Sen. Karina Villa

Filed: 4/7/2021

AMENDMENT TO SENATE BILL 516

AMENDMENT NO. _____. Amend Senate Bill 516 by replacing everything after the enacting clause with the following:

"Section 1. Short title. This Act may be cited as the Illinois Drug Reuse Opportunity 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.

"Dispense" has the same meaning as defined in Section 3 of the Pharmacy Practice Act.

"Donor" means any person, including an individual member of the public, or any entity legally authorized to possess medicine, including, but not limited to, a wholesaler or distributor, third party logistic provider, pharmacy, dispenser, clinic, surgical or health center, detention and rehabilitation center, jail, prison laboratory, medical or

pharmacy school, prescriber or other health care professional, long-term care facility, or healthcare facility. "Donor" includes government agencies and entities that are federally authorized to possess medicine, including, but not limited to, drug manufacturers, repackagers, relabelers, outsourcing facilities, health care facilities operated by the U.S. Department of Veterans Affairs, and prisons.

"Drug" means a prescription drug, over-the-counter drug, or supplies needed to administer a prescription or over-the-counter drug.

"Eligible patient" means an individual:

(1) with a prescription for the drug, if a prescription is required to dispense the drug, or who reports symptoms treated by the drug if the drug is over-the-counter; and

(2) who is registered with the drug's manufacturer in accordance with federal Food and Drug Administration requirements, if the registration is required to dispense the drug.

"Manufacturer" has the same meaning as defined in Section 15 of the Wholesale Drug Distribution Licensing Act.

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

"Practitioner" means a person licensed in this State to

dispense or administer drugs or who is licensed in another state as a person authorized to dispense or administer drugs.

"Prescription drug" means any prescribed drug that may be legally dispensed by a pharmacy.

"Priority patient" means an eligible patient who is an Illinois resident and who is indigent, uninsured, underinsured, or enrolled in a public health benefits program.

"Recipient" means any person or entity legally authorized to possess medicine with a license or permit in the state in which the person or entity is located, including, but not limited to, a wholesaler or distributor, reverse distributor, repackager, hospital, pharmacy, clinic, or prescriber office.

"Returns processor" has the same meaning as defined in paragraph (18) of 21 U.S.C. 360eee. "Returns processor" includes, but is not limited to, a reverse distributor.

"Unopened tamper-evident packaging" has the same meaning as defined in the United States Pharmacopeia (USP) General Chapter 659, Packaging and Storage Requirements, including, but not limited to, unopened unit-dose, multiple-dose, immediate, secondary, and tertiary packaging.

Section 10. Donating and receiving drugs. Notwithstanding any other law or rule, donors may donate drugs to recipients and recipients may receive donated drugs from donors. Recipients shall only dispense or administer drugs to eligible patients as described in Section 20, further donate drugs to

another recipient as described in Section 30, or dispose of drugs as described in Section 35.

Section 15. Cost-free provision of drugs. Drugs donated for use under this Act are considered nonsaleable. When dispensing a drug to an eligible patient, the recipient must do so at no cost to the eligible patient, except that a reasonable handling fee may be charged. The handling fee may not exceed the direct or indirect cost to the recipient of providing the drug. Charging the fee does not constitute reselling.

Section 20. Requirements for dispensing drugs; priority.

(a) A recipient may only dispense or administer a prescription drug or provide an over-the-counter drug:

(1) if the recipient is otherwise permitted by law to dispense or administer the drug;

(2) that meets the requirements in Section 25;

(3) that is repackaged into a new container or is in its original container with all previous patient information redacted or removed;

(4) that is properly labeled in accordance with the rules and regulations of the Board of Pharmacy;

(5) that has an expiration or beyond-use date brought forward from the donated prescription drug or over-the-counter drug that will not expire before the use

by the eligible patient based on the prescribing practitioner's directions for use or, for over-the-counter medicine, on the package's label; and

(6) that is not adulterated or misbranded, as determined by a pharmacist or practitioner.

(b) Recipients shall, to the greatest extent practicable, dispense drugs received under this Act to priority patients.

Section 25. Requirements for accepting drugs. A drug received but not yet accepted into inventory shall be kept in a separate designated area. A drug may be accepted under this Act only if all of the following requirements are met:

(1) The drug is in unopened tamper-evident packaging or has been repackaged according to Section 30.

(2) The drug is not expired.

(3) The drug is not a controlled substance.

(4) The recipient maintains a written or electronic record of a donation made under this Act consisting of the name, strength, and quantity of each accepted drug and the name, address, and telephone number of the donor, unless a recipient is further donating to a recipient under common ownership or common control. Notwithstanding any other law or rule, no other record of a donation is required.

(5) The donor has removed or redacted any patient name and prescription number on the drug or otherwise maintains patient confidentiality by executing a confidentiality

agreement with the recipient.

(6) The drug has a method recognized by the United States Pharmacopeia to detect improper temperature variations if the drug requires temperature control other than room temperature storage.

Section 30. Donating and repackaging. Notwithstanding any other law or rule, a recipient may:

(1) further donate drugs to another recipient;

(2) repackage donated drugs as necessary for storage, dispensing, administration, or transfers in accordance with the following:

(A) repackaged medicine shall be labeled with the drug's name, strength, and expiration date, and shall be kept in a separate designated area until inspected and initialed by a pharmacist, practitioner, or a pharmacy technician; and

(B) if multiple packaged donated medicines with varied expiration dates are repackaged together, the shortest expiration date shall be used; and

(3) replenish a drug of the same drug name and strength previously dispensed or administered to an eligible patient in accordance with Section 340B of the federal Public Health Service Act.

Section 35. Disposition of drugs. A donated drug that does

not meet the requirements of Section 25 must be disposed of by returning it to the donor, destroying it by an incinerator, medical waste hauler, or other lawful method, or transferring it to a returns processor. A record of disposal shall consist of the disposal method, the date of disposal, and the name and quantity of the drug disposed of. Notwithstanding any other law or rule, no other record of disposal shall be required.

Section 40. Participation not required. Nothing in this Act requires that a pharmacy or pharmacist be a recipient of drugs under this Act.

Section 45. Recordkeeping requirements. When performing any action associated with a program under this Act or otherwise processing a donated drug for tax, manufacturer, or other credit, a recipient shall be considered to be acting as a returns processor and shall comply with all recordkeeping requirements for nonsaleable returns under federal law.

Section 50. Change of ownership. A donation or other transfer of possession or control of a drug under this Act shall not be construed as a change of ownership unless it is specified as such by the recipient. If a record of the donation's transaction information or history is required, the history shall begin with the donor of the drug, include all prior donations, and, if the drug was previously dispensed,

only include drug information required to be on the patient label in accordance with the Board of Pharmacy's rules and regulations.

Section 55. Retention of records. All records required under this Act shall be retained in physical or electronic format and on or off the recipient's premises for a period of 6 years. Donors or recipients may contract with one another or a third party to create or maintain records on each other's behalf. An identifier, such as a serial number or bar code, may be used in place of any or all information required by a record or label pursuant to this Act if it allows for such information to be readily retrievable. Upon request by a State or federal regulatory agency, the identifier used for requested records shall be replaced with the original information. An identifier shall not be used on patient labels when dispensing or administering a drug.

Section 60. Authority. This Act supersedes any inconsistent law or rule for activities conducted under this Act.

Section 65. Immunity.

(a) Except as provided in subsection (b), no manufacturer, donor, or recipient shall be liable in any criminal or civil action, or be subject to professional discipline, for

activities solely and directly attributable to donating, receiving, or dispensing drugs under this Act.

(b) The immunity provided in subsection (a) shall not apply:

(1) if it is shown that the act or omission was an unreasonable, willful, wanton, or reckless act;

(2) if it is shown that the person or entity knew or should have known that the donated drug was adulterated or misbranded; or

(3) to acts or omissions outside the scope of a program under this Act.

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, 2023)

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 drugs to the extent permitted under the Illinois Drug Reuse Opportunity 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, third-party logistics provider, 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; 100-863, eff. 8-14-18; 101-420, eff. 8-16-19.)

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, or a facility of a third-party logistics provider where prescription drugs are stored or handled.

"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 drugs only to the extent permitted under the Illinois Drug Reuse Opportunity 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.

"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 drugs to the extent permitted under the Illinois Drug Reuse Opportunity 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; 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. 101-420, eff. 8-16-19.)

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. The term also does not include anyone who is engaged in the packaging, repackaging, or labeling of drugs only to the extent permitted under the Illinois Drug Reuse Opportunity 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 permitted under the Illinois Drug Reuse Opportunity 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.)

Section 110. The Illinois Controlled Substances Act is amended by changing Section 102 as follows:

(720 ILCS 570/102) (from Ch. 56 1/2, par. 1102)

Sec. 102. Definitions. As used in this Act, unless the context otherwise requires:

(a) "Addict" means any person who habitually uses any drug, chemical, substance or dangerous drug other than alcohol so as to endanger the public morals, health, safety or welfare or who is so far addicted to the use of a dangerous drug or controlled substance other than alcohol as to have lost the power of self control with reference to his or her addiction.

(b) "Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion, or any other means, to the body of a patient, research subject, or animal (as defined by the Humane Euthanasia in Animal Shelters Act) by:

(1) a practitioner (or, in his or her presence, by his or her authorized agent),

(2) the patient or research subject pursuant to an order, or

(3) a euthanasia technician as defined by the Humane Euthanasia in Animal Shelters Act.

(c) "Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, dispenser, prescriber, or practitioner. It does not include a common or contract carrier, public warehouseman or employee of the carrier or warehouseman.

(c-1) "Anabolic Steroids" means any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone), and includes:

(i) 3[beta],17-dihydroxy-5a-androstane,

(ii) 3[alpha],17[beta]-dihydroxy-5a-androstane,

(iii) 5[alpha]-androstan-3,17-dione,

(iv) 1-androstenediol (3[beta],

17[beta]-dihydroxy-5[alpha]-androst-1-ene),

(v) 1-androstenediol (3[alpha],

17[beta]-dihydroxy-5[alpha]-androst-1-ene),

(vi) 4-androstenediol

(3[beta],17[beta]-dihydroxy-androst-4-ene),

(vii) 5-androstenediol

(3[beta],17[beta]-dihydroxy-androst-5-ene),

(viii) 1-androstenedione

([5alpha]-androst-1-en-3,17-dione),

(ix) 4-androstenedione

(androst-4-en-3,17-dione),

(x) 5-androstenedione

(androst-5-en-3,17-dione),

(xi) bolasterone (7[alpha],17a-dimethyl-17[beta]-hydroxyandrost-4-en-3-one),

(xii) boldenone (17[beta]-hydroxyandrost-1,4,-diene-3-one),

(xiii) boldione (androsta-1,4-diene-3,17-dione),

(xiv) calusterone (7[beta],17[alpha]-dimethyl-17[beta]-hydroxyandrost-4-en-3-one),

(xv) clostebol (4-chloro-17[beta]-hydroxyandrost-4-en-3-one),

(xvi) dehydrochloromethyltestosterone (4-chloro-17[beta]-hydroxy-17[alpha]-methyl-androst-1,4-dien-3-one),

(xvii) desoxymethyltestosterone

(17[alpha]-methyl-5[alpha]

-androst-2-en-17[beta]-ol)(a.k.a., madol),

(xviii) [delta]1-dihydrotestosterone (a.k.a. '1-testosterone') (17[beta]-hydroxy-5[alpha]-androst-1-en-3-one),

(xix) 4-dihydrotestosterone (17[beta]-hydroxy-androstan-3-one),

(xx) drostanolone (17[beta]-hydroxy-2[alpha]-methyl-5[alpha]-androstan-3-one),

(xxi) ethylestrenol (17[alpha]-ethyl-17[beta]-hydroxyestr-4-ene),

(xxii) fluoxymesterone (9-fluoro-17[alpha]-methyl-1[beta],17[beta]-dihydroxyandrost-4-en-3-one),

(xxiii) formebolone (2-formyl-17[alpha]-methyl-11[alpha], 17[beta]-dihydroxyandrost-1,4-dien-3-one),

(xxiv) furazabol (17[alpha]-methyl-17[beta]-hydroxyandrostano[2,3-c]-furazan),

(xxv) 13[beta]-ethyl-17[beta]-hydroxygon-4-en-3-one,

(xxvi) 4-hydroxytestosterone (4,17[beta]-dihydroxy-androst-4-en-3-one),

(xxvii) 4-hydroxy-19-nortestosterone (4,17[beta]-dihydroxy-estr-4-en-3-one),

(xxviii) mestanolone (17[alpha]-methyl-17[beta]-hydroxy-5-androstan-3-one),

(xxix) mesterolone (1amethyl-17[beta]-hydroxy-[5a]-androstan-3-one),

(xxx) methandienone (17[alpha]-methyl-17[beta]-

hydroxyandrost-1,4-dien-3-one),

(xxxi) methandriol (17[alpha]-methyl-3[beta],17[beta]-dihydroxyandrost-5-ene),

(xxxii) methenolone (1-methyl-17[beta]-hydroxy-5[alpha]-androst-1-en-3-one),

(xxxiii) 17[alpha]-methyl-3[beta], 17[beta]-dihydroxy-5a-androstane,

(xxxiv) 17[alpha]-methyl-3[alpha],17[beta]-dihydroxy-5a-androstane,

(xxxv) 17[alpha]-methyl-3[beta],17[beta]-dihydroxyandrost-4-ene),

(xxxvi) 17[alpha]-methyl-4-hydroxynandrolone (17[alpha]-methyl-4-hydroxy-17[beta]-hydroxyestr-4-en-3-one),

(xxxvii) methyldienolone (17[alpha]-methyl-17[beta]-hydroxyestra-4,9(10)-dien-3-one),

(xxxviii) methyltrienolone (17[alpha]-methyl-17[beta]-hydroxyestra-4,9-11-trien-3-one),

(xxxix) methyltestosterone (17[alpha]-methyl-17[beta]-hydroxyandrost-4-en-3-one),

(xl) mibolerone (7[alpha],17a-dimethyl-17[beta]-hydroxyestr-4-en-3-one),

(xli) 17[alpha]-methyl-[delta]1-dihydrotestosterone (17b[beta]-hydroxy-17[alpha]-methyl-5[alpha]-androst-1-en-3-one)(a.k.a. '17-[alpha]-methyl-1-testosterone'),

(xlii) nandrolone (17[beta]-hydroxyestr-4-en-3-one),

(xliii) 19-nor-4-androstenediol (3[beta], 17[beta]-dihydroxyestr-4-ene),

(xliv) 19-nor-4-androstenediol (3[alpha], 17[beta]-dihydroxyestr-4-ene),

(xlv) 19-nor-5-androstenediol (3[beta], 17[beta]-dihydroxyestr-5-ene),

(xlvi) 19-nor-5-androstenediol (3[alpha], 17[beta]-dihydroxyestr-5-ene),

(xlvii) 19-nor-4,9(10)-androstadienedione (estra-4,9(10)-diene-3,17-dione),

(xlviii) 19-nor-4-androstenedione (estr-4-en-3,17-dione),

(xlix) 19-nor-5-androstenedione (estr-5-en-3,17-dione),

(l) norbolethone (13[beta], 17a-diethyl-17[beta]-hydroxygon-4-en-3-one),

(li) norclostebol (4-chloro-17[beta]-hydroxyestr-4-en-3-one),

(lii) norethandrolone (17[alpha]-ethyl-17[beta]-hydroxyestr-4-en-3-one),

(liii) normethandrolone (17[alpha]-methyl-17[beta]-hydroxyestr-4-en-3-one),

(liv) oxandrolone (17[alpha]-methyl-17[beta]-hydroxy-2-oxa-5[alpha]-androstan-3-one),

(lv) oxymesterone (17[alpha]-methyl-4,17[beta]-dihydroxyandrost-4-en-3-one),

(lvi) oxymetholone (17[alpha]-methyl-2-hydroxymethylene-17[beta]-hydroxy-(5[alpha]-androstan-3-one),

(lvii) stanozolol (17[alpha]-methyl-17[beta]-hydroxy-(5[alpha]-androst-2-eno[3,2-c]-pyrazole),

(lviii) stenbolone (17[beta]-hydroxy-2-methyl-(5[alpha]-androst-1-en-3-one),

(lix) testolactone (13-hydroxy-3-oxo-13,17-secoandrosta-1,4-dien-17-oic acid lactone),

(lx) testosterone (17[beta]-hydroxyandrost-4-en-3-one),

(lxi) tetrahydrogestrinone (13[beta], 17[alpha]-diethyl-17[beta]-hydroxygon-4,9,11-trien-3-one),

(lxii) trenbolone (17[beta]-hydroxyestr-4,9,11-trien-3-one).

Any person who is otherwise lawfully in possession of an anabolic steroid, or who otherwise lawfully manufactures, distributes, dispenses, delivers, or possesses with intent to deliver an anabolic steroid, which anabolic steroid is expressly intended for and lawfully allowed to be administered through implants to livestock or other nonhuman species, and which is approved by the Secretary of Health and Human Services for such administration, and which the person intends to administer or have administered through such implants, shall not be considered to be in unauthorized possession or to

unlawfully manufacture, distribute, dispense, deliver, or possess with intent to deliver such anabolic steroid for purposes of this Act.

(d) "Administration" means the Drug Enforcement Administration, United States Department of Justice, or its successor agency.

(d-5) "Clinical Director, Prescription Monitoring Program" means a Department of Human Services administrative employee licensed to either prescribe or dispense controlled substances who shall run the clinical aspects of the Department of Human Services Prescription Monitoring Program and its Prescription Information Library.

(d-10) "Compounding" means the preparation and mixing of components, excluding flavorings, (1) as the result of a prescriber's prescription drug order or initiative based on the prescriber-patient-pharmacist relationship in the course of professional practice or (2) for the purpose of, or incident to, research, teaching, or chemical analysis and not for sale or dispensing. "Compounding" includes the preparation of drugs or devices in anticipation of receiving prescription drug orders based on routine, regularly observed dispensing patterns. Commercially available products may be compounded for dispensing to individual patients only if both of the following conditions are met: (i) the commercial product is not reasonably available from normal distribution channels in a timely manner to meet the patient's needs and (ii) the

prescribing practitioner has requested that the drug be compounded.

(e) "Control" means to add a drug or other substance, or immediate precursor, to a Schedule whether by transfer from another Schedule or otherwise.

(f) "Controlled Substance" means (i) a drug, substance, immediate precursor, or synthetic drug in the Schedules of Article II of this Act or (ii) a drug or other substance, or immediate precursor, designated as a controlled substance by the Department through administrative rule. The term does not include distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in the Liquor Control Act of 1934 and the Tobacco Products Tax Act of 1995.

(f-5) "Controlled substance analog" means a substance:

(1) the chemical structure of which is substantially similar to the chemical structure of a controlled substance in Schedule I or II;

(2) which has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in Schedule I or II; or

(3) with respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central

nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in Schedule I or II.

(g) "Counterfeit substance" means a controlled substance, which, or the container or labeling of which, without authorization bears the trademark, trade name, or other identifying mark, imprint, number or device, or any likeness thereof, of a manufacturer, distributor, or dispenser other than the person who in fact manufactured, distributed, or dispensed the substance.

(h) "Deliver" or "delivery" means the actual, constructive or attempted transfer of possession of a controlled substance, with or without consideration, whether or not there is an agency relationship. <u>"Deliver" or "delivery" does not include the donation of drugs to the extent permitted under the Illinois Drug Reuse Opportunity Program Act.</u>

(i) "Department" means the Illinois Department of Human Services (as successor to the Department of Alcoholism and Substance Abuse) or its successor agency.

(j) (Blank).

(k) "Department of Corrections" means the Department of Corrections of the State of Illinois or its successor agency.

(l) "Department of Financial and Professional Regulation" means the Department of Financial and Professional Regulation of the State of Illinois or its successor agency.

(m) "Depressant" means any drug that (i) causes an overall depression of central nervous system functions, (ii) causes impaired consciousness and awareness, and (iii) can be habit-forming or lead to a substance abuse problem, including but not limited to alcohol, cannabis and its active principles and their analogs, benzodiazepines and their analogs, barbiturates and their analogs, opioids (natural and synthetic) and their analogs, and chloral hydrate and similar sedative hypnotics.

(n) (Blank).

(o) "Director" means the Director of the Illinois State Police or his or her designated agents.

(p) "Dispense" means to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a prescriber, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery.

(q) "Dispenser" means a practitioner who dispenses.

(r) "Distribute" means to deliver, other than by administering or dispensing, a controlled substance.

(s) "Distributor" means a person who distributes.

(t) "Drug" means (1) substances recognized as drugs in the official United States Pharmacopoeia, Official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; (2) substances intended for use in diagnosis, cure, mitigation, treatment, or

prevention of disease in man or animals; (3) substances (other than food) intended to affect the structure of any function of the body of man or animals and (4) substances intended for use as a component of any article specified in clause (1), (2), or (3) of this subsection. It does not include devices or their components, parts, or accessories.

(t-3) "Electronic health record" or "EHR" means an electronic record of health-related information on an individual that is created, gathered, managed, and consulted by authorized health care clinicians and staff.

(t-4) "Emergency medical services personnel" has the meaning ascribed to it in the Emergency Medical Services (EMS) Systems Act.

(t-5) "Euthanasia agency" means an entity certified by the Department of Financial and Professional Regulation for the purpose of animal euthanasia that holds an animal control facility license or animal shelter license under the Animal Welfare Act. A euthanasia agency is authorized to purchase, store, possess, and utilize Schedule II nonnarcotic and Schedule III nonnarcotic drugs for the sole purpose of animal euthanasia.

(t-10) "Euthanasia drugs" means Schedule II or Schedule III substances (nonnarcotic controlled substances) that are used by a euthanasia agency for the purpose of animal euthanasia.

(u) "Good faith" means the prescribing or dispensing of a

controlled substance by a practitioner in the regular course of professional treatment to or for any person who is under his or her treatment for a pathology or condition other than that individual's physical or psychological dependence upon or addiction to a controlled substance, except as provided herein: and application of the term to a pharmacist shall mean the dispensing of a controlled substance pursuant to the prescriber's order which in the professional judgment of the pharmacist is lawful. The pharmacist shall be guided by accepted professional standards including, but not limited to the following, in making the judgment:

(1) lack of consistency of prescriber-patient relationship,

(2) frequency of prescriptions for same drug by one prescriber for large numbers of patients,

(3) quantities beyond those normally prescribed,

(4) unusual dosages (recognizing that there may be clinical circumstances where more or less than the usual dose may be used legitimately),

(5) unusual geographic distances between patient, pharmacist and prescriber,

(6) consistent prescribing of habit-forming drugs.

(u-0.5) "Hallucinogen" means a drug that causes markedly altered sensory perception leading to hallucinations of any type.

(u-1) "Home infusion services" means services provided by

a pharmacy in compounding solutions for direct administration to a patient in a private residence, long-term care facility, or hospice setting by means of parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion.

(u-5) "Illinois State Police" means the State Police of the State of Illinois, or its successor agency.

(v) "Immediate precursor" means a substance:

(1) which the Department has found to be and by rule designated as being a principal compound used, or produced primarily for use, in the manufacture of a controlled substance;

(2) which is an immediate chemical intermediary used or likely to be used in the manufacture of such controlled substance; and

(3) the control of which is necessary to prevent, curtail or limit the manufacture of such controlled substance.

(w) "Instructional activities" means the acts of teaching, educating or instructing by practitioners using controlled substances within educational facilities approved by the State Board of Education or its successor agency.

(x) "Local authorities" means a duly organized State, County or Municipal peace unit or police force.

(y) "Look-alike substance" means a substance, other than a controlled substance which (1) by overall dosage unit appearance, including shape, color, size, markings or lack

thereof, taste, consistency, or any other identifying physical characteristic of the substance, would lead a reasonable person to believe that the substance is a controlled substance, or (2) is expressly or impliedly represented to be a controlled substance or is distributed under circumstances which would lead a reasonable person to believe that the substance is a controlled substance. For the purpose of determining whether the representations made or the circumstances of the distribution would lead a reasonable person to believe the substance to be a controlled substance under this clause (2) of subsection (y), the court or other authority may consider the following factors in addition to any other factor that may be relevant:

(a) statements made by the owner or person in control of the substance concerning its nature, use or effect;

(b) statements made to the buyer or recipient that the substance may be resold for profit;

(c) whether the substance is packaged in a manner normally used for the illegal distribution of controlled substances;

(d) whether the distribution or attempted distribution included an exchange of or demand for money or other property as consideration, and whether the amount of the consideration was substantially greater than the reasonable retail market value of the substance.

Clause (1) of this subsection (y) shall not apply to a

noncontrolled substance in its finished dosage form that was initially introduced into commerce prior to the initial introduction into commerce of a controlled substance in its finished dosage form which it may substantially resemble.

Nothing in this subsection (y) prohibits the dispensing or distributing of noncontrolled substances by persons authorized to dispense and distribute controlled substances under this Act, provided that such action would be deemed to be carried out in good faith under subsection (u) if the substances involved were controlled substances.

Nothing in this subsection (y) or in this Act prohibits the manufacture, preparation, propagation, compounding, processing, packaging, advertising or distribution of a drug or drugs by any person registered pursuant to Section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360).

(y-1) "Mail-order pharmacy" means a pharmacy that is located in a state of the United States that delivers, dispenses or distributes, through the United States Postal Service or other common carrier, to Illinois residents, any substance which requires a prescription.

(z) "Manufacture" means the production, preparation, propagation, compounding, conversion or processing of a controlled substance other than methamphetamine, either directly or indirectly, by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical

synthesis, and includes any packaging or repackaging of the substance or labeling of its container, except that this term does not include:

(1) by an ultimate user, the preparation or compounding of a controlled substance for his or her own use; ~~or~~

(2) by a practitioner, or his or her authorized agent under his or her supervision, the preparation, compounding, packaging, or labeling of a controlled substance:

(a) as an incident to his or her administering or dispensing of a controlled substance in the course of his or her professional practice; or

(b) as an incident to lawful research, teaching or chemical analysis and not for sale; or~~.~~

(3) the packaging, repackaging, or labeling of drugs only to the extent permitted under the Illinois Drug Reuse Opportunity Program Act.

(z-1) (Blank).

(z-5) "Medication shopping" means the conduct prohibited under subsection (a) of Section 314.5 of this Act.

(z-10) "Mid-level practitioner" means (i) a physician assistant who has been delegated authority to prescribe through a written delegation of authority by a physician licensed to practice medicine in all of its branches, in accordance with Section 7.5 of the Physician Assistant

Practice Act of 1987, (ii) an advanced practice registered nurse who has been delegated authority to prescribe through a written delegation of authority by a physician licensed to practice medicine in all of its branches or by a podiatric physician, in accordance with Section 65-40 of the Nurse Practice Act, (iii) an advanced practice registered nurse certified as a nurse practitioner, nurse midwife, or clinical nurse specialist who has been granted authority to prescribe by a hospital affiliate in accordance with Section 65-45 of the Nurse Practice Act, (iv) an animal euthanasia agency, or (v) a prescribing psychologist.

(aa) "Narcotic drug" means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(1) opium, opiates, derivatives of opium and opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation; however the term "narcotic drug" does not include the isoquinoline alkaloids of opium;

(2) (blank);

(3) opium poppy and poppy straw;

(4) coca leaves, except coca leaves and extracts of

coca leaves from which substantially all of the cocaine and ecgonine, and their isomers, derivatives and salts, have been removed;

(5) cocaine, its salts, optical and geometric isomers, and salts of isomers;

(6) ecgonine, its derivatives, their salts, isomers, and salts of isomers;

(7) any compound, mixture, or preparation which contains any quantity of any of the substances referred to in subparagraphs (1) through (6).

(bb) "Nurse" means a registered nurse licensed under the Nurse Practice Act.

(cc) (Blank).

(dd) "Opiate" means any substance having an addiction forming or addiction sustaining liability similar to morphine or being capable of conversion into a drug having addiction forming or addiction sustaining liability.

(ee) "Opium poppy" means the plant of the species Papaver somniferum L., except its seeds.

(ee-5) "Oral dosage" means a tablet, capsule, elixir, or solution or other liquid form of medication intended for administration by mouth, but the term does not include a form of medication intended for buccal, sublingual, or transmucosal administration.

(ff) "Parole and Pardon Board" means the Parole and Pardon Board of the State of Illinois or its successor agency.

(gg) "Person" means any individual, corporation, mail-order pharmacy, government or governmental subdivision or agency, business trust, estate, trust, partnership or association, or any other entity.

(hh) "Pharmacist" means any person who holds a license or certificate of registration as a registered pharmacist, a local registered pharmacist or a registered assistant pharmacist under the Pharmacy Practice Act.

(ii) "Pharmacy" means any store, ship or other place in which pharmacy is authorized to be practiced under the Pharmacy Practice Act.

(ii-5) "Pharmacy shopping" means the conduct prohibited under subsection (b) of Section 314.5 of this Act.

(ii-10) "Physician" (except when the context otherwise requires) means a person licensed to practice medicine in all of its branches.

(jj) "Poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.

(kk) "Practitioner" means a physician licensed to practice medicine in all its branches, dentist, optometrist, podiatric physician, veterinarian, scientific investigator, pharmacist, physician assistant, advanced practice registered nurse, licensed practical nurse, registered nurse, emergency medical services personnel, hospital, laboratory, or pharmacy, or other person licensed, registered, or otherwise lawfully permitted by the United States or this State to distribute,

dispense, conduct research with respect to, administer or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

(ll) "Pre-printed prescription" means a written prescription upon which the designated drug has been indicated prior to the time of issuance; the term does not mean a written prescription that is individually generated by machine or computer in the prescriber's office.

(mm) "Prescriber" means a physician licensed to practice medicine in all its branches, dentist, optometrist, prescribing psychologist licensed under Section 4.2 of the Clinical Psychologist Licensing Act with prescriptive authority delegated under Section 4.3 of the Clinical Psychologist Licensing Act, podiatric physician, or veterinarian who issues a prescription, a physician assistant who issues a prescription for a controlled substance in accordance with Section 303.05, a written delegation, and a written collaborative agreement required under Section 7.5 of the Physician Assistant Practice Act of 1987, an advanced practice registered nurse with prescriptive authority delegated under Section 65-40 of the Nurse Practice Act and in accordance with Section 303.05, a written delegation, and a written collaborative agreement under Section 65-35 of the Nurse Practice Act, an advanced practice registered nurse certified as a nurse practitioner, nurse midwife, or clinical nurse specialist who has been granted authority to prescribe

by a hospital affiliate in accordance with Section 65-45 of the Nurse Practice Act and in accordance with Section 303.05, or an advanced practice registered nurse certified as a nurse practitioner, nurse midwife, or clinical nurse specialist who has full practice authority pursuant to Section 65-43 of the Nurse Practice Act.

(nn) "Prescription" means a written, facsimile, or oral order, or an electronic order that complies with applicable federal requirements, of a physician licensed to practice medicine in all its branches, dentist, podiatric physician or veterinarian for any controlled substance, of an optometrist in accordance with Section 15.1 of the Illinois Optometric Practice Act of 1987, of a prescribing psychologist licensed under Section 4.2 of the Clinical Psychologist Licensing Act with prescriptive authority delegated under Section 4.3 of the Clinical Psychologist Licensing Act, of a physician assistant for a controlled substance in accordance with Section 303.05, a written delegation, and a written collaborative agreement required under Section 7.5 of the Physician Assistant Practice Act of 1987, of an advanced practice registered nurse with prescriptive authority delegated under Section 65-40 of the Nurse Practice Act who issues a prescription for a controlled substance in accordance with Section 303.05, a written delegation, and a written collaborative agreement under Section 65-35 of the Nurse Practice Act, of an advanced practice registered nurse certified as a nurse practitioner,

nurse midwife, or clinical nurse specialist who has been granted authority to prescribe by a hospital affiliate in accordance with Section 65-45 of the Nurse Practice Act and in accordance with Section 303.05 when required by law, or of an advanced practice registered nurse certified as a nurse practitioner, nurse midwife, or clinical nurse specialist who has full practice authority pursuant to Section 65-43 of the Nurse Practice Act.

(nn-5) "Prescription Information Library" (PIL) means an electronic library that contains reported controlled substance data.

(nn-10) "Prescription Monitoring Program" (PMP) means the entity that collects, tracks, and stores reported data on controlled substances and select drugs pursuant to Section 316.

(oo) "Production" or "produce" means manufacture, planting, cultivating, growing, or harvesting of a controlled substance other than methamphetamine.

(pp) "Registrant" means every person who is required to register under Section 302 of this Act.

(qq) "Registry number" means the number assigned to each person authorized to handle controlled substances under the laws of the United States and of this State.

(qq-5) "Secretary" means, as the context requires, either the Secretary of the Department or the Secretary of the Department of Financial and Professional Regulation, and the

Secretary's designated agents.

(rr) "State" includes the State of Illinois and any state, district, commonwealth, territory, insular possession thereof, and any area subject to the legal authority of the United States of America.

(rr-5) "Stimulant" means any drug that (i) causes an overall excitation of central nervous system functions, (ii) causes impaired consciousness and awareness, and (iii) can be habit-forming or lead to a substance abuse problem, including but not limited to amphetamines and their analogs, methylphenidate and its analogs, cocaine, and phencyclidine and its analogs.

(rr-10) "Synthetic drug" includes, but is not limited to, any synthetic cannabinoids or piperazines or any synthetic cathinones as provided for in Schedule I.

(ss) "Ultimate user" means a person who lawfully possesses a controlled substance for his or her own use or for the use of a member of his or her household or for administering to an animal owned by him or her or by a member of his or her household.

(Source: P.A. 99-78, eff. 7-20-15; 99-173, eff. 7-29-15; 99-371, eff. 1-1-16; 99-480, eff. 9-9-15; 99-642, eff. 7-28-16; 100-280, eff. 1-1-18; 100-453, eff. 8-25-17; 100-513, eff. 1-1-18; 100-789, eff. 1-1-19; 100-863, eff. 8-14-18.)

Section 115. The Cannabis and Controlled Substances Tort

Claims Act is amended by changing Section 3 as follows:

(740 ILCS 20/3) (from Ch. 70, par. 903)

Sec. 3. Definitions. As used in this Act, unless the context otherwise requires:

"Cannabis" includes marihuana, hashish, and other substances that are identified as including any parts of the plant Cannabis Sativa, whether growing or not, the seeds of that plant, the resin extracted from any part of that plant, and any compound, manufacture, salt, derivative, mixture, or preparation of that plant, its seeds, or resin, including tetrahydrocannabinol (THC) and all other cannabinol derivatives, including its naturally occurring or synthetically produced ingredients, whether produced directly or indirectly by extraction, independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis. "Cannabis" does not include the mature stalks of that plant, fiber produced from those stalks, oil or cake made from the seeds of that plant, any other compound, manufacture, salt, derivative, mixture, or preparation of mature stalks (except the extracted resin), fiber, oil or cake, or the sterilized seeds of that plant that are incapable of germination.

"Controlled substance" means a drug, substance, or immediate precursor in the Schedules of Article II of the Illinois Controlled Substances Act.

"Counterfeit substance" means a controlled substance or the container or labeling of a controlled substance that, without authorization, bears the trademark, trade name, or other identifying mark, imprint, number, device, or any likeness thereof of a manufacturer, distributor, or dispenser other than the person who in fact manufactured, distributed, or dispensed the substance.

"Deliver" or "delivery" means the actual, constructive, or attempted transfer of possession of a controlled substance or cannabis, with or without consideration, whether or not there is an agency relationship. <u>"Deliver" or "delivery" does not include the donation of drugs to the extent permitted under the Illinois Drug Reuse Opportunity Program Act.</u>

"Manufacture" means the production, preparation, propagation, compounding, conversion, or processing of a controlled substance, either directly or indirectly, by extraction from substances of natural origin, independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling of its container, except that the term does not include:

(1) by an ultimate user, the preparation or compounding of a controlled substance for his own use;

(2) by a practitioner or his authorized agent under his supervision, the preparation, compounding, packaging, or labeling of a controlled substance:

(A) as an incident to his administering or dispensing of a controlled substance in the course of his professional practice; or

(B) as an incident to lawful research, teaching or chemical analysis and not for sale; ~~or~~

(3) the preparation, compounding, packaging, or labeling of cannabis as an incident to lawful research, teaching, or chemical analysis and not for sale; or ~~.~~

(4) the packaging, repackaging, or labeling of drugs only to the extent permitted under the Illinois Drug Reuse Opportunity Program Act.

"Owner" means a person who has possession of or any interest whatsoever in the property involved.

"Person" means an individual, a corporation, a government, a governmental subdivision or agency, a business trust, an estate, a trust, a partnership or association, or any other entity.

"Production" means planting, cultivating, tending, or harvesting.

"Property" means real property, including things growing on, affixed to, and found in land, and tangible or intangible personal property, including rights, services, privileges, interests, claims, and securities.

(Source: P.A. 96-328, eff. 8-11-09.)".