

1 AN ACT concerning health.

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

4 Section 1. Short title. This Act may be cited as the
5 Illinois Drug Reuse Opportunity 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 "Dispense" has the same meaning as defined in Section 3 of
10 the Pharmacy Practice Act.

11 "Donor" means any person, including an individual member
12 of the public, or any entity legally authorized to possess
13 medicine, including, but not limited to, a wholesaler or
14 distributor, third party logistic provider, pharmacy,
15 dispenser, clinic, surgical or health center, detention and
16 rehabilitation center, jail, prison laboratory, medical or
17 pharmacy school, prescriber or other health care professional,
18 long-term care facility, or healthcare facility. "Donor"
19 includes government agencies and entities that are federally
20 authorized to possess medicine, including, but not limited to,
21 drug manufacturers, repackagers, relabelers, outsourcing
22 facilities, health care facilities operated by the U.S.
23 Department of Veterans Affairs, and prisons.

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

4 "Eligible patient" means an individual:

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

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

13 "Manufacturer" has the same meaning as defined in Section
14 15 of the Wholesale Drug Distribution Licensing Act.

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

19 "Practitioner" means a person licensed in this State to
20 dispense or administer drugs or who is licensed in another
21 state as a person authorized to dispense or administer drugs.

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

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

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

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

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

14 Section 10. Donating and receiving drugs. Notwithstanding
15 any other law or rule, donors may donate drugs to recipients
16 and recipients may receive donated drugs from donors.
17 Recipients shall only dispense or administer drugs to eligible
18 patients as described in Section 20, further donate drugs to
19 another recipient as described in Section 30, or dispose of
20 drugs as described in Section 35.

21 Section 15. Cost-free provision of drugs. Drugs donated
22 for use under this Act are considered nonsaleable. When
23 dispensing a drug to an eligible patient, the recipient must
24 do so at no cost to the eligible patient, except that a

1 reasonable handling fee may be charged. The handling fee may
2 not exceed the direct or indirect cost to the recipient of
3 providing the drug. Charging the fee does not constitute
4 reselling.

5 Section 20. Requirements for dispensing drugs; priority.

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

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

10 (2) that meets the requirements in Section 25;

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

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

16 (5) that has an expiration or beyond-use date brought
17 forward from the donated prescription drug or
18 over-the-counter drug that will not expire before the use
19 by the eligible patient based on the prescribing
20 practitioner's directions for use or, for over-the-counter
21 medicine, on the package's label; and

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

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

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

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

7 (2) The drug is not expired.

8 (3) The drug is not a controlled substance.

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

16 (5) The donor has removed or redacted any patient name
17 and prescription number on the drug or otherwise maintains
18 patient confidentiality by executing a confidentiality
19 agreement with the recipient.

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

24 Section 30. Donating and repackaging. Notwithstanding any

1 other law or rule, a recipient may:

2 (1) further donate drugs to another recipient;

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

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

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

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

18 Section 35. Disposition of drugs. A donated drug that does
19 not meet the requirements of Section 25 must be disposed of by
20 returning it to the donor, destroying it by an incinerator,
21 medical waste hauler, or other lawful method, or transferring
22 it to a returns processor. A record of disposal shall consist
23 of the disposal method, the date of disposal, and the name and
24 quantity of the drug disposed of. Notwithstanding any other
25 law or rule, no other record of disposal shall be required.

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

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

10 Section 50. Change of ownership. A donation or other
11 transfer of possession or control of a drug under this Act
12 shall not be construed as a change of ownership unless it is
13 specified as such by the recipient. If a record of the
14 donation's transaction information or history is required, the
15 history shall begin with the donor of the drug, include all
16 prior donations, and, if the drug was previously dispensed,
17 only include drug information required to be on the patient
18 label in accordance with the Board of Pharmacy's rules and
19 regulations.

20 Section 55. Retention of records. All records required
21 under this Act shall be retained in physical or electronic
22 format and on or off the recipient's premises for a period of 6

1 years. Donors or recipients may contract with one another or a
2 third party to create or maintain records on each other's
3 behalf. An identifier, such as a serial number or bar code, may
4 be used in place of any or all information required by a record
5 or label pursuant to this Act if it allows for such information
6 to be readily retrievable. Upon request by a State or federal
7 regulatory agency, the identifier used for requested records
8 shall be replaced with the original information. An identifier
9 shall not be used on patient labels when dispensing or
10 administering a drug.

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

14 Section 65. Immunity.

15 (a) Except as provided in subsection (b), no manufacturer,
16 donor, or recipient shall be liable in any criminal or civil
17 action, or be subject to professional discipline, for
18 activities solely and directly attributable to donating,
19 receiving, or dispensing drugs under this Act.

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

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

24 (2) if it is shown that the person or entity knew or

1 should have known that the donated drug was adulterated or
2 misbranded; or

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

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

7 (225 ILCS 85/4) (from Ch. 111, par. 4124)

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

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

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

18 (b) the sale of compressed gases;

19 (c) the sale of patent or proprietary medicines and
20 household remedies when sold in original and unbroken
21 packages only, if such patent or proprietary medicines and
22 household remedies be properly and adequately labeled as
23 to content and usage and generally considered and accepted
24 as harmless and nonpoisonous when used according to the

1 directions on the label, and also do not contain opium or
2 coca leaves, or any compound, salt or derivative thereof,
3 or any drug which, according to the latest editions of the
4 following authoritative pharmaceutical treatises and
5 standards, namely, The United States
6 Pharmacopoeia/National Formulary (USP/NF), the United
7 States Dispensatory, and the Accepted Dental Remedies of
8 the Council of Dental Therapeutics of the American Dental
9 Association or any or either of them, in use on the
10 effective date of this Act, or according to the existing
11 provisions of the Federal Food, Drug, and Cosmetic Act and
12 Regulations of the Department of Health and Human
13 Services, Food and Drug Administration, promulgated
14 thereunder now in effect, is designated, described or
15 considered as a narcotic, hypnotic, habit forming,
16 dangerous, or poisonous drug;

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

20 (e) the sale of poisonous substances or mixture of
21 poisonous substances, in unbroken packages, for
22 nonmedicinal use in the arts or industries or for
23 insecticide purposes; provided, they are properly and
24 adequately labeled as to content and such nonmedicinal
25 usage, in conformity with the provisions of all applicable
26 federal, state and local laws and regulations promulgated

1 thereunder now in effect relating thereto and governing
2 the same, and those which are required under such
3 applicable laws and regulations to be labeled with the
4 word "Poison", are also labeled with the word "Poison"
5 printed thereon in prominent type and the name of a
6 readily obtainable antidote with directions for its
7 administration;

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

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

23 (g-5) the donation or acceptance, or the packaging,
24 repackaging, or labeling, of drugs to the extent permitted
25 under the Illinois Drug Reuse Opportunity Program Act; and

26 (h) the sale or distribution of dialysate or devices

1 necessary to perform home peritoneal renal dialysis for
2 patients with end-stage renal disease, provided that all
3 of the following conditions are met:

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

8 (2) the dialysate or devices are lawfully held by
9 a manufacturer or the manufacturer's agent, which is
10 properly registered with the Board as a manufacturer,
11 third-party logistics provider, or wholesaler;

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

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

23 (5) the manufacturer or the manufacturer's agent
24 delivers the dialysate or devices directly to: (i) a
25 patient with end-stage renal disease, or his or her
26 designee, for the patient's self-administration of the

1 dialysis therapy or (ii) a health care provider or
2 institution for administration or delivery of the
3 dialysis therapy to a patient with end-stage renal
4 disease.

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

11 (Source: P.A. 100-218, eff. 8-18-17; 100-513, eff. 1-1-18;
12 100-863, eff. 8-14-18; 101-420, eff. 8-16-19.)

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

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

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

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

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

22 "Authorized distributor of record" means a wholesale
23 distributor with whom a manufacturer has established an
24 ongoing relationship to distribute the manufacturer's

1 prescription drug. An ongoing relationship is deemed to exist
2 between a wholesale distributor and a manufacturer when the
3 wholesale distributor, including any affiliated group of the
4 wholesale distributor, as defined in Section 1504 of the
5 Internal Revenue Code, complies with the following:

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

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

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

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

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

19 "Chain pharmacy warehouse" means a physical location for
20 prescription drugs that acts as a central warehouse and
21 performs intracompany sales or transfers of the drugs to a
22 group of chain or mail order pharmacies that have the same
23 common ownership and control. Notwithstanding any other
24 provision of this Act, a chain pharmacy warehouse shall be
25 considered part of the normal distribution channel.

26 "Co-licensed partner or product" means an instance where

1 one or more parties have the right to engage in the
2 manufacturing or marketing of a prescription drug, consistent
3 with the FDA's implementation of the Prescription Drug
4 Marketing Act.

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

7 "Drop shipment" means the sale of a prescription drug to a
8 wholesale distributor by the manufacturer of the prescription
9 drug or that manufacturer's co-licensed product partner, that
10 manufacturer's third party logistics provider, or that
11 manufacturer's exclusive distributor or by an authorized
12 distributor of record that purchased the product directly from
13 the manufacturer or one of these entities whereby the
14 wholesale distributor or chain pharmacy warehouse takes title
15 but not physical possession of such prescription drug and the
16 wholesale distributor invoices the pharmacy, chain pharmacy
17 warehouse, or other person authorized by law to dispense or
18 administer such drug to a patient and the pharmacy, chain
19 pharmacy warehouse, or other authorized person receives
20 delivery of the prescription drug directly from the
21 manufacturer, that manufacturer's third party logistics
22 provider, or that manufacturer's exclusive distributor or from
23 an authorized distributor of record that purchased the product
24 directly from the manufacturer or one of these entities.

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

1 the drug.

2 "Facility" means a facility of a wholesale distributor
3 where prescription drugs are stored, handled, repackaged, or
4 offered for sale, or a facility of a third-party logistics
5 provider where prescription drugs are stored or handled.

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

8 "Manufacturer" means a person licensed or approved by the
9 FDA to engage in the manufacture of drugs or devices,
10 consistent with the definition of "manufacturer" set forth in
11 the FDA's regulations and guidances implementing the
12 Prescription Drug Marketing Act. "Manufacturer" does not
13 include anyone who is engaged in the packaging, repackaging,
14 or labeling of drugs only to the extent permitted under the
15 Illinois Drug Reuse Opportunity Program Act.

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

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

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

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

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

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

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

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

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

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

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

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

26 "Repackage" means repackaging or otherwise changing the

1 container, wrapper, or labeling to further the distribution of
2 a prescription drug, excluding that completed by the
3 pharmacist responsible for dispensing the product to a
4 patient.

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

7 "Third-party logistics provider" means anyone who
8 contracts with a prescription drug manufacturer to provide or
9 coordinate warehousing, distribution, or other services on
10 behalf of a manufacturer, but does not take title to the
11 prescription drug or have general responsibility to direct the
12 prescription drug's sale or disposition.

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

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

22 (2) The sale, purchase, distribution, trade, or
23 transfer of a prescription drug or offer to sell,
24 purchase, distribute, trade, or transfer a prescription
25 drug for emergency medical reasons.

26 (3) The distribution of prescription drug samples by

1 manufacturers' representatives.

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

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

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

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

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

26 (9) The delivery of or the offer to deliver a

1 prescription drug by a common carrier solely in the common
2 carrier's usual course of business of transporting
3 prescription drugs when the common carrier does not store,
4 warehouse, or take legal ownership of the prescription
5 drug.

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

11 (11) The donation of drugs to the extent permitted
12 under the Illinois Drug Reuse Opportunity Program Act.

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

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

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

4 (320 ILCS 50/10)

5 Sec. 10. Definitions. In this Act:

6 "Manufacturer" includes:

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

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

19 The term does not include a wholesale distributor of
20 drugs, drugstore chain organization, or retail pharmacy
21 licensed by the State. The term also does not include anyone
22 who is engaged in the packaging, repackaging, or labeling of
23 drugs only to the extent permitted under the Illinois Drug
24 Reuse Opportunity Program Act.

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

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

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

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

11 (410 ILCS 620/16) (from Ch. 56 1/2, par. 516)

12 Sec. 16. (a) The Director is hereby authorized to
13 promulgate regulations exempting from any labeling or
14 packaging requirement of this Act drugs and devices which are
15 (i) in accordance with the practice of the trade, to be
16 processed, labeled or repacked in substantial quantities at
17 establishments other than those where originally processed or
18 packaged on condition that such drugs and devices are not
19 adulterated or misbranded under the provisions of this Act
20 upon removal from such processing, labeling or repacking
21 establishment or (ii) packaged, repackaged, or labeled to the
22 extent permitted under the Illinois Drug Reuse Opportunity
23 Program Act.

24 (b) Drugs and device labeling or packaging exemptions

1 adopted under the Federal Act and supplements thereto or
2 revisions thereof shall apply to drugs and devices in Illinois
3 except insofar as modified or rejected by regulations
4 promulgated by the Director.

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

19 (d) Any drug dispensed by filling or refilling a written
20 or oral prescription of a practitioner licensed by law to
21 administer such drug shall be exempt from the requirements of
22 Section 15, except subsections (a), (k) and (l) and clauses
23 (2) and (3) of subsection (i), and the packaging requirements
24 of subsections (g), (h) and (q), if the drug bears a label
25 containing the proprietary name or names, or if there is none,
26 the established name or names of the drugs, the dosage and

1 quantity, unless the prescribing practitioner, in the interest
2 of the health of the patient, directs otherwise in writing,
3 the name and address of the dispenser, the serial number and
4 date of the prescription or of its filling, the name of the
5 prescriber and, if stated in the prescription, the name of the
6 patient, and the directions for use and the cautionary
7 statements, if any, contained in such prescription. This
8 exemption shall not apply to any drug dispensed in the course
9 of the conduct of business of dispensing drugs pursuant to
10 diagnosis by mail, or to a drug dispensed in violation of
11 subsection (a) of this Section.

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

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

25 (g) Nothing in this Section shall be construed to relieve
26 any person from any requirement prescribed by or under

1 authority of law with respect to controlled substances now
2 included or which may hereafter be included within the
3 classifications of controlled substances cannabis as defined
4 in applicable Federal laws relating to controlled substances
5 or cannabis or the Cannabis Control Act.

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

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

9 (720 ILCS 570/102) (from Ch. 56 1/2, par. 1102)

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

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

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

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

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

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

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

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

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

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

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

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

18 17[beta]-dihydroxy-5[alpha]-androst-1-ene),

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

20 17[beta]-dihydroxy-5[alpha]-androst-1-ene),

21 (vi) 4-androstenediol

22 (3[beta],17[beta]-dihydroxy-androst-4-ene),

23 (vii) 5-androstenediol

24 (3[beta],17[beta]-dihydroxy-androst-5-ene),

25 (viii) 1-androstenedione

26 ([5alpha]-androst-1-en-3,17-dione),

- 1 (ix) 4-androstenedione
2 (androst-4-en-3,17-dione),
3 (x) 5-androstenedione
4 (androst-5-en-3,17-dione),
5 (xi) bolasterone (7[alpha],17a-dimethyl-17[beta]-
6 hydroxyandrost-4-en-3-one),
7 (xii) boldenone (17[beta]-hydroxyandrost-
8 1,4,-diene-3-one),
9 (xiii) boldione (androsta-1,4-
10 diene-3,17-dione),
11 (xiv) calusterone (7[beta],17[alpha]-dimethyl-17
12 [beta]-hydroxyandrost-4-en-3-one),
13 (xv) clostebol (4-chloro-17[beta]-
14 hydroxyandrost-4-en-3-one),
15 (xvi) dehydrochloromethyltestosterone (4-chloro-
16 17[beta]-hydroxy-17[alpha]-methyl-
17 androst-1,4-dien-3-one),
18 (xvii) desoxymethyltestosterone
19 (17[alpha]-methyl-5[alpha]
20 -androst-2-en-17[beta]-ol) (a.k.a., madol),
21 (xviii) [delta]1-dihydrotestosterone (a.k.a.
22 '1-testosterone') (17[beta]-hydroxy-
23 5[alpha]-androst-1-en-3-one),
24 (xix) 4-dihydrotestosterone (17[beta]-hydroxy-
25 androstan-3-one),
26 (xx) drostanolone (17[beta]-hydroxy-2[alpha]-methyl-

1 5[alpha]-androst-3-one),
2 (xxi) ethylestrenol (17[alpha]-ethyl-17[beta]-
3 hydroxyestr-4-ene),
4 (xxii) fluoxymesterone (9-fluoro-17[alpha]-methyl-
5 1[beta],17[beta]-dihydroxyandrost-4-en-3-one),
6 (xxiii) formebolone (2-formyl-17[alpha]-methyl-11[alpha],
7 17[beta]-dihydroxyandrost-1,4-dien-3-one),
8 (xxiv) furazabol (17[alpha]-methyl-17[beta]-
9 hydroxyandrostano[2,3-c]-furan),
10 (xxv) 13[beta]-ethyl-17[beta]-hydroxygon-4-en-3-one,
11 (xxvi) 4-hydroxytestosterone (4,17[beta]-dihydroxy-
12 androst-4-en-3-one),
13 (xxvii) 4-hydroxy-19-nortestosterone (4,17[beta]-
14 dihydroxy-estr-4-en-3-one),
15 (xxviii) mestanolone (17[alpha]-methyl-17[beta]-
16 hydroxy-5-androst-3-one),
17 (xxix) mesterolone (1-methyl-17[beta]-hydroxy-
18 [5a]-androst-3-one),
19 (xxx) methandienone (17[alpha]-methyl-17[beta]-
20 hydroxyandrost-1,4-dien-3-one),
21 (xxxi) methandriol (17[alpha]-methyl-3[beta],17[beta]-
22 dihydroxyandrost-5-ene),
23 (xxxii) methenolone (1-methyl-17[beta]-hydroxy-
24 5[alpha]-androst-1-en-3-one),
25 (xxxiii) 17[alpha]-methyl-3[beta], 17[beta]-
26 dihydroxy-5a-androstane,

- 1 (xxxiv) 17[alpha]-methyl-3[alpha],17[beta]-dihydroxy
2 -5a-androstane,
3 (xxxv) 17[alpha]-methyl-3[beta],17[beta]-
4 dihydroxyandrost-4-ene),
5 (xxxvi) 17[alpha]-methyl-4-hydroxynandrolone (17[alpha]-
6 methyl-4-hydroxy-17[beta]-hydroxyestr-4-en-3-one),
7 (xxxvii) methyldienolone (17[alpha]-methyl-17[beta]-
8 hydroxyestra-4,9(10)-dien-3-one),
9 (xxxviii) methyltrienolone (17[alpha]-methyl-17[beta]-
10 hydroxyestra-4,9-11-trien-3-one),
11 (xxxix) methyltestosterone (17[alpha]-methyl-17[beta]-
12 hydroxyandrost-4-en-3-one),
13 (xl) mibolerone (7[alpha],17a-dimethyl-17[beta]-
14 hydroxyestr-4-en-3-one),
15 (xli) 17[alpha]-methyl-[delta]1-dihydrotestosterone
16 (17b[beta]-hydroxy-17[alpha]-methyl-5[alpha]-
17 androst-1-en-3-one) (a.k.a. '17-[alpha]-methyl-
18 1-testosterone'),
19 (xlii) nandrolone (17[beta]-hydroxyestr-4-en-3-one),
20 (xliii) 19-nor-4-androstenediol (3[beta], 17[beta]-
21 dihydroxyestr-4-ene),
22 (xliv) 19-nor-4-androstenediol (3[alpha], 17[beta]-
23 dihydroxyestr-4-ene),
24 (xlv) 19-nor-5-androstenediol (3[beta], 17[beta]-
25 dihydroxyestr-5-ene),
26 (xlvi) 19-nor-5-androstenediol (3[alpha], 17[beta]-

1 dihydroxyestr-5-ene),
2 (xlvii) 19-nor-4,9(10)-androstadienedione
3 (estra-4,9(10)-diene-3,17-dione),
4 (xlviii) 19-nor-4-androstenedione (estr-4-
5 en-3,17-dione),
6 (xlix) 19-nor-5-androstenedione (estr-5-
7 en-3,17-dione),
8 (l) norbolethone (13[beta], 17a-diethyl-17[beta]-
9 hydroxygon-4-en-3-one),
10 (li) norclostebol (4-chloro-17[beta]-
11 hydroxyestr-4-en-3-one),
12 (lii) norethandrolone (17[alpha]-ethyl-17[beta]-
13 hydroxyestr-4-en-3-one),
14 (liii) normethandrolone (17[alpha]-methyl-17[beta]-
15 hydroxyestr-4-en-3-one),
16 (liv) oxandrolone (17[alpha]-methyl-17[beta]-hydroxy-
17 2-oxa-5[alpha]-androstan-3-one),
18 (lv) oxymesterone (17[alpha]-methyl-4,17[beta]-
19 dihydroxyandrost-4-en-3-one),
20 (lvi) oxymetholone (17[alpha]-methyl-2-hydroxymethylene-
21 17[beta]-hydroxy-(5[alpha]-androstan-3-one),
22 (lvii) stanozolol (17[alpha]-methyl-17[beta]-hydroxy-
23 (5[alpha]-androst-2-eno[3,2-c]-pyrazole),
24 (lviii) stenbolone (17[beta]-hydroxy-2-methyl-
25 (5[alpha]-androst-1-en-3-one),
26 (lix) testolactone (13-hydroxy-3-oxo-13,17-

1 secoandrosta-1,4-dien-17-oic
2 acid lactone),
3 (lx) testosterone (17[beta]-hydroxyandrost-
4 4-en-3-one),
5 (lxi) tetrahydrogestrinone (13[beta], 17[alpha]-
6 diethyl-17[beta]-hydroxygon-
7 4,9,11-trien-3-one),
8 (lxii) trenbolone (17[beta]-hydroxyestr-4,9,
9 11-trien-3-one).

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

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

26 (d-5) "Clinical Director, Prescription Monitoring Program"

1 means a Department of Human Services administrative employee
2 licensed to either prescribe or dispense controlled substances
3 who shall run the clinical aspects of the Department of Human
4 Services Prescription Monitoring Program and its Prescription
5 Information Library.

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

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

25 (f) "Controlled Substance" means (i) a drug, substance,
26 immediate precursor, or synthetic drug in the Schedules of

1 Article II of this Act or (ii) a drug or other substance, or
2 immediate precursor, designated as a controlled substance by
3 the Department through administrative rule. The term does not
4 include distilled spirits, wine, malt beverages, or tobacco,
5 as those terms are defined or used in the Liquor Control Act of
6 1934 and the Tobacco Products Tax Act of 1995.

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

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

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

17 (3) with respect to a particular person, which such
18 person represents or intends to have a stimulant,
19 depressant, or hallucinogenic effect on the central
20 nervous system that is substantially similar to or greater
21 than the stimulant, depressant, or hallucinogenic effect
22 on the central nervous system of a controlled substance in
23 Schedule I or II.

24 (g) "Counterfeit substance" means a controlled substance,
25 which, or the container or labeling of which, without
26 authorization bears the trademark, trade name, or other

1 identifying mark, imprint, number or device, or any likeness
2 thereof, of a manufacturer, distributor, or dispenser other
3 than the person who in fact manufactured, distributed, or
4 dispensed the substance.

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

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

14 (j) (Blank).

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

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

20 (m) "Depressant" means any drug that (i) causes an overall
21 depression of central nervous system functions, (ii) causes
22 impaired consciousness and awareness, and (iii) can be
23 habit-forming or lead to a substance abuse problem, including
24 but not limited to alcohol, cannabis and its active principles
25 and their analogs, benzodiazepines and their analogs,
26 barbiturates and their analogs, opioids (natural and

1 synthetic) and their analogs, and chloral hydrate and similar
2 sedative hypnotics.

3 (n) (Blank).

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

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

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

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

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

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

26 (t-3) "Electronic health record" or "EHR" means an

1 electronic record of health-related information on an
2 individual that is created, gathered, managed, and consulted
3 by authorized health care clinicians and staff.

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

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

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

19 (u) "Good faith" means the prescribing or dispensing of a
20 controlled substance by a practitioner in the regular course
21 of professional treatment to or for any person who is under his
22 or her treatment for a pathology or condition other than that
23 individual's physical or psychological dependence upon or
24 addiction to a controlled substance, except as provided
25 herein: and application of the term to a pharmacist shall mean
26 the dispensing of a controlled substance pursuant to the

1 prescriber's order which in the professional judgment of the
2 pharmacist is lawful. The pharmacist shall be guided by
3 accepted professional standards including, but not limited to
4 the following, in making the judgment:

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

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

9 (3) quantities beyond those normally prescribed,

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

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

15 (6) consistent prescribing of habit-forming drugs.

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

19 (u-1) "Home infusion services" means services provided by
20 a pharmacy in compounding solutions for direct administration
21 to a patient in a private residence, long-term care facility,
22 or hospice setting by means of parenteral, intravenous,
23 intramuscular, subcutaneous, or intraspinal infusion.

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

26 (v) "Immediate precursor" means a substance:

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

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

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

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

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

17 (y) "Look-alike substance" means a substance, other than a
18 controlled substance which (1) by overall dosage unit
19 appearance, including shape, color, size, markings or lack
20 thereof, taste, consistency, or any other identifying physical
21 characteristic of the substance, would lead a reasonable
22 person to believe that the substance is a controlled
23 substance, or (2) is expressly or impliedly represented to be
24 a controlled substance or is distributed under circumstances
25 which would lead a reasonable person to believe that the
26 substance is a controlled substance. For the purpose of

1 determining whether the representations made or the
2 circumstances of the distribution would lead a reasonable
3 person to believe the substance to be a controlled substance
4 under this clause (2) of subsection (y), the court or other
5 authority may consider the following factors in addition to
6 any other factor that may be relevant:

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

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

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

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

19 Clause (1) of this subsection (y) shall not apply to a
20 noncontrolled substance in its finished dosage form that was
21 initially introduced into commerce prior to the initial
22 introduction into commerce of a controlled substance in its
23 finished dosage form which it may substantially resemble.

24 Nothing in this subsection (y) prohibits the dispensing or
25 distributing of noncontrolled substances by persons authorized
26 to dispense and distribute controlled substances under this

1 Act, provided that such action would be deemed to be carried
2 out in good faith under subsection (u) if the substances
3 involved were controlled substances.

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

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

14 (z) "Manufacture" means the production, preparation,
15 propagation, compounding, conversion or processing of a
16 controlled substance other than methamphetamine, either
17 directly or indirectly, by extraction from substances of
18 natural origin, or independently by means of chemical
19 synthesis, or by a combination of extraction and chemical
20 synthesis, and includes any packaging or repackaging of the
21 substance or labeling of its container, except that this term
22 does not include:

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

26 (2) by a practitioner, or his or her authorized agent

1 under his or her supervision, the preparation,
2 compounding, packaging, or labeling of a controlled
3 substance:

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

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

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

12 (z-1) (Blank).

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

15 (z-10) "Mid-level practitioner" means (i) a physician
16 assistant who has been delegated authority to prescribe
17 through a written delegation of authority by a physician
18 licensed to practice medicine in all of its branches, in
19 accordance with Section 7.5 of the Physician Assistant
20 Practice Act of 1987, (ii) an advanced practice registered
21 nurse who has been delegated authority to prescribe through a
22 written delegation of authority by a physician licensed to
23 practice medicine in all of its branches or by a podiatric
24 physician, in accordance with Section 65-40 of the Nurse
25 Practice Act, (iii) an advanced practice registered nurse
26 certified as a nurse practitioner, nurse midwife, or clinical

1 nurse specialist who has been granted authority to prescribe
2 by a hospital affiliate in accordance with Section 65-45 of
3 the Nurse Practice Act, (iv) an animal euthanasia agency, or
4 (v) a prescribing psychologist.

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

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

17 (2) (blank);

18 (3) opium poppy and poppy straw;

19 (4) coca leaves, except coca leaves and extracts of
20 coca leaves from which substantially all of the cocaine
21 and ecgonine, and their isomers, derivatives and salts,
22 have been removed;

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

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

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

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

6 (cc) (Blank).

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

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

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

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

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

24 (hh) "Pharmacist" means any person who holds a license or
25 certificate of registration as a registered pharmacist, a
26 local registered pharmacist or a registered assistant

1 pharmacist under the Pharmacy Practice Act.

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

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

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

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

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

23 (ll) "Pre-printed prescription" means a written
24 prescription upon which the designated drug has been indicated
25 prior to the time of issuance; the term does not mean a written
26 prescription that is individually generated by machine or

1 computer in the prescriber's office.

2 (mm) "Prescriber" means a physician licensed to practice
3 medicine in all its branches, dentist, optometrist,
4 prescribing psychologist licensed under Section 4.2 of the
5 Clinical Psychologist Licensing Act with prescriptive
6 authority delegated under Section 4.3 of the Clinical
7 Psychologist Licensing Act, podiatric physician, or
8 veterinarian who issues a prescription, a physician assistant
9 who issues a prescription for a controlled substance in
10 accordance with Section 303.05, a written delegation, and a
11 written collaborative agreement required under Section 7.5 of
12 the Physician Assistant Practice Act of 1987, an advanced
13 practice registered nurse with prescriptive authority
14 delegated under Section 65-40 of the Nurse Practice Act and in
15 accordance with Section 303.05, a written delegation, and a
16 written collaborative agreement under Section 65-35 of the
17 Nurse Practice Act, an advanced practice registered nurse
18 certified as a nurse practitioner, nurse midwife, or clinical
19 nurse specialist who has been granted authority to prescribe
20 by a hospital affiliate in accordance with Section 65-45 of
21 the Nurse Practice Act and in accordance with Section 303.05,
22 or an advanced practice registered nurse certified as a nurse
23 practitioner, nurse midwife, or clinical nurse specialist who
24 has full practice authority pursuant to Section 65-43 of the
25 Nurse Practice Act.

26 (nn) "Prescription" means a written, facsimile, or oral

1 order, or an electronic order that complies with applicable
2 federal requirements, of a physician licensed to practice
3 medicine in all its branches, dentist, podiatric physician or
4 veterinarian for any controlled substance, of an optometrist
5 in accordance with Section 15.1 of the Illinois Optometric
6 Practice Act of 1987, of a prescribing psychologist licensed
7 under Section 4.2 of the Clinical Psychologist Licensing Act
8 with prescriptive authority delegated under Section 4.3 of the
9 Clinical Psychologist Licensing Act, of a physician assistant
10 for a controlled substance in accordance with Section 303.05,
11 a written delegation, and a written collaborative agreement
12 required under Section 7.5 of the Physician Assistant Practice
13 Act of 1987, of an advanced practice registered nurse with
14 prescriptive authority delegated under Section 65-40 of the
15 Nurse Practice Act who issues a prescription for a controlled
16 substance in accordance with Section 303.05, a written
17 delegation, and a written collaborative agreement under
18 Section 65-35 of the Nurse Practice Act, of an advanced
19 practice registered nurse certified as a nurse practitioner,
20 nurse midwife, or clinical nurse specialist who has been
21 granted authority to prescribe by a hospital affiliate in
22 accordance with Section 65-45 of the Nurse Practice Act and in
23 accordance with Section 303.05 when required by law, or of an
24 advanced practice registered nurse certified as a nurse
25 practitioner, nurse midwife, or clinical nurse specialist who
26 has full practice authority pursuant to Section 65-43 of the

1 Nurse Practice Act.

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

5 (nn-10) "Prescription Monitoring Program" (PMP) means the
6 entity that collects, tracks, and stores reported data on
7 controlled substances and select drugs pursuant to Section
8 316.

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

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

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

17 (qq-5) "Secretary" means, as the context requires, either
18 the Secretary of the Department or the Secretary of the
19 Department of Financial and Professional Regulation, and the
20 Secretary's designated agents.

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

25 (rr-5) "Stimulant" means any drug that (i) causes an
26 overall excitation of central nervous system functions, (ii)

1 causes impaired consciousness and awareness, and (iii) can be
2 habit-forming or lead to a substance abuse problem, including
3 but not limited to amphetamines and their analogs,
4 methylphenidate and its analogs, cocaine, and phencyclidine
5 and its analogs.

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

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

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

18 Section 115. The Cannabis and Controlled Substances Tort
19 Claims Act is amended by changing Section 3 as follows:

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

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

23 "Cannabis" includes marihuana, hashish, and other
24 substances that are identified as including any parts of the

1 plant Cannabis Sativa, whether growing or not, the seeds of
2 that plant, the resin extracted from any part of that plant,
3 and any compound, manufacture, salt, derivative, mixture, or
4 preparation of that plant, its seeds, or resin, including
5 tetrahydrocannabinol (THC) and all other cannabinol
6 derivatives, including its naturally occurring or
7 synthetically produced ingredients, whether produced directly
8 or indirectly by extraction, independently by means of
9 chemical synthesis, or by a combination of extraction and
10 chemical synthesis. "Cannabis" does not include the mature
11 stalks of that plant, fiber produced from those stalks, oil or
12 cake made from the seeds of that plant, any other compound,
13 manufacture, salt, derivative, mixture, or preparation of
14 mature stalks (except the extracted resin), fiber, oil or
15 cake, or the sterilized seeds of that plant that are incapable
16 of germination.

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

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

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

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

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

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

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

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

25 (3) the preparation, compounding, packaging, or
26 labeling of cannabis as an incident to lawful research,

1 teaching, or chemical analysis and not for sale; or -
2 (4) the packaging, repackaging, or labeling of drugs
3 only to the extent permitted under the Illinois Drug Reuse
4 Opportunity Program Act.

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

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

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

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

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