



95TH GENERAL ASSEMBLY

State of Illinois

2007 and 2008

SB2943

Introduced 2/15/2008, by Sen. Jacqueline Y. Collins

SYNOPSIS AS INTRODUCED:

See Index

Creates the Cancer Drug Repository Program Act. Requires the Department of Public Health to establish a cancer drug repository program, under which any person may donate a cancer drug or supplies needed to administer a cancer drug for use by an individual who meets eligibility criteria specified by the Department. Sets forth requirements that cancer drugs or supplies must meet in order to be accepted and dispensed under the program. Provides that no drugs or supplies donated under the cancer drug repository program may be resold. Provides that nothing in the Act requires that a medical facility, pharmacy, pharmacist, or practitioner participate in the cancer 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 cancer drugs or supplies under the cancer drug repository program. Requires the Department to adopt certain rules to implement the cancer drug repository program. Amends the Pharmacy Practice Act of 1987, the Wholesale Drug Distribution Licensing Act, the Senior Pharmaceutical Assistance Act, the Illinois Food, Drug and Cosmetic Act, the Illinois Controlled Substances Act, and the Cannabis and Controlled Substances Tort Claims Act to provide that persons engaged in donating or accepting, or packaging, repackaging, or labeling, prescription drugs to the extent permitted or required under the Cancer Drug Repository Program Act are exempt from provisions of those other Acts that might prohibit or otherwise regulate such activity.

LRB095 20012 DRJ 46448 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 Cancer
5 Drug Repository Program Act.

6 Section 5. Definitions. In this Act:

7 "Cancer drug" means a prescription drug that is used to
8 treat any of the following:

9 (1) Cancer or side effects of cancer.

10 (2) The side effects of any prescription drug that is
11 used to treat cancer or side effects of cancer.

12 "Cancer drug" does not include drugs for the treatment of
13 cancer that can only be dispensed to a patient registered with
14 the drug manufacturer in accordance with federal Food and Drug
15 Administration requirements.

16 "Department" means the Department of Public Health.

17 "Dispense" has the meaning given to that term in the
18 Pharmacy Practice Act of 1987.

19 "Pharmacist" means an individual licensed to engage in the
20 practice of pharmacy under the Pharmacy Practice Act of 1987.

21 "Pharmacy" means a pharmacy registered in this State under
22 the Pharmacy Practice Act of 1987.

23 "Practitioner" means a person licensed in this State to

1 prescribe and administer drugs or licensed in another state and
2 recognized by this State as a person authorized to prescribe
3 and administer drugs.

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

6 "Program" means the cancer drug repository program
7 established under this Act.

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

23 Section 15. Requirements for accepting and dispensing
24 cancer drugs and supplies. A cancer drug or supplies needed to

1 administer a cancer drug may be accepted and dispensed under
2 the program only if all of the following requirements are met:

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

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

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

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

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

23 Section 25. Participation in program not required. Nothing
24 in this Act requires that a pharmacy or pharmacist participate

1 in the cancer drug repository program.

2 Section 30. Immunity.

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

9 (b) Unless the person's conduct is wilful and wanton, a
10 person is immune from civil liability for injury to or the
11 death of the individual to whom the cancer drug or supply is
12 dispensed and may not be found guilty of unprofessional conduct
13 for his or her acts or omissions related to donating,
14 accepting, distributing, or dispensing a cancer drug or supply
15 under this Act.

16 Section 35. Rules. The Department shall adopt all of the
17 following as rules:

18 (1) Requirements for pharmacies to accept and dispense
19 donated cancer drugs or supplies needed to administer
20 cancer drugs under this Act, including all of the
21 following:

22 (A) Eligibility criteria.

23 (B) Standards and procedures for accepting, safely
24 storing, and dispensing donated cancer drugs or

1 supplies needed to administer cancer drugs.

2 (C) Standards and procedures for inspecting
3 donated cancer drugs or supplies needed to administer
4 cancer drugs to determine whether the drugs or supplies
5 are in their original, unopened, sealed, and
6 tamper-evident unit-dose packaging or, if packaged in
7 single-unit doses, the single-unit-dose packaging is
8 unopened.

9 (D) Standards and procedures for inspecting
10 donated cancer drugs or supplies needed to administer
11 cancer drugs to determine that the drugs or supplies
12 needed to administer cancer drugs are not adulterated
13 or misbranded.

14 (2) Eligibility criteria for individuals to receive
15 donated cancer drugs or supplies needed to administer
16 cancer drugs dispensed under the cancer drug repository
17 program. The standards shall prioritize dispensation to
18 individuals who are uninsured or indigent but must permit
19 dispensation to others if an uninsured or indigent
20 individual is unavailable.

21 (3) A means, such as an identification card, by which
22 an individual who is eligible to receive a donated cancer
23 drug or supplies needed to administer a cancer drug may
24 indicate that eligibility.

25 (4) Necessary forms for administration of the cancer
26 drug repository program, including forms for use by persons

1 that donate, accept, distribute, or dispense cancer drugs
2 or supplies needed to administer cancer drugs under the
3 program.

4 (5) The maximum handling fee that a pharmacy may charge
5 for accepting, distributing, or dispensing donated cancer
6 drugs or supplies needed to administer cancer drugs.

7 (6) A list of cancer drugs and supplies needed to
8 administer cancer drugs, arranged by category or by
9 individual cancer drug or supply, that the cancer drug
10 repository program will accept for dispensing.

11 (7) A list of cancer drugs and supplies needed to
12 administer cancer drugs, arranged by category or by
13 individual cancer drug or supply, that the cancer drug
14 repository program will not accept for dispensing. The list
15 must include a statement that specifies the reason that the
16 drug or supplies are ineligible for donation.

17 The Department may also adopt any other rules deemed
18 necessary to implement this Act.

19 Section 90. The Pharmacy Practice Act of 1987 is amended by
20 changing Section 4 as follows:

21 (225 ILCS 85/4) (from Ch. 111, par. 4124)

22 (Section scheduled to be repealed on January 1, 2018)

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

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

7 (b) the sale of compressed gases;

8 (c) the sale of patent or proprietary medicines and
9 household remedies when sold in original and unbroken packages
10 only, if such patent or proprietary medicines and household
11 remedies be properly and adequately labeled as to content and
12 usage and generally considered and accepted as harmless and
13 nonpoisonous when used according to the directions on the
14 label, and also do not contain opium or coca leaves, or any
15 compound, salt or derivative thereof, or any drug which,
16 according to the latest editions of the following authoritative
17 pharmaceutical treatises and standards, namely, The United
18 States Pharmacopoeia/National Formulary (USP/NF), the United
19 States Dispensatory, and the Accepted Dental Remedies of the
20 Council of Dental Therapeutics of the American Dental
21 Association or any or either of them, in use on the effective
22 date of this Act, or according to the existing provisions of
23 the Federal Food, Drug, and Cosmetic Act and Regulations of the
24 Department of Health and Human Services, Food and Drug
25 Administration, promulgated thereunder now in effect, is
26 designated, described or considered as a narcotic, hypnotic,

1 habit forming, dangerous, or poisonous drug;

2 (d) the sale of poultry and livestock remedies in original
3 and unbroken packages only, labeled for poultry and livestock
4 medication;

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

17 (f) the delegation of limited prescriptive authority by a
18 physician licensed to practice medicine in all its branches to
19 a physician assistant under Section 7.5 of the Physician
20 Assistant Practice Act of 1987. This delegated authority under
21 Section 7.5 of the Physician Assistant Practice Act of 1987 may
22 but is not required to include prescription of controlled
23 substances, as defined in Article II of the Illinois Controlled
24 Substances Act, in accordance with written guidelines; ~~and~~

25 (g) the ~~The~~ delegation of prescriptive authority by a
26 physician licensed to practice medicine in all its branches to

1 an advanced practice nurse in accordance with a written
2 collaborative agreement under Section 65-35 of the Nurse
3 Practice Act. This authority, which is delegated under Section
4 65-40 of the Nurse Practice Act, may but is not required to
5 include the prescription of Schedule III, IV, or V controlled
6 substances as defined in Article II of the Illinois Controlled
7 Substances Act; and -

8 (h) the donation or acceptance, or the packaging,
9 repackaging, or labeling, of prescription drugs to the extent
10 permitted or required under the Cancer Drug Repository Program
11 Act.

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

13 Section 91. 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, 2013)

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 ongoing
24 relationship to distribute the manufacturer's prescription

1 drug. An ongoing relationship is deemed to exist between a
2 wholesale distributor and a manufacturer when the wholesale
3 distributor, including any affiliated group of the wholesale
4 distributor, as defined in Section 1504 of the Internal Revenue
5 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 and
14 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 Department
18 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 wholesale
14 distributor or chain pharmacy warehouse takes title but not
15 physical possession of such prescription drug and the wholesale
16 distributor invoices the pharmacy, chain pharmacy warehouse,
17 or other person authorized by law to dispense or administer
18 such drug to a patient and the pharmacy, chain pharmacy
19 warehouse, or other authorized person receives delivery of the
20 prescription drug directly from the manufacturer, that
21 manufacturer's third party logistics provider, or that
22 manufacturer's exclusive distributor or from an authorized
23 distributor of record that purchased the product directly from
24 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.

5 "FDA" means the United States Food and Drug Administration.

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

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

24 "Normal distribution channel" means a chain of custody for
25 a prescription drug that goes, directly or by drop shipment,
26 from (i) a manufacturer of the prescription drug, (ii) that

1 manufacturer to that manufacturer's co-licensed partner, (iii)
2 that manufacturer to that manufacturer's third party logistics
3 provider, or (iv) that manufacturer to that manufacturer's
4 exclusive distributor to:

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

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

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

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

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

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

26 "Pedigree" means a document or electronic file containing

1 information that records each wholesale distribution of any
2 given prescription drug from the point of origin to the final
3 wholesale distribution point of any given prescription drug.

4 "Person" means and includes a natural person, partnership,
5 association or corporation.

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

26 "Secretary" means the Secretary of Financial and

1 Professional Regulation.

2 "Third party logistics provider" means anyone who
3 contracts with a prescription drug manufacturer to provide or
4 coordinate warehousing, distribution, or other services on
5 behalf of a manufacturer, but does not take title to the
6 prescription drug or have general responsibility to direct the
7 prescription drug's sale or disposition. A third party
8 logistics provider must be licensed as a wholesale distributor
9 under this Act and, in order to be considered part of the
10 normal distribution channel, must also be an authorized
11 distributor of record.

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

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

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

25 (3) The distribution of prescription drug samples by
26 manufacturers' representatives.

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

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

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

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

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

24 (9) The delivery of or the offer to deliver a
25 prescription drug by a common carrier solely in the common
26 carrier's usual course of business of transporting

1 prescription drugs when the common carrier does not store,
2 warehouse, or take legal ownership of the prescription
3 drug.

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

9 (11) The donation of prescription drugs to the extent
10 permitted under the Cancer Drug Repository Program Act.

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

25 (Source: P.A. 95-689, eff. 10-29-07.)

1 Section 92. The Senior Pharmaceutical Assistance Act is
2 amended by changing Section 10 as follows:

3 (320 ILCS 50/10)

4 Sec. 10. Definitions. In this Act:

5 "Manufacturer" includes:

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

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

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

24 "Prescription drug" means a drug that may be dispensed only
25 upon prescription by an authorized prescriber and that is

1 approved for safety and effectiveness as a prescription drug
2 under Section 505 or 507 of the Federal Food, Drug and Cosmetic
3 Act.

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

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

7 Section 93. The Illinois Food, Drug and Cosmetic Act is
8 amended by changing Section 16 as follows:

9 (410 ILCS 620/16) (from Ch. 56 1/2, par. 516)

10 Sec. 16. (a) The Director is hereby authorized to
11 promulgate regulations exempting from any labeling or
12 packaging requirement of this Act drugs and devices which are
13 (i) in accordance with the practice of the trade, to be
14 processed, labeled or repacked in substantial quantities at
15 establishments other than those where originally processed or
16 packaged on condition that such drugs and devices are not
17 adulterated or misbranded under the provisions of this Act upon
18 removal from such processing, labeling or repacking
19 establishment or (ii) packaged, repackaged, or labeled to the
20 extent required under the Cancer Drug Repository Program 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 or
17 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 (2)
20 and (3) of subsection (i), and the packaging requirements of
21 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, the
26 name and address of the dispenser, the serial number and date

1 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 or
2 cannabis or the Cannabis Control Act.

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

4 Section 94. The Illinois Controlled Substances Act is
5 amended by changing Section 102 as follows:

6 (720 ILCS 570/102) (from Ch. 56 1/2, par. 1102)

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

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

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

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

22 (2) the patient or research subject at the lawful
23 direction of the practitioner, or

24 (3) a euthanasia technician as defined by the Humane

1 Euthanasia in Animal Shelters Act.

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

6 (c-1) "Anabolic Steroids" means any drug or hormonal
7 substance, chemically and pharmacologically related to
8 testosterone (other than estrogens, progestins, and
9 corticosteroids) that promotes muscle growth, and includes:

- 10 (i) boldenone,
- 11 (ii) chlorotestosterone,
- 12 (iii) chostebol,
- 13 (iv) dehydrochlormethyltestosterone,
- 14 (v) dihydrotestosterone,
- 15 (vi) drostanolone,
- 16 (vii) ethylestrenol,
- 17 (viii) fluoxymesterone,
- 18 (ix) formebulone,
- 19 (x) mesterolone,
- 20 (xi) methandienone,
- 21 (xii) methandranone,
- 22 (xiii) methandriol,
- 23 (xiv) methandrostenolone,
- 24 (xv) methenolone,
- 25 (xvi) methyltestosterone,
- 26 (xvii) mibolerone,

1 (xviii) nandrolone,
2 (xix) norethandrolone,
3 (xx) oxandrolone,
4 (xxi) oxymesterone,
5 (xxii) oxymetholone,
6 (xxiii) stanolone,
7 (xxiv) stanozolol,
8 (xxv) testolactone,
9 (xxvi) testosterone,
10 (xxvii) trenbolone, and
11 (xxviii) any salt, ester, or isomer of a drug or
12 substance described or listed in this paragraph, if
13 that salt, ester, or isomer promotes muscle growth.

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

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

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

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

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

16 (h) "Deliver" or "delivery" means the actual, constructive
17 or attempted transfer of possession of a controlled substance,
18 with or without consideration, whether or not there is an
19 agency relationship. The term does not include the donation of
20 prescription drugs to the extent permitted under the Cancer
21 Drug Repository Program Act.

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

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

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

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

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

7 (1) a drug which contains any quantity of (i)
8 barbituric acid or any of the salts of barbituric acid
9 which has been designated as habit forming under section
10 502 (d) of the Federal Food, Drug, and Cosmetic Act (21
11 U.S.C. 352 (d)); or

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

20 (3) lysergic acid diethylamide; or

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

26 (n) (Blank).

1 (o) "Director" means the Director of the Department of
2 State Police or the Department of Professional Regulation or
3 his designated agents.

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

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

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

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

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

24 (t-5) "Euthanasia agency" means an entity certified by the
25 Department of Professional Regulation for the purpose of animal
26 euthanasia that holds an animal control facility license or

1 animal shelter license under the Animal Welfare Act. A
2 euthanasia agency is authorized to purchase, store, possess,
3 and utilize Schedule II nonnarcotic and Schedule III
4 nonnarcotic drugs for the sole purpose of animal euthanasia.

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

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

20 (1) lack of consistency of doctor-patient
21 relationship,

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

24 (3) quantities beyond those normally prescribed,

25 (4) unusual dosages,

26 (5) unusual geographic distances between patient,

1 pharmacist and prescriber,

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

3 (u-1) "Home infusion services" means services provided by a
4 pharmacy in compounding solutions for direct administration to
5 a patient in a private residence, long-term care facility, or
6 hospice setting by means of parenteral, intravenous,
7 intramuscular, subcutaneous, or intraspinal infusion.

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

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

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

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

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

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

25 (y) "Look-alike substance" means a substance, other than a
26 controlled substance which (1) by overall dosage unit

1 appearance, including shape, color, size, markings or lack
2 thereof, taste, consistency, or any other identifying physical
3 characteristic of the substance, would lead a reasonable person
4 to believe that the substance is a controlled substance, or (2)
5 is expressly or impliedly represented to be a controlled
6 substance or is distributed under circumstances which would
7 lead a reasonable person to believe that the substance is a
8 controlled substance. For the purpose of determining whether
9 the representations made or the circumstances of the
10 distribution would lead a reasonable person to believe the
11 substance to be a controlled substance under this clause (2) of
12 subsection (y), the court or other authority may consider the
13 following factors in addition to any other factor that may be
14 relevant:

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

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

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

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

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

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

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

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

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

1 synthesis, or by a combination of extraction and chemical
2 synthesis, and includes any packaging or repackaging of the
3 substance or labeling of its container, except that this term
4 does not include:

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

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

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

13 (b) as an incident to lawful research, teaching or
14 chemical analysis and not for sale; or -

15 (3) the packaging, repackaging, or labeling of
16 prescription drugs only to the extent required under the
17 Cancer Drug Repository Program Act.

18 (z-1) (Blank).

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

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

26 (2) any salt, compound, isomer, derivative, or

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

4 (3) opium poppy and poppy straw;

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

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

17 (cc) (Blank).

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

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

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

26 (gg) "Person" means any individual, corporation,

1 mail-order pharmacy, government or governmental subdivision or
2 agency, business trust, estate, trust, partnership or
3 association, or any other entity.

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

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

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

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

24 (ll) "Pre-printed prescription" means a written
25 prescription upon which the designated drug has been indicated
26 prior to the time of issuance.

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

12 (nn) "Prescription" means a lawful written, facsimile, or
13 verbal order of a physician licensed to practice medicine in
14 all its branches, dentist, podiatrist or veterinarian for any
15 controlled substance, of an optometrist for a Schedule III, IV,
16 or V controlled substance in accordance with Section 15.1 of
17 the Illinois Optometric Practice Act of 1987, of a physician
18 assistant for a Schedule III, IV, or V controlled substance in
19 accordance with Section 303.05 and the written guidelines
20 required under Section 7.5 of the Physician Assistant Practice
21 Act of 1987, or of an advanced practice nurse with prescriptive
22 authority delegated under Section 65-40 of the Nurse Practice
23 Act who issues a prescription for a Schedule III, IV, or V
24 controlled substance in accordance with Section 303.05 and a
25 written collaborative agreement under Section 65-35 of the
26 Nurse Practice Act.

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

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

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

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

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

17 (Source: P.A. 94-556, eff. 9-11-05; 95-242, eff. 1-1-08;
18 95-639, eff. 10-5-07; 95-689, eff. 10-29-07; revised
19 11-19-07.)

20 Section 95. The Cannabis and Controlled Substances Tort
21 Claims Act is amended by changing Section 3 as follows:

22 (740 ILCS 20/3) (from Ch. 70, par. 903)

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

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

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

22 "Counterfeit substance" means a controlled substance or
23 the container or labeling of a controlled substance that,
24 without authorization, bears the trademark, trade name, or
25 other identifying mark, imprint, number, device, or any
26 likeness thereof of a manufacturer, distributor, or dispenser

1 other than the person who in fact manufactured, distributed, or
2 dispensed the substance.

3 "Deliver" or "delivery" means the actual, constructive, or
4 attempted transfer of possession of a controlled substance or
5 cannabis, with or without consideration, whether or not there
6 is an agency relationship. The term does not include the
7 donation of prescription drugs to the extent permitted under
8 the Cancer Drug Repository Program Act.

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

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

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

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

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

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

4 (4) the packaging, repackaging, or labeling of
5 prescription drugs only to the extent required under the
6 Cancer Drug Repository Program Act.

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

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

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

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

19 (Source: P.A. 87-544.)

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Statutes amended in order of appearance

New Act

- 225 ILCS 85/4 from Ch. 111, par. 4124
- 225 ILCS 120/15 from Ch. 111, par. 8301-15
- 320 ILCS 50/10
- 410 ILCS 620/16 from Ch. 56 1/2, par. 516
- 720 ILCS 570/102 from Ch. 56 1/2, par. 1102
- 740 ILCS 20/3 from Ch. 70, par. 903