



102ND GENERAL ASSEMBLY

State of Illinois

2021 and 2022

SB0600

Introduced 2/24/2021, by Sen. Sue Rezin

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 a donor 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 uninsured and underinsured individuals shall be given priority over other eligible persons for drugs and supplies donated under the Act. 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. Contains other provisions. Amends the Pharmacy Practice Act, the Wholesale Drug Distribution Licensing Act, the Senior Pharmaceutical Assistance Act, the Illinois Food, Drug and Cosmetic 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 16677 CPF 22078 b

FISCAL NOTE ACT
MAY APPLY

A BILL FOR

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 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 "Donor" means any person, including an individual member
13 of the public, or any entity legally authorized to possess
14 medicine with a license or permit in the state in which it is
15 located, including, but not limited to, the following:
16 wholesalers, distributors, third-party logistic providers,
17 pharmacies, dispensers, clinics, surgical or health centers,
18 detention and rehabilitation centers, laboratories, medical or
19 pharmacy schools, prescribers or other health care
20 professionals, or health care facilities. "Donor" includes
21 government agencies and entities that are federally authorized
22 to possess medicine, including, but not limited to, drug
23 manufacturers, repackagers, relabelers, outsourcing

1 facilities, Veterans Affairs hospitals, and prisons.

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

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

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

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

12 "Recipient pharmacy" means a pharmacy licensed under the
13 Pharmacy Practice Act that receives a donated prescription
14 drug or supplies needed to administer a prescription drug
15 under this Act.

16 Section 10. Prescription drug repository program. The
17 Department shall, by rule, establish and maintain a
18 prescription drug repository program, under which a donor may
19 donate a prescription drug or supplies needed to administer a
20 prescription drug for use by an individual who meets
21 appropriate eligibility criteria. The Department shall adopt
22 the rules within one year after the effective date of this Act.
23 A recipient pharmacy may charge an individual who receives a
24 prescription drug or supplies needed to administer a
25 prescription drug under this Act a handling fee that may not

1 exceed an appropriate amount. A recipient pharmacy may
2 distribute the prescription drug or supplies to another
3 eligible recipient pharmacy for use under the program or to
4 another state's drug repository program.

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

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

13 (1) The prescription drug or supplies needed to
14 administer a prescription drug are in their original,
15 unopened, sealed, and tamper-evident packaging or, if
16 packaged in single-unit doses, the single-unit-dose
17 packaging is unopened. A prescription drug or supplies
18 needed to administer a prescription drug originally packed
19 by a pharmacy, whether or not it is a recipient pharmacy,
20 is acceptable for donation.

21 (2) The prescription drug is not expired.

22 (3) The prescription drug or supplies needed to
23 administer a prescription drug are not adulterated or
24 misbranded, as determined by a pharmacist employed by, or

1 under contract with, the pharmacy, whether or not it is a
2 recipient pharmacy, where the drug or supplies needed to
3 administer a prescription drug are accepted or dispensed.
4 The pharmacist must inspect the drug or supplies needed to
5 administer a prescription drug before the drug or supplies
6 needed to administer a prescription drug are dispensed.

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

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

12 (6) If the prescription drug can be dispensed only to
13 a patient registered with the drug's manufacturer in
14 accordance with federal Food and Drug Administration
15 requirements, the prescription drug may not be dispensed
16 through the program unless the patient receiving the drug
17 is registered with the manufacturer at the time the drug
18 is dispensed and the amount dispensed does not exceed the
19 duration of the registration period.

20 (7) The recipient pharmacy maintains a written or
21 electronic record of a donation made under this Act
22 consisting of the name, strength, and quantity of each
23 accepted drug and the name, address, and telephone number
24 of the donor. No other record of a donation is required.

25 Section 25. Resale of donated drugs or supplies

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

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

7 Section 35. Immunity.

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

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

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

3 (225 ILCS 85/4) (from Ch. 111, par. 4124)

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

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

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

14 (b) the sale of compressed gases;

15 (c) the sale of patent or proprietary medicines and
16 household remedies when sold in original and unbroken
17 packages only, if such patent or proprietary medicines and
18 household remedies be properly and adequately labeled as
19 to content and usage and generally considered and accepted
20 as harmless and nonpoisonous when used according to the
21 directions on the label, and also do not contain opium or
22 coca leaves, or any compound, salt or derivative thereof,
23 or any drug which, according to the latest editions of the
24 following authoritative pharmaceutical treatises and
25 standards, namely, The United States

1 Pharmacopoeia/National Formulary (USP/NF), the United
2 States Dispensatory, and the Accepted Dental Remedies of
3 the Council of Dental Therapeutics of the American Dental
4 Association or any or either of them, in use on the
5 effective date of this Act, or according to the existing
6 provisions of the Federal Food, Drug, and Cosmetic Act and
7 Regulations of the Department of Health and Human
8 Services, Food and Drug Administration, promulgated
9 thereunder now in effect, is designated, described or
10 considered as a narcotic, hypnotic, habit forming,
11 dangerous, or poisonous drug;

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

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

1 readily obtainable antidote with directions for its
2 administration;

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

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

18 (g-5) the donation or acceptance, or the packaging,
19 repackaging, or labeling, of prescription drugs to the
20 extent permitted or required under the Prescription Drug
21 Repository Program Act; and

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

26 (1) the dialysate, comprised of dextrose or

1 icodextrin, or devices are approved or cleared by the
2 federal Food and Drug Administration, as required by
3 federal law;

4 (2) the dialysate or devices are lawfully held by
5 a manufacturer or the manufacturer's agent, which is
6 properly registered with the Board as a manufacturer,
7 third-party logistics provider, or wholesaler;

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

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

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

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

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

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

11 (225 ILCS 120/15) (from Ch. 111, par. 8301-15)

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

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

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

18 "Authorized distributor of record" means a wholesale
19 distributor with whom a manufacturer has established an
20 ongoing relationship to distribute the manufacturer's
21 prescription drug. An ongoing relationship is deemed to exist
22 between a wholesale distributor and a manufacturer when the
23 wholesale distributor, including any affiliated group of the
24 wholesale distributor, as defined in Section 1504 of the

1 Internal Revenue Code, complies with the following:

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

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

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

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

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

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

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

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

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

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

24 "Facility" means a facility of a wholesale distributor
25 where prescription drugs are stored, handled, repackaged, or
26 offered for sale, or a facility of a third-party logistics

1 provider where prescription drugs are stored or handled.

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

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

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

23 "Normal distribution channel" means a chain of custody for
24 a prescription drug that goes, directly or by drop shipment,
25 from (i) a manufacturer of the prescription drug, (ii) that
26 manufacturer to that manufacturer's co-licensed partner, (iii)

1 that manufacturer to that manufacturer's third party logistics
2 provider, or (iv) that manufacturer to that manufacturer's
3 exclusive distributor to:

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

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

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

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

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

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

25 "Pedigree" means a document or electronic file containing
26 information that records each wholesale distribution of any

1 given prescription drug from the point of origin to the final
2 wholesale distribution point of any given prescription drug.

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

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

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

22 "Repackage" means repackaging or otherwise changing the
23 container, wrapper, or labeling to further the distribution of
24 a prescription drug, excluding that completed by the
25 pharmacist responsible for dispensing the product to a
26 patient.

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

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

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

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

18 (2) The sale, purchase, distribution, trade, or
19 transfer of a prescription drug or offer to sell,
20 purchase, distribute, trade, or transfer a prescription
21 drug for emergency medical reasons.

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

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

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

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

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

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

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

1 drug.

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

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

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

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

25 Section 100. The Senior Pharmaceutical Assistance Act is

1 amended by changing Section 10 as follows:

2 (320 ILCS 50/10)

3 Sec. 10. Definitions. In this Act:

4 "Manufacturer" includes:

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

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

17 The term does not include a wholesale distributor of
18 drugs, drugstore chain organization, or retail pharmacy
19 licensed by the State. The term also does not include anyone
20 who is engaged in the packaging, repackaging, or labeling of
21 prescription drugs only to the extent required under the
22 Prescription Drug Repository Program Act.

23 "Prescription drug" means a drug that may be dispensed
24 only upon prescription by an authorized prescriber and that is
25 approved for safety and effectiveness as a prescription drug

1 under Section 505 or 507 of the Federal Food, Drug and Cosmetic
2 Act.

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

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

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

8 (410 ILCS 620/16) (from Ch. 56 1/2, par. 516)

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

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

1 promulgated by the Director.

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

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

1 date of the prescription or of its filling, the name of the
2 prescriber and, if stated in the prescription, the name of the
3 patient, and the directions for use and the cautionary
4 statements, if any, contained in such prescription. This
5 exemption shall not apply to any drug dispensed in the course
6 of the conduct of business of dispensing drugs pursuant to
7 diagnosis by mail, or to a drug dispensed in violation of
8 subsection (a) of this Section.

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

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

22 (g) Nothing in this Section shall be construed to relieve
23 any person from any requirement prescribed by or under
24 authority of law with respect to controlled substances now
25 included or which may hereafter be included within the
26 classifications of controlled substances cannabis as defined

1 in applicable Federal laws relating to controlled substances
2 or cannabis or the Cannabis Control Act.

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

4 Section 110. The Cannabis and Controlled Substances Tort
5 Claims Act is amended by changing Section 3 as follows:

6 (740 ILCS 20/3) (from Ch. 70, par. 903)

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

9 "Cannabis" includes marihuana, hashish, and other
10 substances that are identified as including any parts of the
11 plant Cannabis Sativa, whether growing or not, the seeds of
12 that plant, the resin extracted from any part of that plant,
13 and any compound, manufacture, salt, derivative, mixture, or
14 preparation of that plant, its seeds, or resin, including
15 tetrahydrocannabinol (THC) and all other cannabinol
16 derivatives, including its naturally occurring or
17 synthetically produced ingredients, whether produced directly
18 or indirectly by extraction, independently by means of
19 chemical synthesis, or by a combination of extraction and
20 chemical synthesis. "Cannabis" does not include the mature
21 stalks of that plant, fiber produced from those stalks, oil or
22 cake made from the seeds of that plant, any other compound,
23 manufacture, salt, derivative, mixture, or preparation of
24 mature stalks (except the extracted resin), fiber, oil or

1 cake, or the sterilized seeds of that plant that are incapable
2 of germination.

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

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

13 "Deliver" or "delivery" means the actual, constructive, or
14 attempted transfer of possession of a controlled substance or
15 cannabis, with or without consideration, whether or not there
16 is an agency relationship. "Deliver" or "delivery" does not
17 include the donation of prescription drugs to the extent
18 permitted under the Prescription Drug Repository Program Act.

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

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

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

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

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

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

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

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

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

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

25 "Property" means real property, including things growing
26 on, affixed to, and found in land, and tangible or intangible

1 personal property, including rights, services, privileges,
2 interests, claims, and securities.

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

1 INDEX

2 Statutes amended in order of appearance

3 New Act

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

5 225 ILCS 120/15 from Ch. 111, par. 8301-15

6 320 ILCS 50/10

7 410 ILCS 620/16 from Ch. 56 1/2, par. 516

8 740 ILCS 20/3 from Ch. 70, par. 903