturer or the manufacturer's agent in the original, sealed packaging from the manufacturing facility;

(4) the dialysate or devices are delivered only upon receipt of a physician's prescription by a licensed pharmacy in which the prescription is processed in accordance with provisions set forth in this Act, and the transmittal of an order from the licensed pharmacy to the manufacturer or the manufacturer's agent; and

(5) the manufacturer or the manufacturer's agent

delivers the dialysate or devices directly to: (i) a patient with end-stage renal disease, or his or her designee, for the patient's self-administration of the dialysis therapy or (ii) a health care provider or institution for administration or delivery of the dialysis therapy to a patient with end-stage renal disease.

This paragraph (h) does not include any other drugs for peritoneal dialysis, except dialysate, as described in item (1) of this paragraph (h). All records of sales and distribution of dialysate to patients made pursuant to this paragraph (h) must be retained in accordance with Section 18 of this Act.

(Source: P.A. 100-218, eff. 8-18-17; 100-513, eff. 1-1-18; revised 9-29-17.)

Section 95. The Wholesale Drug Distribution Licensing Act is amended by changing Section 15 as follows:

(225 ILCS 120/15) (from Ch. 111, par. 8301-15)

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

Sec. 15. Definitions. As used in this Act:

"Authentication" means the affirmative verification, before any wholesale distribution of a prescription drug occurs, that each transaction listed on the pedigree has occurred.

"Authorized distributor of record" means a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drug. An ongoing relationship is deemed to exist between a wholesale distributor and a manufacturer when the wholesale distributor, including any affiliated group of the wholesale distributor, as defined in Section 1504 of the Internal Revenue Code, complies with the following:

(1) The wholesale distributor has a written agreement currently in effect with the manufacturer evidencing the ongoing relationship; and

(2) The wholesale distributor is listed on the manufacturer's current list of authorized distributors of record, which is updated by the manufacturer on no less than a monthly basis.

"Blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

"Blood component" means that part of blood separated by physical or mechanical means.

"Board" means the State Board of Pharmacy of the Department of Professional Regulation.

"Chain pharmacy warehouse" means a physical location for prescription drugs that acts as a central warehouse and performs intracompany sales or transfers of the drugs to a group of chain or mail order pharmacies that have the same common ownership and control. Notwithstanding any other

provision of this Act, a chain pharmacy warehouse shall be considered part of the normal distribution channel.

"Co-licensed partner or product" means an instance where one or more parties have the right to engage in the manufacturing or marketing of a prescription drug, consistent with the FDA's implementation of the Prescription Drug Marketing Act.

"Department" means the Department of Financial and Professional Regulation.

"Drop shipment" means the sale of a prescription drug to a wholesale distributor by the manufacturer of the prescription drug or that manufacturer's co-licensed product partner, that manufacturer's third party logistics provider, or that manufacturer's exclusive distributor or by an authorized distributor of record that purchased the product directly from the manufacturer or one of these entities whereby the wholesale distributor or chain pharmacy warehouse takes title but not physical possession of such prescription drug and the wholesale distributor invoices the pharmacy, chain pharmacy warehouse, or other person authorized by law to dispense or administer such drug to a patient and the pharmacy, chain pharmacy warehouse, or other authorized person receives delivery of the prescription drug directly from the manufacturer, that manufacturer's third party logistics provider, or that manufacturer's exclusive distributor or from an authorized distributor of record that purchased the product directly from

the manufacturer or one of these entities.

"Drug sample" means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

"Facility" means a facility of a wholesale distributor where prescription drugs are stored, handled, repackaged, or offered for sale.

"FDA" means the United States Food and Drug Administration.

"Manufacturer" means a person licensed or approved by the FDA to engage in the manufacture of drugs or devices, consistent with the definition of "manufacturer" set forth in the FDA's regulations and guidances implementing the Prescription Drug Marketing Act. <u>"Manufacturer" does not include anyone who is engaged in the packaging, repackaging, or labeling of prescription drugs only to the extent required under the Prescription Drug Repository Program Act.</u>

"Manufacturer's exclusive distributor" means anyone who contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer and who takes title to that manufacturer's prescription drug, but who does not have general responsibility to direct the sale or disposition of the manufacturer's prescription drug. A manufacturer's exclusive distributor must be licensed as a wholesale distributor under this Act and, in order to be considered part of the normal distribution channel, must also be an authorized distributor of record.

"Normal distribution channel" means a chain of custody for a prescription drug that goes, directly or by drop shipment, from (i) a manufacturer of the prescription drug, (ii) that manufacturer to that manufacturer's co-licensed partner, (iii) that manufacturer to that manufacturer's third party logistics provider, or (iv) that manufacturer to that manufacturer's exclusive distributor to:

(1) a pharmacy or to other designated persons authorized by law to dispense or administer the drug to a patient;

(2) a wholesale distributor to a pharmacy or other designated persons authorized by law to dispense or administer the drug to a patient;

(3) a wholesale distributor to a chain pharmacy warehouse to that chain pharmacy warehouse's intracompany pharmacy to a patient or other designated persons authorized by law to dispense or administer the drug to a patient;

(4) a chain pharmacy warehouse to the chain pharmacy warehouse's intracompany pharmacy or other designated persons authorized by law to dispense or administer the drug to the patient;

(5) an authorized distributor of record to one other authorized distributor of record to an office-based health care practitioner authorized by law to dispense or administer the drug to the patient; or

(6) an authorized distributor to a pharmacy or other persons licensed to dispense or administer the drug.

"Pedigree" means a document or electronic file containing information that records each wholesale distribution of any given prescription drug from the point of origin to the final wholesale distribution point of any given prescription drug.

"Person" means and includes a natural person, partnership, association, corporation, or any other legal business entity.

"Pharmacy distributor" means any pharmacy licensed in this State or hospital pharmacy that is engaged in the delivery or distribution of prescription drugs either to any other pharmacy licensed in this State or to any other person or entity including, but not limited to, a wholesale drug distributor engaged in the delivery or distribution of prescription drugs who is involved in the actual, constructive, or attempted transfer of a drug in this State to other than the ultimate consumer except as otherwise provided for by law.

"Prescription drug" means any human drug, including any biological product (except for blood and blood components intended for transfusion or biological products that are also medical devices), required by federal law or regulation to be dispensed only by a prescription, including finished dosage forms and bulk drug substances subject to Section 503 of the Federal Food, Drug and Cosmetic Act.

"Repackage" means repackaging or otherwise changing the container, wrapper, or labeling to further the distribution of

a prescription drug, excluding that completed by the pharmacist responsible for dispensing the product to a patient.

"Secretary" means the Secretary of Financial and Professional Regulation.

"Third party logistics provider" means anyone who contracts with a prescription drug manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer, but does not take title to the prescription drug or have general responsibility to direct the prescription drug's sale or disposition. A third party logistics provider must be licensed as a wholesale distributor under this Act and, in order to be considered part of the normal distribution channel, must also be an authorized distributor of record.

"Wholesale distribution" means the distribution of prescription drugs to persons other than a consumer or patient, but does not include any of the following:

(1) Intracompany sales of prescription drugs, meaning (i) any transaction or transfer between any division, subsidiary, parent, or affiliated or related company under the common ownership and control of a corporate entity or (ii) any transaction or transfer between co-licensees of a co-licensed product.

(2) The sale, purchase, distribution, trade, or transfer of a prescription drug or offer to sell, purchase, distribute, trade, or transfer a prescription drug for

emergency medical reasons.

(3) The distribution of prescription drug samples by manufacturers' representatives.

(4) Drug returns, when conducted by a hospital, health care entity, or charitable institution in accordance with federal regulation.

(5) The sale of minimal quantities of prescription drugs by licensed pharmacies to licensed practitioners for office use or other licensed pharmacies.

(6) The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription.

(7) The sale, transfer, merger, or consolidation of all or part of the business of a pharmacy or pharmacies from or with another pharmacy or pharmacies, whether accomplished as a purchase and sale of stock or business assets.

(8) The sale, purchase, distribution, trade, or transfer of a prescription drug from one authorized distributor of record to one additional authorized distributor of record when the manufacturer has stated in writing to the receiving authorized distributor of record that the manufacturer is unable to supply the prescription drug and the supplying authorized distributor of record states in writing that the prescription drug being supplied had until that time been exclusively in the normal distribution channel.

(9) The delivery of or the offer to deliver a prescription drug by a common carrier solely in the common carrier's usual course of business of transporting prescription drugs when the common carrier does not store, warehouse, or take legal ownership of the prescription drug.

(10) The sale or transfer from a retail pharmacy, mail order pharmacy, or chain pharmacy warehouse of expired, damaged, returned, or recalled prescription drugs to the original manufacturer, the originating wholesale distributor, or a third party returns processor.

(11) The donation of prescription drugs to the extent permitted under the Prescription Drug Repository Program Act.

"Wholesale drug distributor" means anyone engaged in the wholesale distribution of prescription drugs into, out of, or within the State, including without limitation manufacturers; repackers; own label distributors; jobbers; private label distributors; brokers; warehouses, including manufacturers' and distributors' warehouses; manufacturer's exclusive distributors; and authorized distributors of record; drug wholesalers or distributors; independent wholesale drug traders; specialty wholesale distributors; third party logistics providers; and retail pharmacies that conduct wholesale distribution; and chain pharmacy warehouses that conduct wholesale distribution. In order to be considered part

of the normal distribution channel, a wholesale distributor must also be an authorized distributor of record.

(Source: P.A. 97-804, eff. 1-1-13.)

Section 100. The Senior Pharmaceutical Assistance Act is amended by changing Section 10 as follows:

(320 ILCS 50/10)

Sec. 10. Definitions. In this Act:

"Manufacturer" includes:

(1) An entity that is engaged in (a) the production, preparation, propagation, compounding, conversion, or processing of prescription drug products (i) directly or indirectly by extraction from substances of natural origin, (ii) independently by means of chemical synthesis, or (iii) by combination of extraction and chemical synthesis; or (b) the packaging, repackaging, labeling or re-labeling, or distribution of prescription drug products.

(2) The entity holding legal title to or possession of the national drug code number for the covered prescription drug.

The term does not include a wholesale distributor of drugs, drugstore chain organization, or retail pharmacy licensed by the State. <u>The term also does not include anyone who is engaged in the packaging, repackaging, or labeling of prescription</u>

drugs only to the extent required under the Prescription Drug Repository Program Act.

"Prescription drug" means a drug that may be dispensed only upon prescription by an authorized prescriber and that is approved for safety and effectiveness as a prescription drug under Section 505 or 507 of the Federal Food, Drug and Cosmetic Act.

"Senior citizen" or "senior" means a person 65 years of age or older.

(Source: P.A. 92-594, eff. 6-27-02.)

Section 105. The Illinois Food, Drug and Cosmetic Act is amended by changing Section 16 as follows:

(410 ILCS 620/16) (from Ch. 56 1/2, par. 516)

Sec. 16. (a) The Director is hereby authorized to promulgate regulations exempting from any labeling or packaging requirement of this Act drugs and devices which are (i), in accordance with the practice of the trade, to be processed, labeled or repacked in substantial quantities at establishments other than those where originally processed or packaged on condition that such drugs and devices are not adulterated or misbranded under the provisions of this Act upon removal from such processing, labeling or repacking establishment or (ii) packaged, repackaged, or labeled to the extent required under the Prescription Drug Repository Program

Act.

(b) Drugs and device labeling or packaging exemptions adopted under the Federal Act and supplements thereto or revisions thereof shall apply to drugs and devices in Illinois except insofar as modified or rejected by regulations promulgated by the Director.

(c) A drug intended for use by man which (A) is a habit-forming drug to which Section 15 (d) applies; or (B) because of its toxicity or other potentiality for harmful effect or the method of its use or the collateral measures necessary to its use is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or (C) is limited by an approved application under Section 505 of the Federal Act or Section 17 of this Act to use under the professional supervision of a practitioner licensed by law to administer such drug, shall be dispensed only in accordance with the provisions of the "Illinois Controlled Substances Act". The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in a drug being misbranded while held for sale.

(d) Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of Section 15, except subsections (a), (k) and (l) and clauses (2) and (3) of subsection (i), and the packaging requirements of subsections (g), (h) and (q), if the drug bears a label

containing the proprietary name or names, or if there is none, the established name or names of the drugs, the dosage and quantity, unless the prescribing practitioner, in the interest of the health of the patient, directs otherwise in writing, the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber and, if stated in the prescription, the name of the patient, and the directions for use and the cautionary statements, if any, contained in such prescription. This exemption shall not apply to any drug dispensed in the course of the conduct of business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of subsection (a) of this Section.

(e) The Director may by regulation remove drugs subject to Section 15 (d) and Section 17 from the requirements of subsection (c) of this Section when such requirements are not necessary for the protection of the public health.

(f) A drug which is subject to subsection (c) of this Section shall be deemed to be misbranded if at any time before dispensing its label fails to bear the statement "Caution: Federal Law Prohibits Dispensing Without Prescription" or "Caution: State Law Prohibits Dispensing Without Prescription". A drug to which subsection (c) of this Section does not apply shall be deemed to be misbranded if at any time prior to dispensing its label bears the caution statement quoted in the preceding sentence.

(g) Nothing in this Section shall be construed to relieve any person from any requirement prescribed by or under authority of law with respect to controlled substances now included or which may hereafter be included within the classifications of controlled substances cannabis as defined in applicable Federal laws relating to controlled substances or cannabis or the Cannabis Control Act.

(Source: P.A. 84-1308.)".