
THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 2602 Session of
1992

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PISTELLA, KOSINSKI AND JAMES, APRIL 6, 1992

SENATOR LOEPER, RULES AND EXECUTIVE NOMINATIONS, IN SENATE, RE-
REPORTED AS AMENDED, NOVEMBER 17, 1992

AN ACT

1 Providing minimum standards, terms and conditions for the
2 licensing of persons who engage in wholesale distributions in
3 interstate commerce of prescription drugs; and making a
4 repeal.

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8 The General Assembly of the Commonwealth of Pennsylvania
9 hereby enacts as follows:

10 Section 1. Short title.

11 This act shall be known and may be cited as the Wholesale
12 Prescription Drug Distributors License Act.

13 Section 2. Legislative intent.

14 (a) Findings.--The General Assembly finds and declares as
15 follows:

16 (1) The economic interests of this Commonwealth and of
17 its wholesale prescription drug industry will be promoted by
18 requiring the licensure of persons who engage in the
19 wholesale distribution of prescription drugs in interstate
20 commerce under the Federal Prescription Drug Marketing Act of
21 1987 (Public Law 100-293, 102 Stat. 95).

22 (2) Pennsylvania consumers of prescription drugs will be
23 better assured of safe and effective prescription drug
24 products if the Commonwealth joins with other jurisdictions
25 to require the licensure of all persons who operate
26 facilities from which they engage in the wholesale
27 distribution of prescription drugs.

28 (b) Intent.--It is the intent of the General Assembly that
29 this act satisfy the requirements of the Federal Prescription
30 Drug Marketing Act of 1987. It is the further intent of the

1 General Assembly to promote the safety and effectiveness of
2 prescription drug products by requiring all persons who operate
3 facilities within this Commonwealth from which they engage in
4 the wholesale distribution of prescription drugs to secure a
5 license and meet minimum quality assurance and operational
6 standards as required by this act.

7 Section 3. Definitions.

8 The following words and phrases when used in this act shall
9 have the meanings given to them in this section unless the
10 context clearly indicates otherwise:

11 "Blood." Whole blood collected from a single donor and
12 processed either for transfusion or further manufacturing.

13 "Blood component." That part of blood separated by physical
14 or mechanical means.

15 "Common control." The power to direct or cause the direction
16 of the management and policies of a person or an organization,
17 whether by ownership of stock, voting rights, contract or
18 otherwise.

19 "Department." The Department of Health of the Commonwealth.

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

23 "Intracompany sales." A transaction or transfer between any
24 division, subsidiary, parent or affiliated or related company
25 under the common ownership and control of a corporate entity.

26 "License." A wholesale prescription drug distributor
27 license.

28 "Manufacturer." Any entity engaged in manufacturing,
29 preparing, propagating, compounding, processing, packaging,
30 repackaging or labeling of a prescription drug.

1 "Prescription drug." Any human drug required by Federal law,
2 the act of April 14, 1972 (P.L.233, No.64), known as The
3 Controlled Substance, Drug, Device and Cosmetic Act, or
4 regulations promulgated under either, to be dispensed only by a
5 prescription, including finished dosage forms and active
6 ingredients subject to section 503(b) of the Federal Food, Drug,
7 and Cosmetic Act (52 Stat. 1040, 21 U.S.C. § 503(b)).

8 "Wholesale distribution of prescription drugs." Distribution
9 in interstate commerce of prescription drugs to persons other
10 than a consumer or patient, but does not include:

11 (1) Intracompany sales OR JOINING TOGETHER OF FIVE OR ←
12 FEWER PHARMACIES TO PLACE A DIRECT ORDER OF MEDICINE FROM THE
13 PHARMACEUTICAL MANUFACTURER.

14 (2) The purchase or other acquisition by a hospital or
15 other health care entity that is a member of a group
16 purchasing organization of a drug for its own use from the
17 group purchasing organization or from other hospitals or
18 health care entities that are members of such organizations.

19 (3) The sale, purchase or trade of a drug or an offer to
20 sell, purchase or trade a drug by a charitable organization
21 described in section 501(c)(3) of the Internal Revenue Code
22 of 1986 (Public Law 99-514, 26 U.S.C. § 501(c)(3)) to a
23 nonprofit affiliate of the organization to the extent
24 otherwise permitted by law.

25 (4) The sale, purchase or trade of a drug or an offer to
26 sell, purchase or trade a drug among hospitals or other
27 health care entities that are under common control.

28 (5) The sale, purchase or trade of a drug or an offer to
29 sell, purchase or trade a drug for emergency medical reasons,
30 including transfers of prescription drugs by a retail

1 pharmacy to another retail pharmacy to alleviate a temporary
2 shortage.

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 drug
5 pursuant to a prescription.

6 (7) The distribution of drug samples by manufacturers'
7 representatives or distributors' representatives.

8 (8) The sale, purchase or trade of blood and blood
9 components intended for transfusion.

10 (9) The sale of minimal quantities of prescription drugs
11 by a retail pharmacy to licensed practitioners for use within
12 their practice when the sales do not exceed 5% of that retail
13 pharmacy's total annual prescription drug sales.

14 "Wholesale distributor of prescription drugs." A person who
15 operates a facility from which a person engages in the wholesale
16 distribution of prescription drugs, including, but not limited
17 to, manufacturers, repackers, own-label distributors, private-
18 label distributors or jobbers, ~~brokers~~, warehouses, including <—
19 manufacturers' and distributors' warehouses, chain drug
20 warehouses and wholesale drug warehouses, independent wholesale
21 drug traders and retail pharmacies that conduct wholesale
22 distributions.

23 Section 4. License and renewal requirements.

24 (a) License.--After September 14, 1992, a person may not
25 operate a facility within this Commonwealth from which a person
26 engages in the wholesale distribution of prescription drugs
27 without having secured from the department a license and a
28 current renewal of that license. A person shall obtain a
29 separate license to operate each facility.

30 (b) License renewal.--A licensee shall renew its license at

1 the same time it is required to renew the registration issued to
2 it under the act of April 14, 1972 (P.L.233, No.64), known as
3 The Controlled Substance, Drug, Device and Cosmetic Act, or as
4 otherwise required by the department, but in no case shall the
5 period for renewing the license be longer than two years. A form
6 for the license renewal shall be mailed to each licensee on or
7 before the first day of the month in which the current renewal
8 expires. If a completed license renewal is neither postmarked
9 nor received by the department before the first day of the
10 following month, the license shall become invalid. Failure of
11 the licensee to receive the form by mail shall not serve as an
12 excuse for failing to timely renew the license.

13 (c) Fees.--Each person who applies for a license shall
14 submit a fee of \$10 with the license application. The license
15 renewal fee shall be \$100, unless changed by regulation, and
16 shall be submitted with the completed license renewal form. The
17 late submission of a completed license renewal form shall be
18 accompanied by a late payment fee of \$25 for each month or
19 portion thereof that expired after the license renewal was due.
20 The late payment fee shall be in addition to any administrative,
21 civil or criminal penalty that may be imposed against a licensee
22 for continuing to engage in the wholesale distribution of
23 prescription drugs without a current license. Fees under this
24 section may be amended by regulation of the department.

25 Section 5. License application.

26 (a) Information on application.--An applicant for a license
27 shall provide the following information on a license application
28 form approved by the department:

29 (1) The name, full business address and telephone number
30 of the facility for which the applicant is seeking a license

1 to operate.

2 (2) The name, full business address and telephone number
3 of the applicant.

4 (3) All trade or business names used by the applicant.

5 (4) Addresses, telephone numbers and the names of
6 contact persons for all facilities used by the facility for
7 which the license is being sought, for the storage, handling
8 and distribution of prescription drugs.

9 (5) The type of ownership or operation, that is,
10 partnership, corporation or sole proprietorship, of the
11 facility.

12 (6) The name of the owner and operator of the facility
13 as follows:

14 (i) If a sole proprietorship, the full name of the
15 sole proprietor and the name of the business entity.

16 (ii) If a partnership, the name of each partner and
17 the name of the partnership.

18 (iii) If a corporation, the name and title of each
19 corporate officer and director, the corporate name and
20 the name of the state of incorporation.

21 (iv) If a person other than a sole proprietorship,
22 partnership or corporation, the name of the person and of
23 the individual in charge of that person.

24 (7) Any other information required by the department,
25 including information bearing upon whether there are grounds
26 for refusing to grant the license under section 7.

27 (b) Changes in information.--A change in any information
28 provided in the application shall be submitted to the department
29 within 30 days after the change or as otherwise required by the
30 department.

1 Section 6. Storage, handling and recordkeeping.

2 (a) Minimum requirements.--Licensees and their officers,
3 agents, representatives and employees shall satisfy the minimum
4 requirements of this section for the storage and handling of
5 prescription drugs and for the establishment and maintenance of
6 prescription drug distribution records.

7 (b) Facility.--The facility shall:

8 (1) Be of suitable size and construction to facilitate
9 cleaning, maintenance and proper operations.

10 (2) Have storage areas designed to provide adequate
11 lighting, ventilation, temperature, sanitation, humidity,
12 space, equipment and security conditions.

13 (3) Have a quarantine area for storage of prescription
14 drugs that are outdated, damaged, deteriorated, misbranded or
15 adulterated or that are in immediate or sealed, secondary
16 containers that have been opened.

17 (4) Be maintained in a clean and orderly condition.

18 (5) Be free from infestation by insects, rodents, birds
19 or vermin of any kind.

20 (c) Security.--The facility shall be secure from
21 unauthorized entry as follows:

22 (1) Access from outside the premises shall be kept to a
23 minimum and be well controlled.

24 (2) The outside perimeter of the premises shall be well
25 lighted.

26 (3) Entry into areas where prescription drugs are held
27 shall be limited to authorized personnel.

28 (4) The facility shall be equipped with an alarm system
29 to detect entry after hours.

30 (5) The facility shall be equipped with a security

1 system that will provide suitable protection against theft
2 and diversion. When appropriate, the security system shall
3 provide protection against theft or diversion that is
4 facilitated or hidden by tampering with computers or
5 electronic records.

6 (d) Storage.--All prescription drugs shall be stored at
7 appropriate temperatures and under appropriate conditions in
8 accordance with requirements, if any, in the labeling of such
9 drugs or with requirements in the current edition of the United
10 States Pharmacopeia/National Formulary (USP/NF). If no storage
11 requirements are established for a prescription drug, the drug
12 may be held at controlled room temperature, as defined in the
13 USP/NF, to help ensure that its identity, strength, quality and
14 purity are not adversely affected. Appropriate manual,
15 electromechanical or electronic temperature and humidity
16 recording equipment, devices or logs shall be utilized to
17 document proper storage of prescription drugs. The recordkeeping
18 requirements under subsection (g) shall be followed for all
19 stored drugs.

20 (e) Examination of materials.--Upon receipt, each outside
21 shipping container shall be visually examined for identity and
22 to prevent the acceptance of contaminated prescription drugs or
23 prescription drugs that are otherwise unfit for distribution.
24 This examination shall be adequate to reveal container damage
25 that would suggest possible contamination or other damage to the
26 contents. Each outgoing shipment shall be carefully inspected
27 for identity of the prescription drug products and to ensure
28 that there is no delivery of prescription drugs that have been
29 damaged in storage or held under improper conditions. The
30 recordkeeping requirements in subsection (g) shall be followed

1 for all incoming and outgoing prescription drugs.

2 (f) Returned, damaged and outdated prescription drugs.--
3 Prescription drugs that are outdated, damaged, deteriorated,
4 misbranded or adulterated shall be quarantined and physically
5 separated from other prescription drugs until they are destroyed
6 or returned to their supplier. Any prescription drugs whose
7 immediate or sealed outer or sealed secondary containers have
8 been opened or used shall be identified as such and shall be
9 quarantined and physically separated from other prescription
10 drugs until they are either destroyed or returned to the
11 supplier. If the conditions under which a prescription drug has
12 been returned cast doubt on the drug's safety, identity,
13 strength, quality or purity, the drug shall be destroyed or
14 returned to the supplier, unless examination, testing or other
15 investigation proves that the drug meets appropriate standards
16 of safety, identity, strength, quality or purity. In determining
17 whether the conditions under which a drug has been returned cast
18 doubt on the drug's safety, identity, strength, quality or
19 purity, the licensee shall consider, among other things, the
20 conditions under which the drug has been held, stored or shipped
21 before or during its return and the condition of the drug and
22 its container, carton or labeling as a result of storage or
23 shipping. The recordkeeping requirements under subsection (g)
24 shall be followed for all outdated, damaged, deteriorated,
25 misbranded or adulterated prescription drugs.

26 (g) Recordkeeping.--

27 (1) The licensee shall establish and maintain
28 inventories and records of all transactions regarding the
29 receipt and distribution or other disposition of prescription
30 drugs. These records shall include the following information:

1 (i) The source of the drugs, including the name and
2 principal address of the seller or transferor, and the
3 address of the location from which the drugs were
4 shipped.

5 (ii) The identity and quantity of the drugs received
6 and distributed or disposed.

7 (iii) The dates of receipt and distribution or other
8 disposition of the drugs.

9 (2) Inventories and records shall be made available for
10 inspection and photocopying by authorized Federal, State or
11 local law enforcement agency officials for a period of two
12 years following disposition of the drugs.

13 (3) Records described in this section that are kept at
14 the facility or that can be immediately retrieved by computer
15 or other electronic means shall be readily available for
16 authorized inspection during the retention period. Records
17 kept at a central location apart from the facility and not
18 electronically retrievable shall be made available for
19 inspection within two working days of an authorized request
20 by an authorized official of a Federal, State or local law
21 enforcement agency.

22 (h) Written policies and procedures.--The licensee shall
23 establish, maintain and adhere to written policies and
24 procedures, which shall be followed for the receipt, security,
25 storage, inventory and distribution of prescription drugs,
26 including policies and procedures for identifying, recording and
27 reporting losses or thefts, and for correcting all errors and
28 inaccuracies in inventories. The licensee shall include in its
29 written policies and procedures the following:

30 (1) A procedure whereby the oldest approved stock of a

1 prescription drug product is distributed first. The procedure
2 may permit deviation from this requirement if the deviation
3 is temporary and appropriate.

4 (2) A procedure to be followed for handling recalls and
5 withdrawals of prescription drugs. The procedure shall be
6 adequate to deal with recalls and withdrawals due to any of
7 the following:

8 (i) Any action initiated at the request of the
9 department, the United States Food and Drug
10 Administration or other Federal, State or local law
11 enforcement or other government agency.

12 (ii) Any voluntary action by the manufacturer to
13 remove defective or potentially defective drugs from the
14 market.

15 (iii) Any action undertaken to promote public health
16 and safety by replacing existing merchandise with an
17 improved product or new package design.

18 (3) A procedure to ensure that the licensee prepares
19 for, protects against and handles any crisis that affects
20 security or operation of the facility in the event of strike,
21 fire, flood or other natural disaster or other situations of
22 national, State or local emergency.

23 (4) A procedure to ensure that any outdated prescription
24 drugs shall be segregated from other drugs and either
25 returned to the manufacturer or destroyed. This procedure
26 shall provide for written documentation of the disposition of
27 outdated prescription drugs. This documentation shall be
28 maintained for two years after disposition of the outdated
29 drugs.

30 (i) Responsible persons.--The licensee shall:

1 (1) Establish and maintain lists of officers, directors,
2 managers and other persons in charge of wholesale drug
3 distribution, storage and handling, including a description
4 of their duties and a summary of their qualifications.

5 (2) Ensure that all personnel involved in the wholesale
6 distribution of prescription drugs have an adequate
7 combination of education, training and experience to perform
8 their duties in a manner that ensures compliance with this
9 act and applicable regulations.

10 (j) Salvaging and reprocessing.--The licensee shall comply
11 with any applicable Federal, State or local law or regulation
12 that relates to prescription drug salvaging or reprocessing.

13 (k) Compliance with Federal, State and local law.--The
14 licensee shall operate in compliance with applicable Federal,
15 State and local laws and regulations. The licensee shall permit
16 the department and authorized Federal, State and local law
17 enforcement officials to enter and inspect its premises and
18 delivery vehicles and to audit its records and written operating
19 procedures, at reasonable times and in a reasonable manner, to
20 the extent authorized by law. The licensee that deals in
21 controlled substances shall register with the Drug Enforcement
22 Administration (DEA) and shall comply with all applicable DEA,
23 State and local regulations.

24 Section 7. Additional requirements.

25 The department may, BY REGULATION, establish additional <—
26 requirements for the distribution, storage and handling of
27 prescription drugs and for the establishment and maintenance of
28 prescription drug distribution records. The department may also, <—
29 BY REGULATION, modify the standards in section 6 if modification
30 of those standards is necessary to satisfy minimum requirements

1 contained in the United States Department of Health and Human
2 Services regulations setting forth guidelines for state
3 licensing of persons who engage in the wholesale distribution of
4 prescription drugs.

5 Section 8. Persons without license and current renewal.

6 Any person who does not have a license and current renewal
7 and who operates a facility in this Commonwealth through which
8 it engages in the wholesale distribution of prescription drugs
9 shall comply with the requirements of sections 6 and 7,
10 notwithstanding the person's failure to secure a license or a
11 current renewal.

12 Section 9. Refusal, revocation, suspension or limitation of
13 license.

14 (a) Reasons for discipline.--The department may refuse to
15 issue or may suspend, revoke or limit any and all licenses held
16 by a licensee or fine a licensee for any of the following
17 reasons:

18 (1) Failing to demonstrate the qualifications for a
19 license.

20 (2) Violating any provision of this act.

21 (3) Being convicted of a felony or of a crime relating
22 to drug samples, wholesale or retail drug distribution or any
23 other law relating to the handling of drugs.

24 (4) Making misleading, deceptive, untrue or fraudulent
25 representations in obtaining or seeking to obtain a license
26 or registration.

27 (5) Having a license or equivalent authorization
28 currently or previously held for the manufacture or
29 distribution of any drugs denied, suspended, revoked,
30 restricted or subjected to any other sanction for

1 disciplinary reasons by a Federal, State or local government
2 agency.

3 (6) Violating a regulation promulgated by the department
4 or violating a lawful order of the department entered in a
5 disciplinary proceeding.

6 (7) Engaging in conduct which is harmful to the public
7 health, safety or welfare.

8 (b) Notice of deficiencies.--Whenever the department shall,
9 upon inspection, investigation or complain, preliminarily find a
10 violation of this act or the regulations promulgated thereunder,
11 it may, in lieu of proceeding with disciplinary action, issue a
12 written notice to the licensee specifying the violation and
13 directing that the violation be corrected and that a written
14 plan of correction be filed with it by a specified date. The
15 licensee shall respond as directed and shall either deny the
16 alleged violation or provide a plan of correction by the date
17 specified in the notice. If the plan of correction is accepted
18 by the department, the licensee shall implement it as directed
19 by the department.

20 (c) Reinstatement.--A person whose license has been revoked
21 may not apply for reinstatement until five years have expired
22 during which the license was revoked.

23 Section 10. Injunction against unlawful practice.

24 The department may maintain an action for an injunction to
25 restrain a person from operating a facility within this
26 Commonwealth through which it engages in the wholesale
27 distribution of prescription drugs when that person does not
28 have a license and a current renewal of that license as required
29 by this act. To secure an injunction, it shall not be necessary
30 to show that any person has been injured by the actions

1 complained of. The remedy of injunction is an addition to any
2 other administrative, civil or criminal remedy authorized.

3 Section 11. Penalties for unlicensed practice.

4 (a) Civil penalty.--The department shall have authority to
5 assess a civil penalty of up to \$500 for each day that a person
6 engages in the wholesale distribution of prescription drugs
7 without a license as required by this act.

8 (b) Criminal penalty.--A person who engages in the wholesale
9 distribution of prescription drugs without a license as required
10 by this act commits a misdemeanor of the third degree and shall,
11 upon conviction, be sentenced to pay a fine of not more than
12 \$2,000 and to imprisonment for not more than six months, or
13 both, for the first violation. On the second and each subsequent
14 conviction, the person shall be sentenced to pay a fine of not
15 less than \$5,000 nor more than \$20,000 or to imprisonment for
16 not less than six months nor more than one year, or both.

17 Section 12. Disciplinary proceedings.

18 All actions of the department taken under sections 9(a) and
19 11(a) shall be subject to the right of notice, hearing and
20 adjudication and the right of appeal therefrom, in accordance
21 with the provisions of 2 Pa.C.S. (relating to administrative law
22 and procedure).

23 Section 13. Right to enter and inspect.

24 For the purpose of determining the suitability of an
25 applicant for licensure and for the purpose of determining
26 compliance with the provisions of this act and applicable
27 regulations of any person licensed or requiring a license under
28 this act, the department by its authorized agent may enter,
29 visit and inspect the building, grounds and equipment and
30 supplies of any facility engaging or appearing to engage in the

1 wholesale distribution of prescription drugs, shall have full
2 and free access to the records of the facility and to the
3 employees therein and their records and shall have full
4 opportunity to interview employees and inspect such premises and
5 records of the facility. Upon entering the facility, the
6 authorized agents shall properly identify themselves to the
7 individual on the premises then in charge of the facility.

8 Section 14. Rules and regulations.

9 The department may promulgate rules and regulations to
10 administer and enforce this act.

11 Section 15. Severability.

12 The provisions of this act are severable. If any provision of
13 this act or its application to any person or circumstances is
14 held invalid, the invalidity shall not affect other provisions
15 or applications of this act which can be given effect without
16 the invalid provision or application.

17 Section 16. Repeal.

18 The act of April 14, 1972 (P.L.233, No.64), known as The
19 Controlled Substance, Drug, Device and Cosmetic Act, is repealed
20 insofar as it is inconsistent with this act.

21 Section 17. Effective date.

22 This act shall take effect immediately.