
THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 2602 Session of
1992

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PISTELLA AND KOSINSKI, APRIL 6, 1992

AS REPORTED FROM COMMITTEE ON HEALTH AND WELFARE, HOUSE OF
REPRESENTATIVES, AS AMENDED, JUNE 9, 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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7 The General Assembly of the Commonwealth of Pennsylvania
8 hereby enacts as follows:

9 Section 1. Short title.

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

12 Section 2. Legislative intent.

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

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

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

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

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

6 Section 3. Definitions.

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

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

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

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

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

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

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

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

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

30 "Prescription drug." Any human drug required by Federal law,

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

7 "Wholesale distribution of prescription drugs." Distribution
8 IN INTERSTATE COMMERCE of prescription drugs to persons other ←
9 than a consumer or patient, but does not include:

10 (1) Intracompany sales.

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

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

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

25 (5) The sale, purchase or trade of a drug or an offer to
26 sell, purchase or trade a drug for emergency medical reasons,
27 including transfers of prescription drugs by a retail
28 pharmacy to another retail pharmacy to alleviate a temporary
29 shortage.

30 (6) The sale, purchase or trade of a drug, an offer to

1 sell, purchase or trade a drug or the dispensing of a drug
2 pursuant to a prescription.

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

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

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

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

20 Section 4. License and renewal requirements.

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

27 (b) License renewal.--A licensee shall renew its license at
28 the same time it is required to renew the registration issued to
29 it under the act of April 14, 1972 (P.L.233, No.64), known as
30 The Controlled Substance, Drug, Device and Cosmetic Act, or as

1 otherwise required by the department, but in no case shall the
2 period for renewing the license be longer than two years. A form
3 for the license renewal shall be mailed to each licensee on or
4 before the first day of the month in which the current renewal
5 expires. If a completed license renewal is neither postmarked
6 nor received by the department before the first day of the
7 following month, the license shall become invalid. Failure of
8 the licensee to receive the form by mail shall not serve as an
9 excuse for failing to timely renew the license.

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

21 Section 5. License application.

22 (a) Information on application.--An applicant for a license
23 shall provide the following information on a license application
24 form approved by the department:

25 (1) The name, full business address and telephone number
26 of the facility for which the applicant is seeking a license
27 to operate.

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

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

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

5 (5) The type of ownership or operation, that is,
6 partnership, corporation or sole proprietorship, of the
7 facility.

8 (6) The name of the owner and operator of the facility
9 as follows:

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

12 (ii) If a partnership, the name of each partner and
13 the name of the partnership.

14 (iii) If a corporation, the name and title of each
15 corporate officer and director, the corporate name and
16 the name of the state of incorporation.

17 (iv) If a person other than a sole proprietorship,
18 partnership or corporation, the name of the person and of
19 the individual in charge of that person.

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

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

27 Section 6. Storage, handling and recordkeeping.

28 (a) Minimum requirements.--Licensees and their officers,
29 agents, representatives and employees shall satisfy the minimum
30 requirements of this section for the storage and handling of

1 prescription drugs and for the establishment and maintenance of
2 prescription drug distribution records.

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

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

6 (2) Have storage areas designed to provide adequate
7 lighting, ventilation, temperature, sanitation, humidity,
8 space, equipment and security conditions.

9 (3) Have a quarantine area for storage of prescription
10 drugs that are outdated, damaged, deteriorated, misbranded or
11 adulterated or that are in immediate or sealed, secondary
12 containers that have been opened.

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

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

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

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

20 (2) The outside perimeter of the premises shall be well
21 lighted.

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

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

26 (5) The facility shall be equipped with a security
27 system that will provide suitable protection against theft
28 and diversion. When appropriate, the security system shall
29 provide protection against theft or diversion that is
30 facilitated or hidden by tampering with computers or

1 electronic records.

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

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

28 (f) Returned, damaged and outdated prescription drugs.--
29 Prescription drugs that are outdated, damaged, deteriorated,
30 misbranded or adulterated shall be quarantined and physically

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

22 (g) Recordkeeping.--

23 (1) The licensee shall establish and maintain
24 inventories and records of all transactions regarding the
25 receipt and distribution or other disposition of prescription
26 drugs. These records shall include the following information:

27 (i) The source of the drugs, including the name and
28 principal address of the seller or transferor, and the
29 address of the location from which the drugs were
30 shipped.

1 (ii) The identity and quantity of the drugs received
2 and distributed or disposed.

3 (iii) The dates of receipt and distribution or other
4 disposition of the drugs.

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

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

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

26 (1) A procedure whereby the oldest approved stock of a
27 prescription drug product is distributed first. The procedure
28 may permit deviation from this requirement if the deviation
29 is temporary and appropriate.

30 (2) A procedure to be followed for handling recalls and

1 withdrawals of prescription drugs. The procedure shall be
2 adequate to deal with recalls and withdrawals due to any of
3 the following:

4 (i) Any action initiated at the request of the
5 department, the United States Food and Drug
6 Administration or other Federal, State or local law
7 enforcement or other government agency.

8 (ii) Any voluntary action by the manufacturer to
9 remove defective or potentially defective drugs from the
10 market.

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

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

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

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

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

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

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

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

20 Section 7. Additional requirements.

21 The department may establish additional requirements for the
22 distribution, storage and handling of prescription drugs and for
23 the establishment and maintenance of prescription drug
24 distribution records. The department may also modify the
25 standards in section 6 if modification of those standards is
26 necessary to satisfy minimum requirements contained in the
27 United States Department of Health and Human Services
28 regulations setting forth guidelines for state licensing of
29 persons who engage in the wholesale distribution of prescription
30 drugs.

1 Section 8. Persons without license and current renewal.

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

8 Section 9. Refusal, revocation, suspension or limitation of
9 license.

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

14 (1) Failing to demonstrate the qualifications for a
15 license.

16 (2) Violating any provision of this act.

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

20 (4) Making misleading, deceptive, untrue or fraudulent
21 representations in obtaining or seeking to obtain a license
22 or registration.

23 (5) Having a license or equivalent authorization
24 currently or previously held for the manufacture or
25 distribution of any drugs denied, suspended, revoked,
26 restricted or subjected to any other sanction for
27 disciplinary reasons by a Federal, State or local government
28 agency.

29 (6) Violating a regulation promulgated by the department
30 or violating a lawful order of the department entered in a

1 disciplinary proceeding.

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

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

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

19 Section 10. Injunction against unlawful practice.

20 The department may maintain an action for an injunction to
21 restrain a person from operating a facility within this
22 Commonwealth through which it engages in the wholesale
23 distribution of prescription drugs when that person does not
24 have a license and a current renewal of that license as required
25 by this act. To secure an injunction, it shall not be necessary
26 to show that any person has been injured by the actions
27 complained of. The remedy of injunction is an addition to any
28 other administrative, civil or criminal remedy authorized.

29 Section 11. Penalties for unlicensed practice.

30 (a) Civil penalty.--The department shall have authority to

1 assess a civil penalty of up to \$500 for each day that a person
2 engages in the wholesale distribution of prescription drugs
3 without a license as required by this act.

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

13 Section 12. Disciplinary proceedings.

14 All actions of the department taken under sections 9(a) and
15 11(a) shall be subject to the right of notice, hearing and
16 adjudication and the right of appeal therefrom, in accordance
17 with the provisions of 2 Pa.C.S. (relating to administrative law
18 and procedure).

19 Section 13. Right to enter and inspect.

20 For the purpose of determining the suitability of an
21 applicant for licensure and for the purpose of determining
22 compliance with the provisions of this act and applicable
23 regulations of any person licensed or requiring a license under
24 this act, the department by its authorized agent may enter,
25 visit and inspect the building, grounds and equipment and
26 supplies of any facility engaging or appearing to engage in the
27 wholesale distribution of prescription drugs, shall have full
28 and free access to the records of the facility and to the
29 employees therein and their records and shall have full
30 opportunity to interview employees and inspect such premises and

1 records of the facility. Upon entering the facility, the
2 authorized agents shall properly identify themselves to the
3 individual on the premises then in charge of the facility.

4 Section 14. Rules and regulations.

5 The department may promulgate rules and regulations to
6 administer and enforce this act.

7 Section 15. Severability.

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

13 Section 16. Repeal.

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

17 Section 17. Effective date.

18 This act shall take effect immediately.