



## 97TH GENERAL ASSEMBLY

### State of Illinois

2011 and 2012

HB1660

Introduced 2/15/2011, by Rep. Patricia R. Bellock

#### SYNOPSIS AS INTRODUCED:

See Index

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

LRB097 08294 KTG 48421 b

FISCAL NOTE ACT  
MAY APPLY

A BILL FOR

1 AN ACT concerning health.

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

4 Section 1. Short title. This Act may be cited as the  
5 Prescription Drug Repository Program Act.

6 Section 5. Definitions. In this Act:

7 "Department" means the Department of Public Health.

8 "Dispense" has the meaning given to that term in the  
9 Pharmacy Practice Act.

10 "Healthcare facility" means an assisted living facility,  
11 hospice, rehabilitation facility, or long-term care facility.

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

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

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

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

1 accordance with federal Food and Drug Administration  
2 requirements.

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

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

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

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

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

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

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

19           Section 20. Resale of donated drugs or supplies prohibited.  
20 No prescription drug or supplies needed to administer a  
21 prescription drug that are donated for use under this Act may  
22 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 prescription drug repository program.

2 Section 30. Immunity.

3 (a) Except in cases of willful and wanton misconduct, a  
4 manufacturer of a drug or supply is not subject to criminal or  
5 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 prescription drug or supply manufactured by the  
8 manufacturer that is donated under this Act, including  
9 liability for failure to transfer or communicate product or  
10 consumer information or the expiration date of the donated  
11 prescription drug. The provisions of this subsection shall  
12 apply only to the donation, acceptance, or dispensing of drugs  
13 or supplies provided without fee or compensation. Immunity  
14 granted under this subsection is solely applicable to the  
15 donation, acceptance, or dispensing of a drug or supply under  
16 this Act and is not a general waiver of liability that would  
17 have existed under the original prescription.

18 (b) A pharmacist or other health care professional working  
19 in a pharmacy participating in the program dispensing,  
20 furnishing, or otherwise providing in good faith without fee or  
21 compensation donated prescription drugs to eligible  
22 individuals under this Act shall not be subject to professional  
23 or civil liability, except for willful or wanton misconduct.

24 Section 90. The Pharmacy Practice Act is amended by

1 changing Section 4 as follows:

2 (225 ILCS 85/4) (from Ch. 111, par. 4124)

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

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

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

12 (b) the sale of compressed gases;

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

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

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

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

23 (f) the delegation of limited prescriptive authority by a  
24 physician licensed to practice medicine in all its branches to  
25 a physician assistant under Section 7.5 of the Physician  
26 Assistant Practice Act of 1987. This delegated authority under

1 Section 7.5 of the Physician Assistant Practice Act of 1987  
2 may, but is not required to, include prescription of controlled  
3 substances, as defined in Article II of the Illinois Controlled  
4 Substances Act, in accordance with a written supervision  
5 agreement; ~~and~~

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

11 (h) the donation or acceptance, or the packaging,  
12 repackaging, or labeling, of prescription drugs to the extent  
13 permitted or required under the Prescription Drug Repository  
14 Program Act.

15 (Source: P.A. 95-639, eff. 10-5-07; 96-189, eff. 8-10-09;  
16 96-268, eff. 8-11-09.)

17 Section 91. The Wholesale Drug Distribution Licensing Act  
18 is amended by changing Section 15 as follows:

19 (225 ILCS 120/15) (from Ch. 111, par. 8301-15)

20 (Section scheduled to be repealed on January 1, 2013)

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

22 "Authentication" means the affirmative verification,  
23 before any wholesale distribution of a prescription drug  
24 occurs, that each transaction listed on the pedigree has



1 occurred.

2 "Authorized distributor of record" means a wholesale  
3 distributor with whom a manufacturer has established an ongoing  
4 relationship to distribute the manufacturer's prescription  
5 drug. An ongoing relationship is deemed to exist between a  
6 wholesale distributor and a manufacturer when the wholesale  
7 distributor, including any affiliated group of the wholesale  
8 distributor, as defined in Section 1504 of the Internal Revenue  
9 Code, complies with the following:

10 (1) The wholesale distributor has a written agreement  
11 currently in effect with the manufacturer evidencing the  
12 ongoing relationship; and

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

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

19 "Blood component" means that part of blood separated by  
20 physical or mechanical means.

21 "Board" means the State Board of Pharmacy of the Department  
22 of Professional Regulation.

23 "Chain pharmacy warehouse" means a physical location for  
24 prescription drugs that acts as a central warehouse and  
25 performs intracompany sales or transfers of the drugs to a  
26 group of chain or mail order pharmacies that have the same

1 common ownership and control. Notwithstanding any other  
2 provision of this Act, a chain pharmacy warehouse shall be  
3 considered part of the normal distribution channel.

4 "Co-licensed partner or product" means an instance where  
5 one or more parties have the right to engage in the  
6 manufacturing or marketing of a prescription drug, consistent  
7 with the FDA's implementation of the Prescription Drug  
8 Marketing Act.

9 "Department" means the Department of Financial and  
10 Professional Regulation.

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

1 distributor of record that purchased the product directly from  
2 the manufacturer or one of these entities.

3 "Drug sample" means a unit of a prescription drug that is  
4 not intended to be sold and is intended to promote the sale of  
5 the drug.

6 "Facility" means a facility of a wholesale distributor  
7 where prescription drugs are stored, handled, repackaged, or  
8 offered for sale.

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

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

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

1 must also be an authorized distributor of record.

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

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

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

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

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

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

1 administer the drug to the patient; or

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

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

8 "Person" means and includes a natural person, partnership,  
9 association or corporation.

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

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

26 "Repackage" means repackaging or otherwise changing the

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

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

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

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

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

25 (2) The sale, purchase, distribution, trade, or  
26 transfer of a prescription drug or offer to sell, purchase,

1 distribute, trade, or transfer a prescription drug for  
2 emergency medical reasons.

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

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

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

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

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

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

1 distribution channel.

2 (9) The delivery of or the offer to deliver a  
3 prescription drug by a common carrier solely in the common  
4 carrier's usual course of business of transporting  
5 prescription drugs when the common carrier does not store,  
6 warehouse, or take legal ownership of the prescription  
7 drug.

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

13 (11) The donation of prescription drugs to the extent  
14 permitted under the Prescription Drug Repository Program  
15 Act.

16 "Wholesale drug distributor" means anyone engaged in the  
17 wholesale distribution of prescription drugs, including  
18 without limitation manufacturers; repackers; own label  
19 distributors; jobbers; private label distributors; brokers;  
20 warehouses, including manufacturers' and distributors'  
21 warehouses; manufacturer's exclusive distributors; and  
22 authorized distributors of record; drug wholesalers or  
23 distributors; independent wholesale drug traders; specialty  
24 wholesale distributors; third party logistics providers; and  
25 retail pharmacies that conduct wholesale distribution; and  
26 chain pharmacy warehouses that conduct wholesale distribution.



1 In order to be considered part of the normal distribution  
2 channel, a wholesale distributor must also be an authorized  
3 distributor of record.

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

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

7 (320 ILCS 50/10)

8 Sec. 10. Definitions. In this Act:

9 "Manufacturer" includes:

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

19 (2) The entity holding legal title to or possession of  
20 the national drug code number for the covered prescription  
21 drug.

22 The term does not include a wholesale distributor of drugs,  
23 drugstore chain organization, or retail pharmacy licensed by  
24 the State. The term also does not include anyone who is engaged

1 in the packaging, repackaging, or labeling of prescription  
2 drugs only to the extent required under the Prescription Drug  
3 Repository Program Act.

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

9 "Senior citizen" or "senior" means a person 65 years of age  
10 or older.

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

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

14 (410 ILCS 620/16) (from Ch. 56 1/2, par. 516)

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

1 extent required under the Prescription Drug Repository Program  
2 Act.

3 (b) Drugs and device labeling or packaging exemptions  
4 adopted under the Federal Act and supplements thereto or  
5 revisions thereof shall apply to drugs and devices in Illinois  
6 except insofar as modified or rejected by regulations  
7 promulgated by the Director.

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

22 (d) Any drug dispensed by filling or refilling a written or  
23 oral prescription of a practitioner licensed by law to  
24 administer such drug shall be exempt from the requirements of  
25 Section 15, except subsections (a), (k) and (l) and clauses (2)  
26 and (3) of subsection (i), and the packaging requirements of

1 subsections (g), (h) and (q), if the drug bears a label  
2 containing the proprietary name or names, or if there is none,  
3 the established name or names of the drugs, the dosage and  
4 quantity, unless the prescribing practitioner, in the interest  
5 of the health of the patient, directs otherwise in writing, the  
6 name and address of the dispenser, the serial number and date  
7 of the prescription or of its filling, the name of the  
8 prescriber and, if stated in the prescription, the name of the  
9 patient, and the directions for use and the cautionary  
10 statements, if any, contained in such prescription. This  
11 exemption shall not apply to any drug dispensed in the course  
12 of the conduct of business of dispensing drugs pursuant to  
13 diagnosis by mail, or to a drug dispensed in violation of  
14 subsection (a) of this Section.

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

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

1 quoted in the preceding sentence.

2 (g) Nothing in this Section shall be construed to relieve  
3 any person from any requirement prescribed by or under  
4 authority of law with respect to controlled substances now  
5 included or which may hereafter be included within the  
6 classifications of controlled substances cannabis as defined  
7 in applicable Federal laws relating to controlled substances or  
8 cannabis or the Cannabis Control Act.

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

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

12 (720 ILCS 570/102) (from Ch. 56 1/2, par. 1102)

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

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

21 (b) "Administer" means the direct application of a  
22 controlled substance, whether by injection, inhalation,  
23 ingestion, or any other means, to the body of a patient,  
24 research subject, or animal (as defined by the Humane

1 Euthanasia in Animal Shelters Act) by:

2 (1) a practitioner (or, in his presence, by his  
3 authorized agent),

4 (2) the patient or research subject at the lawful  
5 direction of the practitioner, or

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

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

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

16 (i) boldenone,

17 (ii) chlorotestosterone,

18 (iii) chostebol,

19 (iv) dehydrochlormethyltestosterone,

20 (v) dihydrotestosterone,

21 (vi) drostanolone,

22 (vii) ethylestrenol,

23 (viii) fluoxymesterone,

24 (ix) formebulone,

25 (x) mesterolone,

26 (xi) methandienone,

1 (xii) methandranone,  
2 (xiii) methandriol,  
3 (xiv) methandrostenolone,  
4 (xv) methenolone,  
5 (xvi) methyltestosterone,  
6 (xvii) mibolerone,  
7 (xviii) nandrolone,  
8 (xix) norethandrolone,  
9 (xx) oxandrolone,  
10 (xxi) oxymesterone,  
11 (xxii) oxymetholone,  
12 (xxiii) stanolone,  
13 (xxiv) stanozolol,  
14 (xxv) testolactone,  
15 (xxvi) testosterone,  
16 (xxvii) trenbolone, and  
17 (xxviii) any salt, ester, or isomer of a drug or  
18 substance described or listed in this paragraph, if  
19 that salt, ester, or isomer promotes muscle growth.

20 Any person who is otherwise lawfully in possession of an  
21 anabolic steroid, or who otherwise lawfully manufactures,  
22 distributes, dispenses, delivers, or possesses with intent to  
23 deliver an anabolic steroid, which anabolic steroid is  
24 expressly intended for and lawfully allowed to be administered  
25 through implants to livestock or other nonhuman species, and  
26 which is approved by the Secretary of Health and Human Services

1 for such administration, and which the person intends to  
2 administer or have administered through such implants, shall  
3 not be considered to be in unauthorized possession or to  
4 unlawfully manufacture, distribute, dispense, deliver, or  
5 possess with intent to deliver such anabolic steroid for  
6 purposes of this Act.

7 (d) "Administration" means the Drug Enforcement  
8 Administration, United States Department of Justice, or its  
9 successor agency.

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

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

15 (g) "Counterfeit substance" means a controlled substance,  
16 which, or the container or labeling of which, without  
17 authorization bears the trademark, trade name, or other  
18 identifying mark, imprint, number or device, or any likeness  
19 thereof, of a manufacturer, distributor, or dispenser other  
20 than the person who in fact manufactured, distributed, or  
21 dispensed the substance.

22 (h) "Deliver" or "delivery" means the actual, constructive  
23 or attempted transfer of possession of a controlled substance,  
24 with or without consideration, whether or not there is an  
25 agency relationship. The term does not include the donation of  
26 prescription drugs to the extent permitted under the



1 Prescription Drug Repository Program Act.

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

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

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

9 (l) "Department of Professional Regulation" means the  
10 Department of Professional Regulation of the State of Illinois  
11 or its successor agency.

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

13 (1) a drug which contains any quantity of (i)  
14 barbituric acid or any of the salts of barbituric acid  
15 which has been designated as habit forming under section  
16 502 (d) of the Federal Food, Drug, and Cosmetic Act (21  
17 U.S.C. 352 (d)); or

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

26 (3) lysergic acid diethylamide; or

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

6           (n) (Blank).

7           (o) "Director" means the Director of the Department of  
8           State Police or the Department of Professional Regulation or  
9           his designated agents.

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

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

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

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

19          (t) "Drug" means (1) substances recognized as drugs in the  
20          official United States Pharmacopoeia, Official Homeopathic  
21          Pharmacopoeia of the United States, or official National  
22          Formulary, or any supplement to any of them; (2) substances  
23          intended for use in diagnosis, cure, mitigation, treatment, or  
24          prevention of disease in man or animals; (3) substances (other  
25          than food) intended to affect the structure of any function of  
26          the body of man or animals and (4) substances intended for use

1 as a component of any article specified in clause (1), (2), or  
2 (3) of this subsection. It does not include devices or their  
3 components, parts, or accessories.

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

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

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

26 (1) lack of consistency of doctor-patient

1 relationship,

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

4 (3) quantities beyond those normally prescribed,

5 (4) unusual dosages,

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

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

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

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

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

19 (2) which is an immediate chemical intermediary used or  
20 likely to be used in the manufacture of such controlled  
21 substance; and

22 (3) the control of which is necessary to prevent,  
23 curtail or limit the manufacture of such controlled  
24 substance.

25 (w) "Instructional activities" means the acts of teaching,  
26 educating or instructing by practitioners using controlled

1 substances within educational facilities approved by the State  
2 Board of Education or its successor agency.

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

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

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

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

25 (c) whether the substance is packaged in a manner  
26 normally used for the illegal distribution of controlled

1 substances;

2 (d) whether the distribution or attempted distribution  
3 included an exchange of or demand for money or other  
4 property as consideration, and whether the amount of the  
5 consideration was substantially greater than the  
6 reasonable retail market value of the substance.

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

12 Nothing in this subsection (y) prohibits the dispensing or  
13 distributing of noncontrolled substances by persons authorized  
14 to dispense and distribute controlled substances under this  
15 Act, provided that such action would be deemed to be carried  
16 out in good faith under subsection (u) if the substances  
17 involved were controlled substances.

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

23 (y-1) "Mail-order pharmacy" means a pharmacy that is  
24 located in a state of the United States, other than Illinois,  
25 that delivers, dispenses or distributes, through the United  
26 States Postal Service or other common carrier, to Illinois

1 residents, any substance which requires a prescription.

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

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

13 (2) by a practitioner, or his authorized agent under  
14 his supervision, the preparation, compounding, packaging,  
15 or labeling of a controlled substance:

16 (a) as an incident to his administering or  
17 dispensing of a controlled substance in the course of  
18 his professional practice; ~~or~~

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

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

24 (z-1) (Blank).

25 (aa) "Narcotic drug" means any of the following, whether  
26 produced directly or indirectly by extraction from substances

1 of natural origin, or independently by means of chemical  
2 synthesis, or by a combination of extraction and chemical  
3 synthesis:

4 (1) opium and opiate, and any salt, compound,  
5 derivative, or preparation of opium or opiate;

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

10 (3) opium poppy and poppy straw;

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

21 (bb) "Nurse" means a registered nurse licensed under the  
22 Nurse Practice Act.

23 (cc) (Blank).

24 (dd) "Opiate" means any substance having an addiction  
25 forming or addiction sustaining liability similar to morphine  
26 or being capable of conversion into a drug having addiction



1 forming or addiction sustaining liability.

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

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

6 (gg) "Person" means any individual, corporation,  
7 mail-order pharmacy, government or governmental subdivision or  
8 agency, business trust, estate, trust, partnership or  
9 association, or any other entity.

10 (hh) "Pharmacist" means any person who holds a license or  
11 certificate of registration as a registered pharmacist, a local  
12 registered pharmacist or a registered assistant pharmacist  
13 under the Pharmacy Practice Act.

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

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

19 (kk) "Practitioner" means a physician licensed to practice  
20 medicine in all its branches, dentist, optometrist,  
21 podiatrist, veterinarian, scientific investigator, pharmacist,  
22 physician assistant, advanced practice nurse, licensed  
23 practical nurse, registered nurse, hospital, laboratory, or  
24 pharmacy, or other person licensed, registered, or otherwise  
25 lawfully permitted by the United States or this State to  
26 distribute, dispense, conduct research with respect to,

1 administer or use in teaching or chemical analysis, a  
2 controlled substance in the course of professional practice or  
3 research.

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

7 (mm) "Prescriber" means a physician licensed to practice  
8 medicine in all its branches, dentist, optometrist, podiatrist  
9 or veterinarian who issues a prescription, a physician  
10 assistant who issues a prescription for a controlled substance  
11 in accordance with Section 303.05, a written delegation, and a  
12 written supervision agreement required under Section 7.5 of the  
13 Physician Assistant Practice Act of 1987, or an advanced  
14 practice nurse with prescriptive authority delegated under  
15 Section 65-40 of the Nurse Practice Act and in accordance with  
16 Section 303.05, a written delegation, and a written  
17 collaborative agreement under Section 65-35 of the Nurse  
18 Practice Act.

19 (nn) "Prescription" means a lawful written, facsimile, or  
20 verbal order of a physician licensed to practice medicine in  
21 all its branches, dentist, podiatrist or veterinarian for any  
22 controlled substance, of an optometrist for a Schedule III, IV,  
23 or V controlled substance in accordance with Section 15.1 of  
24 the Illinois Optometric Practice Act of 1987, of a physician  
25 assistant for a controlled substance in accordance with Section  
26 303.05, a written delegation, and a written supervision

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

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

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

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

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

20 (ss) "Ultimate user" means a person who lawfully possesses  
21 a controlled substance for his own use or for the use of a  
22 member of his household or for administering to an animal owned  
23 by him or by a member of his household.

24 (Source: P.A. 95-242, eff. 1-1-08; 95-639, eff. 10-5-07;  
25 95-689, eff. 10-29-07; 95-876, eff. 8-21-08; 96-189, eff.  
26 8-10-09; 96-268, eff. 8-11-09.)

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

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

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

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

24           "Controlled substance" means a drug, substance, or

1 immediate precursor in the Schedules of Article II of the  
2 Illinois Controlled Substances Act.

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

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

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

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

26 (2) by a practitioner or his authorized agent under his

1 supervision, the preparation, compounding, packaging, or  
2 labeling of a controlled substance:

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

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

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

11 (4) the packaging, repackaging, or labeling of  
12 prescription drugs only to the extent required under the  
13 Prescription Drug Repository Program Act.

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

16 "Person" means an individual, a corporation, a government,  
17 a governmental subdivision or agency, a business trust, an  
18 estate, a trust, a partnership or association, or any other  
19 entity.

20 "Production" means planting, cultivating, tending, or  
21 harvesting.

22 "Property" means real property, including things growing  
23 on, affixed to, and found in land, and tangible or intangible  
24 personal property, including rights, services, privileges,  
25 interests, claims, and securities.

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

1 INDEX

2 Statutes amended in order of appearance

3 New Act

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

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

6 320 ILCS 50/10

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

8 720 ILCS 570/102 from Ch. 56 1/2, par. 1102

9 740 ILCS 20/3 from Ch. 70, par. 903