102ND GENERAL ASSEMBLY

State of Illinois

2021 and 2022

HB0119

Introduced 1/14/2021, by Rep. Will Guzzardi

SYNOPSIS AS INTRODUCED:

See Index

Creates the Prescription Drug Repository Program Act. Requires the Department of Public Health to, by rule, 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.

LRB102 04093 CPF 14109 b

FISCAL NOTE ACT MAY APPLY

A BILL FOR

1 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.

6 Section 5. Definitions. In this Act:

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

9 "Department" means the Department of Public Health.

10 "Dispense" has the meaning given to that term in the 11 Pharmacy Practice Act.

12 "Pharmacist" means an individual licensed to engage in the 13 practice of pharmacy under the Pharmacy Practice Act.

14 "Pharmacy" means a pharmacy registered in this State under15 the Pharmacy Practice Act.

16 "Practitioner" means a person licensed in this State to 17 prescribe and administer drugs or licensed in another state 18 and recognized by this State as a person authorized to 19 prescribe and administer drugs.

20 "Prescription drug" means any prescribed drug that may be 21 legally dispensed by a pharmacy. "Prescription drug" does not 22 include drugs for the treatment of cancer that can only be 23 dispensed to a patient registered with the drug manufacturer 1 in accordance with federal Food and Drug Administration 2 requirements.

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

5 Section 10. Prescription drug repository program. The 6 shall, by rule, establish and maintain Department а 7 prescription drug repository program, under which any person 8 may donate a prescription drug or supplies needed to 9 administer a prescription drug for use by an individual who 10 meets appropriate eligibility criteria. Donations may be made 11 on the premises of a pharmacy that elects to participate in the 12 program and meets appropriate requirements. The pharmacy may 13 charge an individual who receives a prescription drug or 14 supplies needed to administer a prescription drug under this 15 Act a handling fee that may not exceed an appropriate amount. A 16 pharmacy that receives a donated prescription drug or supplies needed to administer a prescription drug under this Act may 17 distribute the prescription drug or supplies to another 18 19 eligible pharmacy for use under the program.

20 Section 15. Requirements for accepting and dispensing 21 prescription drugs and supplies. A prescription drug or 22 supplies needed to administer a prescription drug may be 23 accepted and dispensed under the program only if all of the 24 following requirements are met:

1 (1) The prescription drug or supplies needed to 2 administer a prescription drug are in their original, 3 unopened, sealed, and tamper-evident unit-dose packaging 4 or, if packaged in single-unit doses, the single-unit-dose 5 packaging is unopened.

6 (2) The prescription drug bears an expiration date 7 that is later than 6 months after the date that the drug 8 was donated.

9 (3) The prescription drug or supplies needed to 10 administer a prescription drug are not adulterated or 11 misbranded, as determined by a pharmacist employed by, or 12 under contract with, the pharmacy where the drug or 13 supplies are accepted or dispensed. The pharmacist must 14 inspect the drug or supplies before the drug or supplies 15 are dispensed.

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

19 (5) The prescription drug is not a controlled20 substance.

21 Section 20. Resale of donated drugs or supplies 22 No prescription drug or supplies needed to prohibited. administer a prescription drug that are donated for use under 23 24 this Act may be resold.

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

4 Section 30. Immunity.

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5 (a) A manufacturer of a drug or supply acting reasonably 6 and in good faith is not subject to criminal or civil liability 7 for injury, death, or loss to a person or property for matters 8 related to the donation, acceptance, or dispensing of a 9 prescription drug or supply manufactured by the manufacturer 10 that is donated by any person under this Act.

11 A person acting reasonably and in good faith, (b) 12 including a pharmacist or other health professional, is immune from civil liability for injury to or the death of the 13 14 individual to whom the prescription drug or supply is 15 dispensed and may not be found guilty of unprofessional 16 conduct for his or her acts or omissions related to donating, accepting, distributing, or dispensing a prescription drug or 17 supply under this Act. The immunity granted under this 18 subsection does not apply to acts or omissions outside the 19 20 scope of the program.

21 Section 90. The Pharmacy Practice Act is amended by 22 changing Section 4 as follows:

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

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(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:

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

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(b) the sale of compressed gases;

12 (c) the sale of patent or proprietary medicines and household remedies when sold in original and unbroken 13 14 packages only, if such patent or proprietary medicines and 15 household remedies be properly and adequately labeled as 16 to content and usage and generally considered and accepted 17 as harmless and nonpoisonous when used according to the directions on the label, and also do not contain opium or 18 19 coca leaves, or any compound, salt or derivative thereof, 20 or any drug which, according to the latest editions of the 21 following authoritative pharmaceutical treatises and 22 standards, The United States namely, 23 Pharmacopoeia/National Formulary (USP/NF), the United 24 States Dispensatory, and the Accepted Dental Remedies of 25 the Council of Dental Therapeutics of the American Dental 26 Association or any or either of them, in use on the

effective date of this Act, or according to the existing 1 2 provisions of the Federal Food, Drug, and Cosmetic Act and 3 Regulations of the Department of Health and Human Services, Food and Drug Administration, promulgated 4 5 thereunder now in effect, is designated, described or narcotic, hypnotic, habit 6 considered as а forming, 7 dangerous, or poisonous drug;

8 (d) the sale of poultry and livestock remedies in 9 original and unbroken packages only, labeled for poultry 10 and livestock medication;

11 (e) the sale of poisonous substances or mixture of 12 poisonous substances, in unbroken packages, for in the arts or industries or 13 nonmedicinal use for 14 insecticide purposes; provided, they are properly and 15 adequately labeled as to content and such nonmedicinal 16 usage, in conformity with the provisions of all applicable 17 federal, state and local laws and regulations promulgated thereunder now in effect relating thereto and governing 18 19 the same, and those which are required under such 20 applicable laws and regulations to be labeled with the word "Poison", are also labeled with the word "Poison" 21 22 printed thereon in prominent type and the name of a 23 readily obtainable antidote with directions for its administration; 24

(f) the delegation of limited prescriptive authorityby 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;

8 (g) the delegation of prescriptive authority by a 9 physician licensed to practice medicine in all its 10 branches or a licensed podiatric physician to an advanced 11 practice registered nurse in accordance with a written 12 collaborative agreement under Sections 65-35 and 65-40 of 13 the Nurse Practice Act; and

14 (g-5) the donation or acceptance, or the packaging, 15 repackaging, or labeling, of prescription drugs to the 16 extent permitted or required under the Prescription Drug 17 Repository Program Act; and

18 (h) the sale or distribution of dialysate or devices 19 necessary to perform home peritoneal renal dialysis for 20 patients with end-stage renal disease, provided that all 21 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

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a manufacturer or the manufacturer's agent, which is
 properly registered with the Board as a manufacturer,
 third-party logistics provider, or wholesaler;

4 (3) the dialysate or devices are held and 5 delivered to the manufacturer or the manufacturer's 6 agent in the original, sealed packaging from the 7 manufacturing facility;

(4) the dialysate or devices are delivered only 8 9 upon receipt of a physician's prescription by a 10 licensed pharmacy in which the prescription is 11 processed in accordance with provisions set forth in 12 this Act, and the transmittal of an order from the 13 licensed pharmacy to the manufacturer the or manufacturer's agent; and 14

15 (5) the manufacturer or the manufacturer's agent 16 delivers the dialysate or devices directly to: (i) a 17 patient with end-stage renal disease, or his or her designee, for the patient's self-administration of the 18 19 dialysis therapy or (ii) a health care provider or 20 institution for administration or delivery of the 21 dialysis therapy to a patient with end-stage renal 22 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

- 9 - LRB102 04093 CPF 14109 b HB0119 this paragraph (h) must be retained in accordance with 1 2 Section 18 of this Act. (Source: P.A. 100-218, eff. 8-18-17; 100-513, eff. 1-1-18; 3 100-863, eff. 8-14-18; 101-420, eff. 8-16-19.) 4 5 Section 95. The Wholesale Drug Distribution Licensing Act is amended by changing Section 15 as follows: 6 7 (225 ILCS 120/15) (from Ch. 111, par. 8301-15) 8 (Section scheduled to be repealed on January 1, 2023) 9 Sec. 15. Definitions. As used in this Act: 10 "Authentication" means the affirmative verification, 11 before any wholesale distribution of a prescription drug occurs, that each transaction listed on the pedigree has 12 13 occurred. 14 "Authorized distributor of record" means a wholesale 15 distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's 16 prescription drug. An ongoing relationship is deemed to exist 17 between a wholesale distributor and a manufacturer when the 18 19 wholesale distributor, including any affiliated group of the

20 wholesale distributor, as defined in Section 1504 of the 21 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

1 (2) The wholesale distributor is listed on the 2 manufacturer's current list of authorized distributors of 3 record, which is updated by the manufacturer on no less 4 than a monthly basis.

5 "Blood" means whole blood collected from a single donor 6 and processed either for transfusion or further manufacturing.

7 "Blood component" means that part of blood separated by 8 physical or mechanical means.

9 "Board" means the State Board of Pharmacy of the 10 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.

18 "Co-licensed partner or product" means an instance where 19 one or more parties have the right to engage in the 20 manufacturing or marketing of a prescription drug, consistent 21 with the FDA's implementation of the Prescription Drug 22 Marketing Act.

23 "Department" means the Department of Financial and 24 Professional Regulation.

25 "Drop shipment" means the sale of a prescription drug to a
26 wholesale distributor by the manufacturer of the prescription

drug or that manufacturer's co-licensed product partner, that 1 2 manufacturer's third party logistics provider, or that 3 manufacturer's exclusive distributor or by an authorized distributor of record that purchased the product directly from 4 5 the manufacturer or one of these entities whereby the 6 wholesale distributor or chain pharmacy warehouse takes title 7 but not physical possession of such prescription drug and the 8 wholesale distributor invoices the pharmacy, chain pharmacy 9 warehouse, or other person authorized by law to dispense or 10 administer such drug to a patient and the pharmacy, chain 11 pharmacy warehouse, or other authorized person receives 12 the prescription drug directly from delivery of the that manufacturer's third party logistics 13 manufacturer, provider, or that manufacturer's exclusive distributor or from 14 15 an authorized distributor of record that purchased the product 16 directly from the manufacturer or one of these entities.

17 "Drug sample" means a unit of a prescription drug that is 18 not intended to be sold and is intended to promote the sale of 19 the drug.

20 "Facility" means a facility of a wholesale distributor 21 where prescription drugs are stored, handled, repackaged, or 22 offered for sale, or a facility of a third-party logistics 23 provider where prescription drugs are stored or handled.

24 "FDA" means the United States Food and Drug 25 Administration.

"Manufacturer" means a person licensed or approved by the

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FDA to engage in the manufacture of drugs or devices, 1 2 consistent with the definition of "manufacturer" set forth in 3 FDA's regulations and guidances implementing the the Prescription Drug Marketing Act. "Manufacturer" does not 4 5 include anyone who is engaged in the packaging, repackaging, or labeling of prescription drugs only to the extent required 6 7 under the Prescription Drug Repository Program Act.

"Manufacturer's exclusive distributor" means anyone who 8 9 contracts with a manufacturer to provide or coordinate 10 warehousing, distribution, or other services on behalf of a 11 manufacturer and who takes title to that manufacturer's 12 but who does prescription drug, not have general 13 responsibility to direct the sale or disposition of the manufacturer's prescription drug. A manufacturer's exclusive 14 15 distributor must be licensed as a wholesale distributor under 16 this Act and, in order to be considered part of the normal 17 distribution channel, must also be an authorized distributor of record. 18

"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:

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(1) a pharmacy or to other designated persons

1 authorized by law to dispense or administer the drug to a 2 patient;

3 (2) a wholesale distributor to a pharmacy or other 4 designated persons authorized by law to dispense or 5 administer the drug to a patient;

6 (3) a wholesale distributor to a chain pharmacy 7 warehouse to that chain pharmacy warehouse's intracompany 8 pharmacy to a patient or other designated persons 9 authorized by law to dispense or administer the drug to a 10 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;

15 (5) an authorized distributor of record to one other 16 authorized distributor of record to an office-based health 17 care practitioner authorized by law to dispense or 18 administer the drug to the patient; or

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

21 "Pedigree" means a document or electronic file containing 22 information that records each wholesale distribution of any 23 given prescription drug from the point of origin to the final 24 wholesale distribution point of any given prescription drug.

25 "Person" means and includes a natural person, partnership,26 association, corporation, or any other legal business entity.

"Pharmacy distributor" means any pharmacy licensed in this 1 2 State or hospital pharmacy that is engaged in the delivery or 3 distribution of prescription drugs either to any other pharmacy licensed in this State or to any other person or 4 5 entity including, but not limited to, a wholesale drug 6 distributor engaged in the delivery or distribution of 7 prescription drugs who is involved in the actual, constructive, or attempted transfer of a drug in this State to 8 9 other than the ultimate consumer except as otherwise provided 10 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.

18 "Repackage" means repackaging or otherwise changing the 19 container, wrapper, or labeling to further the distribution of 20 a prescription drug, excluding that completed by the 21 pharmacist responsible for dispensing the product to a 22 patient.

23 "Secretary" means the Secretary of Financial and24 Professional Regulation.

25 "Third-party logistics provider" means anyone who 26 contracts with a prescription drug manufacturer to provide or

1 coordinate warehousing, distribution, or other services on 2 behalf of a manufacturer, but does not take title to the 3 prescription drug or have general responsibility to direct the 4 prescription drug's sale or disposition.

5 "Wholesale distribution" means the distribution of 6 prescription drugs to persons other than a consumer or 7 patient, but does not include any of the following:

8 (1) Intracompany sales of prescription drugs, meaning 9 (i) any transaction or transfer between any division, 10 subsidiary, parent, or affiliated or related company under 11 the common ownership and control of a corporate entity or 12 (ii) any transaction or transfer between co-licensees of a 13 co-licensed product.

14 (2) The sale, purchase, distribution, trade, or
15 transfer of a prescription drug or offer to sell,
16 purchase, distribute, trade, or transfer a prescription
17 drug for emergency medical reasons.

18 (3) The distribution of prescription drug samples by19 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.

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(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.

3 (7) The sale, transfer, merger, or consolidation of 4 all or part of the business of a pharmacy or pharmacies 5 from or with another pharmacy or pharmacies, whether 6 accomplished as a purchase and sale of stock or business 7 assets.

8 sale, purchase, distribution, trade, (8) The or 9 transfer of a prescription drug from one authorized 10 distributor of record to one additional authorized 11 distributor of record when the manufacturer has stated in 12 writing to the receiving authorized distributor of record that the manufacturer is unable to supply the prescription 13 14 drug and the supplying authorized distributor of record 15 states in writing that the prescription drug being 16 supplied had until that time been exclusively in the 17 normal distribution channel.

18 (9) The delivery of or the offer to deliver a 19 prescription drug by a common carrier solely in the common 20 carrier's usual course of business of transporting 21 prescription drugs when the common carrier does not store, 22 warehouse, or take legal ownership of the prescription 23 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

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original manufacturer, the originating wholesale
 distributor, or a third party returns processor.

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

6 "Wholesale drug distributor" means anyone engaged in the 7 wholesale distribution of prescription drugs into, out of, or 8 within the State, including without limitation manufacturers; 9 repackers; own label distributors; jobbers; private label 10 distributors; brokers; warehouses, including manufacturers' 11 and distributors' warehouses; manufacturer's exclusive 12 distributors; and authorized distributors of record; drug 13 distributors; independent wholesale wholesalers or druq 14 traders; specialty wholesale distributors; and retail 15 pharmacies that conduct wholesale distribution; and chain 16 pharmacy warehouses that conduct wholesale distribution. In 17 order to be considered part of the normal distribution channel, a wholesale distributor must also be an authorized 18 distributor of record. 19

20 (Source: P.A. 101-420, eff. 8-16-19.)

- 21 Section 100. The Senior Pharmaceutical Assistance Act is 22 amended by changing Section 10 as follows:
- 23 (320 ILCS 50/10)
- 24 Sec. 10. Definitions. In this Act:

1 "Manufacturer" includes:

2 (1) An entity that is engaged in (a) the production, 3 preparation, propagation, compounding, conversion, or processing of prescription drug products (i) directly or 4 indirectly by extraction from substances of natural 5 origin, (ii) independently by means of chemical synthesis, 6 7 (iii) by combination of extraction and chemical or 8 synthesis; or (b) the packaging, repackaging, labeling or 9 re-labeling, or distribution of prescription drug 10 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</u> who is engaged in the packaging, repackaging, or labeling of <u>prescription drugs only to the extent required under the</u> <u>Prescription Drug Repository Program Act.</u>

20 "Prescription drug" means a drug that may be dispensed 21 only upon prescription by an authorized prescriber and that is 22 approved for safety and effectiveness as a prescription drug 23 under Section 505 or 507 of the Federal Food, Drug and Cosmetic 24 Act.

25 "Senior citizen" or "senior" means a person 65 years of 26 age or older. HB0119 - 19 - LRB102 04093 CPF 14109 b

1 (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:

4 (410 ILCS 620/16) (from Ch. 56 1/2, par. 516)

The Director is hereby authorized to 5 Sec. 16. (a) 6 promulgate regulations exempting from any labeling or 7 packaging requirement of this Act drugs and devices which are 8 (i) τ in accordance with the practice of the trade, to be 9 processed, labeled or repacked in substantial quantities at 10 establishments other than those where originally processed or 11 packaged on condition that such drugs and devices are not adulterated or misbranded under the provisions of this Act 12 upon removal from such processing, labeling or repacking 13 14 establishment or (ii) packaged, repackaged, or labeled to the 15 extent required under the Prescription Drug Repository Program 16 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 1 2 necessary to its use is not safe for use except under the 3 supervision of a practitioner licensed by law to administer such drug; or (C) is limited by an approved application under 4 5 Section 505 of the Federal Act or Section 17 of this Act to use under the professional supervision of a practitioner licensed 6 by law to administer such drug, shall be dispensed only in 7 accordance with the provisions of the "Illinois Controlled 8 9 Substances Act". The act of dispensing a drug contrary to the 10 provisions of this paragraph shall be deemed to be an act which 11 results in a drug being misbranded while held for sale.

12 (d) Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to 13 14 administer such drug shall be exempt from the requirements of 15 Section 15, except subsections (a), (k) and (l) and clauses 16 (2) and (3) of subsection (i), and the packaging requirements 17 of subsections (g), (h) and (q), if the drug bears a label containing the proprietary name or names, or if there is none, 18 19 the established name or names of the drugs, the dosage and 20 quantity, unless the prescribing practitioner, in the interest of the health of the patient, directs otherwise in writing, 21 22 the name and address of the dispenser, the serial number and 23 date of the prescription or of its filling, the name of the prescriber and, if stated in the prescription, the name of the 24 25 patient, and the directions for use and the cautionary 26 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.

5 (e) The Director may by regulation remove drugs subject to 6 Section 15 (d) and Section 17 from the requirements of 7 subsection (c) of this Section when such requirements are not 8 necessary for the protection of the public health.

9 (f) A drug which is subject to subsection (c) of this 10 Section shall be deemed to be misbranded if at any time before 11 dispensing its label fails to bear the statement "Caution: 12 Federal Law Prohibits Dispensing Without Prescription" or Prohibits 13 "Caution: State Law Dispensing Without 14 Prescription". A drug to which subsection (c) of this Section 15 does not apply shall be deemed to be misbranded if at any time 16 prior to dispensing its label bears the caution statement 17 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.

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

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

3 (720 ILCS 570/102) (from Ch. 56 1/2, par. 1102)

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4 Sec. 102. Definitions. As used in this Act, unless the 5 context otherwise requires:

6 (a) "Addict" means any person who habitually uses any 7 drug, chemical, substance or dangerous drug other than alcohol 8 so as to endanger the public morals, health, safety or welfare 9 or who is so far addicted to the use of a dangerous drug or 10 controlled substance other than alcohol as to have lost the 11 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:

17 (1) a practitioner (or, in his or her presence, by his18 or her authorized agent),

19 (2) the patient or research subject pursuant to an20 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

1 common or contract carrier, public warehouseman or employee of 2 the carrier or warehouseman.

3 (c-1) "Anabolic Steroids" means any drug or hormonal 4 substance, chemically and pharmacologically related to 5 testosterone (other than estrogens, progestins, 6 corticosteroids, and dehydroepiandrosterone), and includes:

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

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

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

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

11 17[beta]-dihydroxy-5[alpha]-androst-1-ene),

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

13 17[beta]-dihydroxy-5[alpha]-androst-1-ene),

14 (vi) 4-androstenediol

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

16 (vii) 5-androstenediol

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

18 (viii) 1-androstenedione

19 ([5alpha]-androst-1-en-3,17-dione),

20 (ix) 4-androstenedione

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

22 (x) 5-androstenedione

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

24 (xi) bolasterone (7[alpha],17a-dimethyl-17[beta]-25 hydroxyandrost-4-en-3-one),

26 (xii) boldenone (17[beta]-hydroxyandrost-

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1	1,4,-diene-3-one),
2	(xiii) boldione (androsta-1,4-
3	diene-3,17-dione),
4	(xiv) calusterone (7[beta],17[alpha]-dimethyl-17
5	[beta]-hydroxyandrost-4-en-3-one),
6	(xv) clostebol (4-chloro-17[beta]-
7	hydroxyandrost-4-en-3-one),
8	(xvi) dehydrochloromethyltestosterone (4-chloro-
9	17[beta]-hydroxy-17[alpha]-methyl-
10	androst-1,4-dien-3-one),
11	(xvii) desoxymethyltestosterone
12	(17[alpha]-methyl-5[alpha]
13	-androst-2-en-17[beta]-ol)(a.k.a., madol),
14	(xviii) [delta]1-dihydrotestosterone (a.k.a.
15	'1-testosterone') (17[beta]-hydroxy-
16	5[alpha]-androst-1-en-3-one),
17	(xix) 4-dihydrotestosterone (17[beta]-hydroxy-
18	androstan-3-one),
19	(xx) drostanolone (17[beta]-hydroxy-2[alpha]-methyl-
20	5[alpha]-androstan-3-one),
21	(xxi) ethylestrenol (17[alpha]-ethyl-17[beta]-
22	hydroxyestr-4-ene),
23	(xxii) fluoxymesterone (9-fluoro-17[alpha]-methyl-
24	<pre>1[beta],17[beta]-dihydroxyandrost-4-en-3-one),</pre>
25	(xxiii) formebolone (2-formyl-17[alpha]-methyl-11[alpha],
26	17[beta]-dihydroxyandrost-1,4-dien-3-one),

1	(xxiv) furazabol (17[alpha]-methyl-17[beta]-
2	hydroxyandrostano[2,3-c]-furazan),
3	(xxv) 13[beta]-ethyl-17[beta]-hydroxygon-4-en-3-one,
4	(xxvi) 4-hydroxytestosterone (4,17[beta]-dihydroxy-
5	androst-4-en-3-one),
6	(xxvii) 4-hydroxy-19-nortestosterone (4,17[beta]-
7	dihydroxy-estr-4-en-3-one),
8	(xxviii) mestanolone (17[alpha]-methyl-17[beta]-
9	hydroxy-5-androstan-3-one),
10	(xxix) mesterolone (lamethyl-17[beta]-hydroxy-
11	[5a]-androstan-3-one),
12	(xxx) methandienone (17[alpha]-methyl-17[beta]-
13	hydroxyandrost-1,4-dien-3-one),
14	(xxxi) methandriol (17[alpha]-methyl-3[beta],17[beta]-
15	dihydroxyandrost-5-ene),
16	(xxxii) methenolone (1-methyl-17[beta]-hydroxy-
17	5[alpha]-androst-1-en-3-one),
18	(xxxiii) 17[alpha]-methyl-3[beta], 17[beta]-
19	dihydroxy-5a-androstane,
20	(xxxiv) 17[alpha]-methyl-3[alpha],17[beta]-dihydroxy
21	-5a-androstane,
22	(xxxv) 17[alpha]-methyl-3[beta],17[beta]-
23	dihydroxyandrost-4-ene),
24	(xxxvi) 17[alpha]-methyl-4-hydroxynandrolone (17[alpha]-
25	<pre>methyl-4-hydroxy-17[beta]-hydroxyestr-4-en-3-one),</pre>
26	(xxxvii) methyldienolone (17[alpha]-methyl-17[beta]-

1	hydroxyestra-4,9(10)-dien-3-one),
2	(xxxviii) methyltrienolone (17[alpha]-methyl-17[beta]-
3	hydroxyestra-4,9-11-trien-3-one),
4	(xxxix) methyltestosterone (17[alpha]-methyl-17[beta]-
5	hydroxyandrost-4-en-3-one),
6	(xl) mibolerone (7[alpha],17a-dimethyl-17[beta]-
7	hydroxyestr-4-en-3-one),
8	(xli) 17[alpha]-methyl-[delta]1-dihydrotestosterone
9	(17b[beta]-hydroxy-17[alpha]-methyl-5[alpha]-
10	androst-1-en-3-one)(a.k.a. '17-[alpha]-methyl-
11	1-testosterone'),
12	(xlii) nandrolone (17[beta]-hydroxyestr-4-en-3-one),
13	(xliii) 19-nor-4-androstenediol (3[beta], 17[beta]-
14	dihydroxyestr-4-ene),
15	(xliv) 19-nor-4-androstenediol (3[alpha], 17[beta]-
16	dihydroxyestr-4-ene),
17	(xlv) 19-nor-5-androstenediol (3[beta], 17[beta]-
18	dihydroxyestr-5-ene),
19	(xlvi) 19-nor-5-androstenediol (3[alpha], 17[beta]-
20	dihydroxyestr-5-ene),
21	(xlvii) 19-nor-4,9(10)-androstadienedione
22	(estra-4,9(10)-diene-3,17-dione),
23	(xlviii) 19-nor-4-androstenedione (estr-4-
24	en-3,17-dione),
25	(xlix) 19-nor-5-androstenedione (estr-5-
26	en-3,17-dione),

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1	(l) norbolethone (13[beta], 17a-diethyl-17[beta]-
2	hydroxygon-4-en-3-one),
3	(li) norclostebol (4-chloro-17[beta]-
4	hydroxyestr-4-en-3-one),
5	(lii) norethandrolone (17[alpha]-ethyl-17[beta]-
6	hydroxyestr-4-en-3-one),
7	(liii) normethandrolone (17[alpha]-methyl-17[beta]-
8	hydroxyestr-4-en-3-one),
9	(liv) oxandrolone (17[alpha]-methyl-17[beta]-hydroxy-
10	2-oxa-5[alpha]-androstan-3-one),
11	(lv) oxymesterone (17[alpha]-methyl-4,17[beta]-
12	dihydroxyandrost-4-en-3-one),
13	(lvi) oxymetholone (17[alpha]-methyl-2-hydroxymethylene-
14	17[beta]-hydroxy-(5[alpha]-androstan-3-one),
15	(lvii) stanozolol (17[alpha]-methyl-17[beta]-hydroxy-
16	(5[alpha]-androst-2-eno[3,2-c]-pyrazole),
17	(lviii) stenbolone (17[beta]-hydroxy-2-methyl-
18	(5[alpha]-androst-1-en-3-one),
19	(lix) testolactone (13-hydroxy-3-oxo-13,17-
20	secoandrosta-1,4-dien-17-oic
21	acid lactone),
22	(lx) testosterone (17[beta]-hydroxyandrost-
23	4-en-3-one),
24	(lxi) tetrahydrogestrinone (13[beta], 17[alpha]-
25	diethyl-17[beta]-hydroxygon-
26	4,9,11-trien-3-one),

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(lxii) trenbolone (17[beta]-hydroxyestr-4,9,

2

11-trien-3-one).

Any person who is otherwise lawfully in possession of an 3 anabolic steroid, or who otherwise lawfully manufactures, 4 distributes, dispenses, delivers, or possesses with intent to 5 deliver an anabolic steroid, which anabolic steroid is 6 7 expressly intended for and lawfully allowed to be administered through implants to livestock or other nonhuman species, and 8 9 which is approved by the Secretary of Health and Human 10 Services for such administration, and which the person intends 11 to administer or have administered through such implants, 12 shall not be considered to be in unauthorized possession or to unlawfully manufacture, distribute, dispense, deliver, or 13 possess with intent to deliver such anabolic steroid for 14 15 purposes of this Act.

16 (d) "Administration" means the Drug Enforcement 17 Administration, United States Department of Justice, or its 18 successor agency.

19 (d-5) "Clinical Director, Prescription Monitoring Program" 20 means a Department of Human Services administrative employee 21 licensed to either prescribe or dispense controlled substances 22 who shall run the clinical aspects of the Department of Human 23 Services Prescription Monitoring Program and its Prescription 24 Information Library.

25 (d-10) "Compounding" means the preparation and mixing of 26 components, excluding flavorings, (1) as the result of a

prescriber's prescription drug order or initiative based on 1 2 the prescriber-patient-pharmacist relationship in the course 3 of professional practice or (2) for the purpose of, or incident to, research, teaching, or chemical analysis and not 4 5 for sale or dispensing. "Compounding" includes the preparation of drugs or devices in anticipation of receiving prescription 6 7 drug orders based on routine, regularly observed dispensing 8 patterns. Commercially available products may be compounded 9 for dispensing to individual patients only if both of the 10 following conditions are met: (i) the commercial product is 11 not reasonably available from normal distribution channels in 12 a timely manner to meet the patient's needs and (ii) the prescribing practitioner has requested that the drug be 13 14 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, 18 19 immediate precursor, or synthetic drug in the Schedules of 20 Article II of this Act or (ii) a drug or other substance, or immediate precursor, designated as a controlled substance by 21 22 the Department through administrative rule. The term does not 23 include distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in the Liquor Control Act of 24 25 1934 and the Tobacco Products Tax Act of 1995.

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

1 (1) the chemical structure of which is substantially 2 similar to the chemical structure of a controlled 3 substance in Schedule I or II;

(2)which has stimulant, depressant, 4 а or 5 hallucinogenic effect on the central nervous system that 6 is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central 7 nervous system of a controlled substance in Schedule I or 8 9 II; or

10 (3) with respect to a particular person, which such 11 person represents or intends to have a stimulant, 12 depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater 13 14 than the stimulant, depressant, or hallucinogenic effect 15 on the central nervous system of a controlled substance in 16 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</u>
 <u>the donation of prescription drugs to the extent permitted</u>
 under the Prescription Drug Repository Program Act.

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

(j) (Blank).

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

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

13 (m) "Depressant" means any drug that (i) causes an overall depression of central nervous system functions, (ii) causes 14 15 impaired consciousness and awareness, and (iii) can be 16 habit-forming or lead to a substance abuse problem, including 17 but not limited to alcohol, cannabis and its active principles and their analogs, benzodiazepines and their analogs, 18 their analogs, opioids (natural 19 barbiturates and and 20 synthetic) and their analogs, and chloral hydrate and similar 21 sedative hypnotics.

22

7

(n) (Blank).

23 (o) "Director" means the Director of the Illinois State24 Police or his or her designated agents.

(p) "Dispense" means to deliver a controlled substance toan 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.

4

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

5 (r) "Distribute" means to deliver, other than by6 administering or dispensing, a controlled substance.

7

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

(t) "Drug" means (1) substances recognized as drugs in the 8 9 official United States Pharmacopoeia, Official Homeopathic 10 Pharmacopoeia of the United States, or official National 11 Formulary, or any supplement to any of them; (2) substances 12 intended for use in diagnosis, cure, mitigation, treatment, or 13 prevention of disease in man or animals; (3) substances (other than food) intended to affect the structure of any function of 14 15 the body of man or animals and (4) substances intended for use 16 as a component of any article specified in clause (1), (2), or 17 (3) of this subsection. It does not include devices or their components, parts, or accessories. 18

19 (t-3) "Electronic health record" or "EHR" means an 20 electronic record of health-related information on an 21 individual that is created, gathered, managed, and consulted 22 by authorized health care clinicians and staff.

23 (t-4) "Emergency medical services personnel" has the 24 meaning ascribed to it in the Emergency Medical Services (EMS) 25 Systems Act.

26

(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.

8 (t-10) "Euthanasia drugs" means Schedule II or Schedule 9 III substances (nonnarcotic controlled substances) that are 10 used by a euthanasia agency for the purpose of animal 11 euthanasia.

12 (u) "Good faith" means the prescribing or dispensing of a 13 controlled substance by a practitioner in the regular course 14 of professional treatment to or for any person who is under his 15 or her treatment for a pathology or condition other than that 16 individual's physical or psychological dependence upon or 17 addiction to a controlled substance, except as provided herein: and application of the term to a pharmacist shall mean 18 19 the dispensing of a controlled substance pursuant to the 20 prescriber's order which in the professional judgment of the pharmacist is lawful. The pharmacist shall be guided by 21 22 accepted professional standards including, but not limited to 23 the following, in making the judgment:

24 (1) lack of consistency of prescriber-patient25 relationship,

26

(2) frequency of prescriptions for same drug by one

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prescriber for large numbers of patients,

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1 2

(3) quantities beyond those normally prescribed,

3 (4) unusual dosages (recognizing that there may be 4 clinical circumstances where more or less than the usual 5 dose may be used legitimately),

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

8

(6) consistent prescribing of habit-forming drugs.

9 (u-0.5) "Hallucinogen" means a drug that causes markedly 10 altered sensory perception leading to hallucinations of any 11 type.

12 (u-1) "Home infusion services" means services provided by 13 a pharmacy in compounding solutions for direct administration 14 to a patient in a private residence, long-term care facility, 15 or hospice setting by means of parenteral, intravenous, 16 intramuscular, subcutaneous, or intraspinal infusion.

17 (u-5) "Illinois State Police" means the State Police of18 the State of Illinois, or its successor agency.

19

(v) "Immediate precursor" means a substance:

20 (1) which the Department has found to be and by rule 21 designated as being a principal compound used, or produced 22 primarily for use, in the manufacture of a controlled 23 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.

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

10 (y) "Look-alike substance" means a substance, other than a 11 controlled substance which (1) by overall dosage unit 12 appearance, including shape, color, size, markings or lack 13 thereof, taste, consistency, or any other identifying physical characteristic of the substance, would lead a reasonable 14 15 person to believe that the substance is a controlled 16 substance, or (2) is expressly or impliedly represented to be 17 a controlled substance or is distributed under circumstances which would lead a reasonable person to believe that the 18 substance is a controlled substance. For the purpose of 19 20 determining whether the representations made or the circumstances of the distribution would lead a reasonable 21 22 person to believe the substance to be a controlled substance 23 under this clause (2) of subsection (y), the court or other authority may consider the following factors in addition to 24 25 any other factor that may be relevant:

26

(a) statements made by the owner or person in control

1

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;

4 (c) whether the substance is packaged in a manner 5 normally used for the illegal distribution of controlled 6 substances;

7 (d) whether the distribution or attempted distribution 8 included an exchange of or demand for money or other 9 property as consideration, and whether the amount of the 10 consideration was substantially greater than the 11 reasonable retail market value of the substance.

12 Clause (1) of this subsection (y) shall not apply to a 13 noncontrolled substance in its finished dosage form that was 14 initially introduced into commerce prior to the initial 15 introduction into commerce of a controlled substance in its 16 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 HB0119 - 37 - LRB102 04093 CPF 14109 b

1 the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360).

2 (y-1) "Mail-order pharmacy" means a pharmacy that is 3 located in a state of the United States that delivers, 4 dispenses or distributes, through the United States Postal 5 Service or other common carrier, to Illinois residents, any 6 substance which requires a prescription.

7 "Manufacture" means the production, preparation, (Z) 8 propagation, compounding, conversion or processing of a 9 controlled substance other than methamphetamine, either 10 directly or indirectly, by extraction from substances of 11 natural origin, or independently by means of chemical 12 synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the 13 substance or labeling of its container, except that this term 14 15 does not include:

16 (1) by an ultimate user, the preparation or 17 compounding of a controlled substance for his or her own 18 use; or

19 (2) by a practitioner, or his or her authorized agent 20 under his or her supervision, the preparation, 21 compounding, packaging, or labeling of a controlled 22 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

26

(b) as an incident to lawful research, teaching or

1chemical analysis and not for sale; or-2(3) the packaging, repackaging, or labeling of3prescription drugs only to the extent required under the4Prescription Drug Repository Program Act.

(z-1) (Blank).

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

(z-10) "Mid-level practitioner" means (i) a physician 8 9 assistant who has been delegated authority to prescribe 10 through a written delegation of authority by a physician licensed to practice medicine in all of its branches, in 11 12 accordance with Section 7.5 of the Physician Assistant 13 Practice Act of 1987, (ii) an advanced practice registered 14 nurse who has been delegated authority to prescribe through a written delegation of authority by a physician licensed to 15 16 practice medicine in all of its branches or by a podiatric 17 physician, in accordance with Section 65-40 of the Nurse Practice Act, (iii) an advanced practice registered nurse 18 certified as a nurse practitioner, nurse midwife, or clinical 19 20 nurse specialist who has been granted authority to prescribe by a hospital affiliate in accordance with Section 65-45 of 21 22 the Nurse Practice Act, (iv) an animal euthanasia agency, or 23 (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

5

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;

10

(2) (blank);

11

(3) opium poppy and poppy straw;

12 (4) coca leaves, except coca leaves and extracts of 13 coca leaves from which substantially all of the cocaine 14 and ecgonine, and their isomers, derivatives and salts, 15 have been removed;

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

18 (6) ecgonine, its derivatives, their salts, isomers,
19 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).

23 (bb) "Nurse" means a registered nurse licensed under the 24 Nurse Practice Act.

25 (cc) (Blank).

26 (dd) "Opiate" means any substance having an addiction

1 forming or addiction sustaining liability similar to morphine 2 or being capable of conversion into a drug having addiction 3 forming or addiction sustaining liability.

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

6 (ee-5) "Oral dosage" means a tablet, capsule, elixir, or 7 solution or other liquid form of medication intended for 8 administration by mouth, but the term does not include a form 9 of medication intended for buccal, sublingual, or transmucosal 10 administration.

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

13 (gg) "Person" means any individual, corporation, 14 mail-order pharmacy, government or governmental subdivision or 15 agency, business trust, estate, trust, partnership or 16 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.

26 (ii-10) "Physician" (except when the context otherwise

1 requires) means a person licensed to practice medicine in all 2 of its branches.

3 (jj) "Poppy straw" means all parts, except the seeds, of4 the opium poppy, after mowing.

5 (kk) "Practitioner" means a physician licensed to practice medicine in all its branches, dentist, optometrist, podiatric 6 physician, veterinarian, scientific investigator, pharmacist, 7 8 physician assistant, advanced practice registered nurse, 9 licensed practical nurse, registered nurse, emergency medical 10 services personnel, hospital, laboratory, or pharmacy, or other person licensed, registered, or otherwise lawfully 11 12 permitted by the United States or this State to distribute, 13 dispense, conduct research with respect to, administer or use 14 in teaching or chemical analysis, a controlled substance in 15 the course of professional practice or research.

16 (11) "Pre-printed prescription" means a written 17 prescription upon which the designated drug has been indicated 18 prior to the time of issuance; the term does not mean a written 19 prescription that is individually generated by machine or 20 computer in the prescriber's office.

(mm) "Prescriber" means a physician licensed to practice 21 22 medicine in all its branches, dentist, optometrist, 23 prescribing psychologist licensed under Section 4.2 of the 24 Clinical Psychologist Licensing Act with prescriptive authority delegated under Section 4.3 of the 25 Clinical 26 Psychologist Licensing Act, podiatric physician, or

veterinarian who issues a prescription, a physician assistant 1 2 who issues a prescription for a controlled substance in accordance with Section 303.05, a written delegation, and a 3 written collaborative agreement required under Section 7.5 of 4 5 the Physician Assistant Practice Act of 1987, an advanced 6 practice registered nurse with prescriptive authority 7 delegated under Section 65-40 of the Nurse Practice Act and in accordance with Section 303.05, a written delegation, and a 8 9 written collaborative agreement under Section 65-35 of the 10 Nurse Practice Act, an advanced practice registered nurse 11 certified as a nurse practitioner, nurse midwife, or clinical 12 nurse specialist who has been granted authority to prescribe by a hospital affiliate in accordance with Section 65-45 of 13 the Nurse Practice Act and in accordance with Section 303.05, 14 15 or an advanced practice registered nurse certified as a nurse 16 practitioner, nurse midwife, or clinical nurse specialist who 17 has full practice authority pursuant to Section 65-43 of the Nurse Practice Act. 18

(nn) "Prescription" means a written, facsimile, or oral 19 20 order, or an electronic order that complies with applicable federal requirements, of a physician licensed to practice 21 22 medicine in all its branches, dentist, podiatric physician or 23 veterinarian for any controlled substance, of an optometrist in accordance with Section 15.1 of the Illinois Optometric 24 Practice Act of 1987, of a prescribing psychologist licensed 25 26 under Section 4.2 of the Clinical Psychologist Licensing Act

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with prescriptive authority delegated under Section 4.3 of the 1 2 Clinical Psychologist Licensing Act, of a physician assistant for a controlled substance in accordance with Section 303.05, 3 a written delegation, and a written collaborative agreement 4 required under Section 7.5 of the Physician Assistant Practice 5 Act of 1987, of an advanced practice registered nurse with 6 7 prescriptive authority delegated under Section 65-40 of the 8 Nurse Practice Act who issues a prescription for a controlled 9 substance in accordance with Section 303.05, a written 10 delegation, and a written collaborative agreement under 11 Section 65-35 of the Nurse Practice Act, of an advanced 12 practice registered nurse certified as a nurse practitioner, 13 nurse midwife, or clinical nurse specialist who has been 14 granted authority to prescribe by a hospital affiliate in 15 accordance with Section 65-45 of the Nurse Practice Act and in 16 accordance with Section 303.05 when required by law, or of an 17 advanced practice registered nurse certified as a nurse practitioner, nurse midwife, or clinical nurse specialist who 18 19 has full practice authority pursuant to Section 65-43 of the 20 Nurse Practice Act.

21 (nn-5) "Prescription Information Library" (PIL) means an 22 electronic library that contains reported controlled substance 23 data.

24 (nn-10) "Prescription Monitoring Program" (PMP) means the 25 entity that collects, tracks, and stores reported data on 26 controlled substances and select drugs pursuant to Section HB0119

1 316.

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

5 (pp) "Registrant" means every person who is required to 6 register under Section 302 of this Act.

7 (qq) "Registry number" means the number assigned to each 8 person authorized to handle controlled substances under the 9 laws of the United States and of this State.

10 (qq-5) "Secretary" means, as the context requires, either 11 the Secretary of the Department or the Secretary of the 12 Department of Financial and Professional Regulation, and the 13 Secretary's designated agents.

14 (rr) "State" includes the State of Illinois and any state, 15 district, commonwealth, territory, insular possession thereof, 16 and any area subject to the legal authority of the United 17 States of America.

(rr-5) "Stimulant" means any drug that (i) causes an 18 overall excitation of central nervous system functions, (ii) 19 20 causes impaired consciousness and awareness, and (iii) can be habit-forming or lead to a substance abuse problem, including 21 22 but not limited to amphetamines and their analogs, 23 methylphenidate and its analogs, cocaine, and phencyclidine 24 and its analogs.

(rr-10) "Synthetic drug" includes, but is not limited to,
 any synthetic cannabinoids or piperazines or any synthetic

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1 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.

7 (Source: P.A. 99-78, eff. 7-20-15; 99-173, eff. 7-29-15;
8 99-371, eff. 1-1-16; 99-480, eff. 9-9-15; 99-642, eff.
9 7-28-16; 100-280, eff. 1-1-18; 100-453, eff. 8-25-17; 100-513,
10 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:

13 (740 ILCS 20/3) (from Ch. 70, par. 903)

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

16 "Cannabis" includes marihuana, hashish, and other 17 substances that are identified as including any parts of the plant Cannabis Sativa, whether growing or not, the seeds of 18 that plant, the resin extracted from any part of that plant, 19 20 and any compound, manufacture, salt, derivative, mixture, or 21 preparation of that plant, its seeds, or resin, including 22 tetrahydrocannabinol (THC) and all other cannabinol 23 derivatives, including its naturally occurring or 24 synthetically produced ingredients, whether produced directly

indirectly by extraction, independently by means of 1 or 2 chemical synthesis, or by a combination of extraction and chemical synthesis. "Cannabis" does not include the mature 3 stalks of that plant, fiber produced from those stalks, oil or 4 5 cake made from the seeds of that plant, any other compound, manufacture, salt, derivative, mixture, or preparation of 6 7 mature stalks (except the extracted resin), fiber, oil or 8 cake, or the sterilized seeds of that plant that are incapable 9 of germination.

10 "Controlled substance" means a drug, substance, or 11 immediate precursor in the Schedules of Article II of the 12 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 20 attempted transfer of possession of a controlled substance or 21 22 cannabis, with or without consideration, whether or not there 23 is an agency relationship. "Deliver" or "delivery" does not 24 include the donation of prescription drugs to the extent 25 permitted under the Prescription Drug Repository Program Act. 26 "Manufacture" means the production, preparation,

1 propagation, compounding, conversion, or processing of a 2 controlled substance, either directly or indirectly, by 3 extraction from substances of natural origin, independently by 4 means of chemical synthesis, or by a combination of extraction 5 and chemical synthesis, and includes any packaging or 6 repackaging of the substance or labeling of its container, 7 except that the term does not include:

8 (1) by an ultimate user, the preparation or 9 compounding of a controlled substance for his own use;

10 (2) by a practitioner or his authorized agent under 11 his supervision, the preparation, compounding, packaging, 12 or labeling of a controlled substance:

13 (A) as an incident to his administering or
14 dispensing of a controlled substance in the course of
15 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 -

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

24 "Owner" means a person who has possession of or any 25 interest whatsoever in the property involved.

26 "Person" means an individual, a corporation, a government,

1 a governmental subdivision or agency, a business trust, an 2 estate, a trust, a partnership or association, or any other 3 entity.

4 "Production" means planting, cultivating, tending, or5 harvesting.

6 "Property" means real property, including things growing 7 on, affixed to, and found in land, and tangible or intangible 8 personal property, including rights, services, privileges, 9 interests, claims, and securities.

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

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