



96TH GENERAL ASSEMBLY

State of Illinois

2009 and 2010

HB2468

Introduced 2/19/2009, by Rep. Greg Harris

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.

LRB096 09927 KTG 20091 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 "Department" means the Department of Public Health.

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

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

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

19 "Practitioner" means a person licensed in this State to
20 prescribe and administer drugs or licensed in another state and
21 recognized by this State as a person authorized to prescribe
22 and administer drugs.

23 "Prescription drug" means any prescribed drug that may be

1 legally dispensed by a pharmacy.

2 "Program" means the cancer drug repository program
3 established under this Act.

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

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

23 (1) The cancer drug or supplies needed to administer a
24 cancer drug are in their original, unopened, sealed, and

1 tamper-evident unit-dose packaging or, if packaged in
2 single-unit doses, the single-unit-dose packaging is
3 unopened.

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

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

13 (4) The cancer drug or supplies needed to administer a
14 cancer drug are prescribed by a practitioner for use by an
15 eligible individual.

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

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

22 Section 30. Immunity.

23 (a) Unless the manufacturer's conduct is wilful and wanton,

1 a manufacturer of a drug or supply is not subject to criminal
2 or civil liability for injury, death, or loss to a person or
3 property for matters related to the donation, acceptance, or
4 dispensing of a cancer drug or supply manufactured by the
5 manufacturer that is donated by any person under this Act.

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

13 Section 35. Rules. The Department shall adopt all of the
14 following as rules:

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

19 (A) Eligibility criteria.

20 (B) Standards and procedures for accepting, safely
21 storing, and dispensing donated cancer drugs or
22 supplies needed to administer cancer drugs.

23 (C) Standards and procedures for inspecting
24 donated cancer drugs or supplies needed to administer
25 cancer drugs to determine whether the drugs or supplies

1 are in their original, unopened, sealed, and
2 tamper-evident unit-dose packaging or, if packaged in
3 single-unit doses, the single-unit-dose packaging is
4 unopened.

5 (D) Standards and procedures for inspecting
6 donated cancer drugs or supplies needed to administer
7 cancer drugs to determine that the drugs or supplies
8 needed to administer cancer drugs are not adulterated
9 or misbranded.

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

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

21 (4) Necessary forms for administration of the cancer
22 drug repository program, including forms for use by persons
23 that donate, accept, distribute, or dispense cancer drugs
24 or supplies needed to administer cancer drugs under the
25 program.

26 (5) The maximum handling fee that a pharmacy may charge

1 for accepting, distributing, or dispensing donated cancer
2 drugs or supplies needed to administer cancer drugs.

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

7 (7) 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 not accept for dispensing. The list
11 must include a statement that specifies the reason that the
12 drug or supplies are ineligible for donation.

13 The Department may also adopt any other rules deemed
14 necessary to implement this Act.

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

17 (225 ILCS 85/4) (from Ch. 111, par. 4124)

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

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

21 (a) the lawful practice of any physician licensed to
22 practice medicine in all of its branches, dentist, podiatrist,
23 veterinarian, or therapeutically or diagnostically certified
24 optometrist within the limits of his or her license, or prevent

1 him or her from supplying to his or her bona fide patients such
2 drugs, medicines, or poisons as may seem to him appropriate;

3 (b) the sale of compressed gases;

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

24 (d) the sale of poultry and livestock remedies in original
25 and unbroken packages only, labeled for poultry and livestock
26 medication;

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

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

21 (g) the ~~The~~ delegation of prescriptive authority by a
22 physician licensed to practice medicine in all its branches to
23 an advanced practice nurse in accordance with a written
24 collaborative agreement under Section 65-35 of the Nurse
25 Practice Act. This authority, which is delegated under Section
26 65-40 of the Nurse Practice Act, may but is not required to

1 include the prescription of Schedule III, IV, or V controlled
2 substances as defined in Article II of the Illinois Controlled
3 Substances Act; and -

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

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

9 Section 91. 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, 2013)

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 ongoing
20 relationship to distribute the manufacturer's prescription
21 drug. An ongoing relationship is deemed to exist between a
22 wholesale distributor and a manufacturer when the wholesale
23 distributor, including any affiliated group of the wholesale
24 distributor, as defined in Section 1504 of the Internal Revenue

1 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 and
10 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 Department
14 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 wholesale
10 distributor or chain pharmacy warehouse takes title but not
11 physical possession of such prescription drug and the wholesale
12 distributor invoices the pharmacy, chain pharmacy warehouse,
13 or other person authorized by law to dispense or administer
14 such drug to a patient and the pharmacy, chain pharmacy
15 warehouse, or other authorized person receives delivery of the
16 prescription drug directly from the manufacturer, that
17 manufacturer's third party logistics provider, or that
18 manufacturer's exclusive distributor or from an authorized
19 distributor of record that purchased the product directly from
20 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.

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

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

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

20 "Normal distribution channel" means a chain of custody for
21 a prescription drug that goes, directly or by drop shipment,
22 from (i) a manufacturer of the prescription drug, (ii) that
23 manufacturer to that manufacturer's co-licensed partner, (iii)
24 that manufacturer to that manufacturer's third party logistics
25 provider, or (iv) that manufacturer to that manufacturer's
26 exclusive distributor to:

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

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

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

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

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

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

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

26 "Person" means and includes a natural person, partnership,

1 association or corporation.

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

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

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

22 "Secretary" means the Secretary of Financial and
23 Professional Regulation.

24 "Third party logistics provider" means anyone who
25 contracts with a prescription drug manufacturer to provide or
26 coordinate warehousing, distribution, or other services on

1 behalf of a manufacturer, but does not take title to the
2 prescription drug or have general responsibility to direct the
3 prescription drug's sale or disposition. A third party
4 logistics provider must be licensed as a wholesale distributor
5 under this Act and, in order to be considered part of the
6 normal distribution channel, must also be an authorized
7 distributor of record.

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

11 (1) Intracompany sales of prescription drugs, meaning

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

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

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

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

26 (5) The sale of minimal quantities of prescription

1 drugs by retail pharmacies to licensed practitioners for
2 office use.

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

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

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

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

26 (10) The sale or transfer from a retail pharmacy, mail

1 order pharmacy, or chain pharmacy warehouse of expired,
2 damaged, returned, or recalled prescription drugs to the
3 original manufacturer, the originating wholesale
4 distributor, or a third party returns processor.

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

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

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

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

24 (320 ILCS 50/10)

1 Sec. 10. Definitions. In this Act:

2 "Manufacturer" includes:

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

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

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

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

26 "Senior citizen" or "senior" means a person 65 years of age

1 or older.

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

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

5 (410 ILCS 620/16) (from Ch. 56 1/2, par. 516)

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

17 (b) Drugs and device labeling or packaging exemptions
18 adopted under the Federal Act and supplements thereto or
19 revisions thereof shall apply to drugs and devices in Illinois
20 except insofar as modified or rejected by regulations
21 promulgated by the Director.

22 (c) A drug intended for use by man which (A) is a
23 habit-forming drug to which Section 15 (d) applies; or (B)
24 because of its toxicity or other potentiality for harmful

1 effect or the method of its use or the collateral measures
2 necessary to its use is not safe for use except under the
3 supervision of a practitioner licensed by law to administer
4 such drug; or (C) is limited by an approved application under
5 Section 505 of the Federal Act or Section 17 of this Act to use
6 under the professional supervision of a practitioner licensed
7 by law to administer such drug, shall be dispensed only in
8 accordance with the provisions of the "Illinois Controlled
9 Substances Act". The act of dispensing a drug contrary to the
10 provisions of this paragraph shall be deemed to be an act which
11 results in a drug being misbranded while held for sale.

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

1 exemption shall not apply to any drug dispensed in the course
2 of the conduct of business of dispensing drugs pursuant to
3 diagnosis by mail, or to a drug dispensed in violation of
4 subsection (a) of this Section.

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

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

18 (g) Nothing in this Section shall be construed to relieve
19 any person from any requirement prescribed by or under
20 authority of law with respect to controlled substances now
21 included or which may hereafter be included within the
22 classifications of controlled substances cannabis as defined
23 in applicable Federal laws relating to controlled substances or
24 cannabis or the Cannabis Control Act.

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

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

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

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

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

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

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

19 (2) the patient or research subject at the lawful
20 direction of the practitioner, or

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

23 (c) "Agent" means an authorized person who acts on behalf
24 of or at the direction of a manufacturer, distributor, or
25 dispenser. It does not include a common or contract carrier,

1 public warehouseman or employee of the carrier or warehouseman.

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

6 (i) boldenone,

7 (ii) chlorotestosterone,

8 (iii) chostebol,

9 (iv) dehydrochlormethyltestosterone,

10 (v) dihydrotestosterone,

11 (vi) drostanolone,

12 (vii) ethylestrenol,

13 (viii) fluoxymesterone,

14 (ix) formebulone,

15 (x) mesterolone,

16 (xi) methandienone,

17 (xii) methandranone,

18 (xiii) methandriol,

19 (xiv) methandrostenolone,

20 (xv) methenolone,

21 (xvi) methyltestosterone,

22 (xvii) mibolerone,

23 (xviii) nandrolone,

24 (xix) norethandrolone,

25 (xx) oxandrolone,

26 (xxi) oxymesterone,

1 (xxii) oxymetholone,
2 (xxiii) stanolone,
3 (xxiv) stanozolol,
4 (xxv) testolactone,
5 (xxvi) testosterone,
6 (xxvii) trenbolone, and
7 (xxviii) any salt, ester, or isomer of a drug or
8 substance described or listed in this paragraph, if
9 that salt, ester, or isomer promotes muscle growth.

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

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

26 (e) "Control" means to add a drug or other substance, or

1 immediate precursor, to a Schedule under Article II of this Act
2 whether by transfer from another Schedule or otherwise.

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

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

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

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

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

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

25 (l) "Department of Professional Regulation" means the
26 Department of Professional Regulation of the State of Illinois

1 or its successor agency.

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

3 (1) a drug which contains any quantity of (i)
4 barbituric acid or any of the salts of barbituric acid
5 which has been designated as habit forming under section
6 502 (d) of the Federal Food, Drug, and Cosmetic Act (21
7 U.S.C. 352 (d)); or

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

16 (3) lysergic acid diethylamide; or

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

22 (n) (Blank).

23 (o) "Director" means the Director of the Department of
24 State Police or the Department of Professional Regulation or
25 his designated agents.

26 (p) "Dispense" means to deliver a controlled substance to

1 an ultimate user or research subject by or pursuant to the
2 lawful order of a prescriber, including the prescribing,
3 administering, packaging, labeling, or compounding necessary
4 to prepare the substance for that delivery.

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

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

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

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

20 (t-5) "Euthanasia agency" means an entity certified by the
21 Department of Professional Regulation for the purpose of animal
22 euthanasia that holds an animal control facility license or
23 animal shelter license under the Animal Welfare Act. A
24 euthanasia agency is authorized to purchase, store, possess,
25 and utilize Schedule II nonnarcotic and Schedule III
26 nonnarcotic drugs for the sole purpose of animal euthanasia.

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

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

16 (1) lack of consistency of doctor-patient
17 relationship,

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

20 (3) quantities beyond those normally prescribed,

21 (4) unusual dosages,

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

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

25 (u-1) "Home infusion services" means services provided by a
26 pharmacy in compounding solutions for direct administration to

1 a patient in a private residence, long-term care facility, or
2 hospice setting by means of parenteral, intravenous,
3 intramuscular, subcutaneous, or intraspinal infusion.

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

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

9 (2) which is an immediate chemical intermediary used or
10 likely to be used in the manufacture of such controlled
11 substance; and

12 (3) the control of which is necessary to prevent,
13 curtail or limit the manufacture of such controlled
14 substance.

15 (w) "Instructional activities" means the acts of teaching,
16 educating or instructing by practitioners using controlled
17 substances within educational facilities approved by the State
18 Board of Education or its successor agency.

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

21 (y) "Look-alike substance" means a substance, other than a
22 controlled substance which (1) by overall dosage unit
23 appearance, including shape, color, size, markings or lack
24 thereof, taste, consistency, or any other identifying physical
25 characteristic of the substance, would lead a reasonable person
26 to believe that the substance is a controlled substance, or (2)

1 is expressly or impliedly represented to be a controlled
2 substance or is distributed under circumstances which would
3 lead a reasonable person to believe that the substance is a
4 controlled substance. For the purpose of determining whether
5 the representations made or the circumstances of the
6 distribution would lead a reasonable person to believe the
7 substance to be a controlled substance under this clause (2) of
8 subsection (y), the court or other authority may consider the
9 following factors in addition to any other factor that may be
10 relevant:

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

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

15 (c) whether the substance is packaged in a manner
16 normally used for the illegal distribution of controlled
17 substances;

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

23 Clause (1) of this subsection (y) shall not apply to a
24 noncontrolled substance in its finished dosage form that was
25 initially introduced into commerce prior to the initial
26 introduction into commerce of a controlled substance in its

1 finished dosage form which it may substantially resemble.

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

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

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

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

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

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 packaging, repackaging, or labeling of
12 prescription drugs only to the extent required under the
13 Cancer Drug Repository Program Act.

14 (z-1) (Blank).

15 (aa) "Narcotic drug" means any of the following, whether
16 produced directly or indirectly by extraction from substances
17 of natural origin, or independently by means of chemical
18 synthesis, or by a combination of extraction and chemical
19 synthesis:

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

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

26 (3) opium poppy and poppy straw;

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

11 (bb) "Nurse" means a registered nurse licensed under the
12 Nurse Practice Act.

13 (cc) (Blank).

14 (dd) "Opiate" means any substance having an addiction
15 forming or addiction sustaining liability similar to morphine
16 or being capable of conversion into a drug having addiction
17 forming or addiction sustaining liability.

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

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

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

26 (hh) "Pharmacist" means any person who holds a license or

1 certificate of registration as a registered pharmacist, a local
2 registered pharmacist or a registered assistant pharmacist
3 under the Pharmacy Practice Act.

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

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

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

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

23 (mm) "Prescriber" means a physician licensed to practice
24 medicine in all its branches, dentist, optometrist, podiatrist
25 or veterinarian who issues a prescription, a physician
26 assistant who issues a prescription for a Schedule III, IV, or

1 V controlled substance in accordance with Section 303.05 and
2 the written guidelines required under Section 7.5 of the
3 Physician Assistant Practice Act of 1987, or an advanced
4 practice nurse with prescriptive authority delegated under
5 Section 65-40 of the Nurse Practice Act and in accordance with
6 Section 303.05 and a written collaborative agreement under
7 Section 65-35 of the Nurse Practice Act.

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

23 (oo) "Production" or "produce" means manufacture,
24 planting, cultivating, growing, or harvesting of a controlled
25 substance other than methamphetamine.

26 (pp) "Registrant" means every person who is required to

1 register under Section 302 of this Act.

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

5 (rr) "State" includes the State of Illinois and any state,
6 district, commonwealth, territory, insular possession thereof,
7 and any area subject to the legal authority of the United
8 States of America.

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

13 (Source: P.A. 94-556, eff. 9-11-05; 95-242, eff. 1-1-08;
14 95-639, eff. 10-5-07; 95-689, eff. 10-29-07; 95-876, eff.
15 8-21-08.)

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

18 (740 ILCS 20/3) (from Ch. 70, par. 903)

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

21 "Cannabis" includes marihuana, hashish, and other
22 substances that are identified as including any parts of the
23 plant Cannabis Sativa, whether growing or not, the seeds of
24 that plant, the resin extracted from any part of that plant,

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

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

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

25 "Deliver" or "delivery" means the actual, constructive, or
26 attempted transfer of possession of a controlled substance or

1 cannabis, with or without consideration, whether or not there
2 is an agency relationship. The term does not include the
3 donation of prescription drugs to the extent permitted under
4 the Cancer Drug Repository Program Act.

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

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

15 (2) by a practitioner or his authorized agent under his
16 supervision, the preparation, compounding, packaging, or
17 labeling of a controlled substance;~~+~~

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

21 (B) as an incident to lawful research, teaching or
22 chemical analysis and not for sale; or

23 (3) the preparation, compounding, packaging, or
24 labeling of cannabis as an incident to lawful research,
25 teaching, or chemical analysis and not for sale;or -

26 (4) the packaging, repackaging, or labeling of

1 prescription drugs only to the extent required under the
2 Cancer Drug Repository Program Act.

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

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

9 "Production" means planting, cultivating, tending, or
10 harvesting.

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

15 (Source: P.A. 87-544; revised 10-23-08.)

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	720 ILCS 570/102	from Ch. 56 1/2, par. 1102
9	740 ILCS 20/3	from Ch. 70, par. 903