HB0277

LRB09603256DRJ13324b

96TH GENERAL ASSEMBLY

State of Illinois

2009 and 2010

HB0277

Introduced 1/23/2009, by Rep. Patricia R. Bellock

SYNOPSIS AS INTRODUCED:

See Index

Creates the Prescription Drug Repository Program Act. Requires the Department of Public Health to establish a prescription drug repository program, under which any person may donate a prescription drug or supplies needed to administer a prescription drug for use by an individual who meets eligibility criteria specified by the Department. Sets forth requirements that prescription drugs or supplies must meet in order to be accepted and dispensed under the program. Provides that no drugs or supplies donated under the prescription drug repository program may be resold. Provides that nothing in the Act requires that a pharmacy or pharmacist participate in the prescription drug repository program. Provides for civil and criminal immunity for drug and supply manufacturers and individuals in relation to the donation, acceptance, or dispensing of prescription drugs or supplies under the prescription drug repository program. Imposes conditions on any rulemaking authority. Amends the Pharmacy Practice Act, the Wholesale Drug Distribution Licensing Act, the Senior Pharmaceutical Assistance Act, the Illinois Food, Drug and Cosmetic Act, the Illinois Controlled Substances Act, and the Cannabis and Controlled Substances Tort Claims Act to provide that persons engaged in donating or accepting, or packaging, repackaging, or labeling, prescription drugs to the extent permitted or required under the Prescription Drug Repository Program Act are exempt from provisions of those other Acts that might prohibit or otherwise regulate such activity.

LRB096 03256 DRJ 13324 b

FISCAL NOTE ACT
MAY APPLY

A BILL FOR

AN ACT concerning health.

Be it enacted by the People of the State of Illinois, represented in the General Assembly:

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

Section 5. Definitions. In this Act:

"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 establish and maintain a prescription drug repository program, under which any person may donate a prescription drug or supplies needed to administer a prescription drug for use by an individual who meets appropriate eligibility criteria. 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. 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 unit-dose packaging or, if packaged in single-unit doses, the single-unit-dose packaging is unopened.

(2) The prescription drug bears an expiration date that is later than 6 months 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.

Section 20. 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 25. Participation in program not required. Nothing in this Act requires that a pharmacy or pharmacist participate in the prescription drug repository program.

Section 30. Immunity.

(a) Unless the manufacturer's conduct is wilful and wanton, a manufacturer of a drug or supply is not subject to criminal or civil liability for injury, death, or loss to a person or property for matters related to the donation, acceptance, or dispensing of a prescription drug or supply manufactured by the manufacturer that is donated by any person under this Act.

(b) Unless the person's conduct is wilful and wanton, a person, including a pharmacist or other health professional, is immune from civil liability for injury to or the death of the individual to whom the prescription drug or supply is dispensed and may not be found guilty of unprofessional conduct for his or her acts or omissions related to donating, accepting, distributing, or dispensing a prescription drug or supply under this Act.

Section 35. Rulemaking conditions. Rulemaking authority to implement this Act, if any, is conditioned on the rules being adopted in accordance with all provisions of the Illinois Administrative Procedure Act and all rules and procedures of the Joint Committee on Administrative Rules; any purported rule not so adopted, for whatever reason, is unauthorized.

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, 2018)

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, podiatrist, 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 written guidelines; ~~and~~

(g) the ~~The~~ delegation of prescriptive authority by a physician licensed to practice medicine in all its branches to an advanced practice nurse in accordance with a written collaborative agreement under Section 65-35 of the Nurse Practice Act. This authority, which is delegated under Section 65-40 of the Nurse Practice Act, may but is not required to include the prescription of Schedule III, IV, or V controlled substances as defined in Article II of the Illinois Controlled Substances Act; and~~.~~

(h) 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.

(Source: P.A. 95-639, eff. 10-5-07.)

Section 91. 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, 2013)

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 or corporation.

"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 retail pharmacies to licensed practitioners for office use.

(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, 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. 95-689, eff. 10-29-07.)

Section 92. 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</u>

in the packaging, repackaging, or labeling of prescription 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 93. 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.)

Section 94. 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 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 presence, by his authorized agent),

(2) the patient or research subject at the lawful direction of the practitioner, 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, or dispenser. 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, and corticosteroids) that promotes muscle growth, and includes:

(i) boldenone,

(ii) chlorotestosterone,

(iii) chostebol,

(iv) dehydrochlormethyltestosterone,

(v) dihydrotestosterone,

(vi) drostanolone,

(vii) ethylestrenol,

(viii) fluoxymesterone,

(ix) formebulone,

(x) mesterolone,

(xi) methandienone,

(xii) methandranone,

(xiii) methandriol,

(xiv) methandrostenolone,

(xv) methenolone,

(xvi) methyltestosterone,

(xvii) mibolerone,

(xviii) nandrolone,

(xix) norethandrolone,

(xx) oxandrolone,

(xxi) oxymesterone,

(xxii) oxymetholone,

(xxiii) stanolone,

(xxiv) stanozolol,

(xxv) testolactone,

(xxvi) testosterone,

(xxvii) trenbolone, and

(xxviii) any salt, ester, or isomer of a drug or substance described or listed in this paragraph, if that salt, ester, or isomer promotes muscle growth.

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.

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

(f) "Controlled Substance" means a drug, substance, or immediate precursor in the Schedules of Article II of this Act.

(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>The term does not include the donation of prescription drugs to the extent permitted under the</u>

Prescription Drug Repository Program Act.

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

(j) "Department of State Police" means the Department of State Police of the State of Illinois or its successor agency.

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

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

(m) "Depressant" or "stimulant substance" means:

(1) a drug which contains any quantity of (i) barbituric acid or any of the salts of barbituric acid which has been designated as habit forming under section 502 (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352 (d)); or

(2) a drug which contains any quantity of (i) amphetamine or methamphetamine and any of their optical isomers; (ii) any salt of amphetamine or methamphetamine or any salt of an optical isomer of amphetamine; or (iii) any substance which the Department, after investigation, has found to be, and by rule designated as, habit forming because of its depressant or stimulant effect on the central nervous system; or

(3) lysergic acid diethylamide; or

(4) any drug which contains any quantity of a substance which the Department, after investigation, has found to have, and by rule designated as having, a potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinogenic effect.

(n) (Blank).

(o) "Director" means the Director of the Department of State Police or the Department of Professional Regulation or his 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-5) "Euthanasia agency" means an entity certified by the Department of 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 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 doctor-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,

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

(6) consistent prescribing of habit-forming drugs.

(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.

(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, other than Illinois, 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 own use; or

(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 packaging, repackaging, or labeling of prescription drugs only to the extent required under the Prescription Drug Repository Program Act.

(z-1) (Blank).

(aa) "Narcotic drug" means any of the following, whether produced 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:

(1) opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate;

(2) any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause (1), but not including the isoquinoline alkaloids of opium;

(3) opium poppy and poppy straw;

(4) coca leaves and any salts, compound, isomer, salt of an isomer, derivative, or preparation of coca leaves including cocaine or ecgonine, and any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, but not including decocainized coca leaves or extractions of coca leaves which do not contain cocaine or ecgonine (for the purpose of this paragraph, the term "isomer" includes optical, positional and geometric isomers).

(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.

(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.

(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, podiatrist, veterinarian, scientific investigator, pharmacist, physician assistant, advanced practice nurse, licensed practical nurse, registered nurse, 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.

(mm) "Prescriber" means a physician licensed to practice medicine in all its branches, dentist, optometrist, podiatrist or veterinarian who issues a prescription, a physician assistant who issues a prescription for a Schedule III, IV, or V controlled substance in accordance with Section 303.05 and the written guidelines required under Section 7.5 of the Physician Assistant Practice Act of 1987, or an advanced practice nurse with prescriptive authority delegated under Section 65-40 of the Nurse Practice Act and in accordance with Section 303.05 and a written collaborative agreement under Section 65-35 of the Nurse Practice Act.

(nn) "Prescription" means a lawful written, facsimile, or verbal order of a physician licensed to practice medicine in all its branches, dentist, podiatrist or veterinarian for any controlled substance, of an optometrist for a Schedule III, IV, or V controlled substance in accordance with Section 15.1 of the Illinois Optometric Practice Act of 1987, of a physician assistant for a Schedule III, IV, or V controlled substance in accordance with Section 303.05 and the written guidelines required under Section 7.5 of the Physician Assistant Practice

Act of 1987, or of an advanced practice nurse with prescriptive authority delegated under Section 65-40 of the Nurse Practice Act who issues a prescription for a Schedule III, IV, or V controlled substance in accordance with Section 303.05 and a written collaborative agreement under Section 65-35 of the Nurse Practice Act.

(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.

(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.

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

(Source: P.A. 94-556, eff. 9-11-05; 95-242, eff. 1-1-08; 95-639, eff. 10-5-07; 95-689, eff. 10-29-07; 95-876, eff. 8-21-08.)

Section 95. 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>The term does not include the donation of prescription drugs to the extent permitted under the Prescription Drug Repository 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 prescription drugs only to the extent required under the Prescription Drug Repository 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. 87-544; revised 10-23-08.)

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