

1 AN ACT concerning the regulation of professions.

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

4 Section 5. The Regulatory Sunset Act is amended by
5 changing Section 4.13 and adding Section 4.23 as follows:

6 (5 ILCS 80/4.13) (from Ch. 127, par. 1904.13)

7 Sec. 4.13. Acts repealed on December 31, 2002. The
8 following Acts are repealed on December 31, 2002:

9 The Environmental Health Practitioner Licensing Act.

10 The Naprapathic Practice Act.

11 ~~The Wholesale Drug Distribution Licensing Act.~~

12 The Dietetic and Nutrition Services Practice Act.

13 The Funeral Directors and Embalmers Licensing Code.

14 The Professional Counselor and Clinical Professional
15 Counselor Licensing Act.

16 (Source: P.A. 88-45; 89-61, eff. 6-30-95; revised 8-22-01.)

17 (5 ILCS 80/4.23 new)

18 Sec. 4.23. Act repealed on January 1, 2013. The
19 following Act is repealed on January 1, 2013:

20 The Wholesale Drug Distribution Licensing Act.

21 Section 10. The Wholesale Drug Distribution Licensing
22 Act is amended by changing Sections 25 and 35 as follows:

23 (225 ILCS 120/25) (from Ch. 111, par. 8301-25)

24 (Section scheduled to be repealed on December 31, 2002)

25 Sec. 25. Wholesale drug distributor licensing
26 requirements. All wholesale distributors and pharmacy
27 distributors, wherever located, who engage in wholesale
28 distribution into, out of, or within the State shall be

1 subject to the following requirements:

2 (a) No person or distribution outlet shall act as a
3 wholesale drug distributor without first obtaining a license
4 to do so from the Department and paying any reasonable fee
5 required by the Department, ~~7--the-fee-not-to--exceed--\$200--per~~
6 year.

7 (b) The Department may grant a temporary license when a
8 wholesale drug distributor first applies for a license to
9 operate within this State. A temporary license shall remain
10 valid until the Department finds that the applicant meets or
11 fails to meet the requirements for regular licensure.
12 Nevertheless, no temporary license shall be valid for more
13 than 90 days from the date of issuance. Any temporary
14 license issued under this subsection shall be renewable for a
15 similar period of time not to exceed 90 days under policies
16 and procedures prescribed by the Department.

17 (c) No license shall be issued or renewed for a
18 wholesale drug distributor to operate unless the wholesale
19 drug distributor shall operate in a manner prescribed by law
20 and according to the rules and regulations promulgated by the
21 Department.

22 (d) The Department may require a separate license for
23 each facility directly or indirectly owned or operated by the
24 same business entity within this State, or for a parent
25 entity with divisions, subsidiaries, and affiliate companies
26 within this State when operations are conducted at more than
27 one location and there exists joint ownership and control
28 among all the entities.

29 (e) As a condition for receiving and renewing any
30 wholesale drug distributor license issued under this Act,
31 each applicant shall satisfy the Department that it has and
32 will continuously maintain:

33 (1) acceptable storage and handling conditions plus
34 facilities standards;

1 (2) minimum liability and other insurance as may be
2 required under any applicable federal or State law;

3 (3) a security system that includes after hours,
4 central alarm or comparable entry detection capability;
5 restricted premises access; adequate outside perimeter
6 lighting; comprehensive employment applicant screening;
7 and safeguards against employee theft;

8 (4) an electronic, manual, or any other reasonable
9 system of records, describing all wholesale distributor
10 activities governed by this Act for the 2 year period
11 following disposition of each product and reasonably
12 accessible during regular business hours as defined by
13 the Department's rules in any inspection authorized by
14 the Department;

15 (5) officers, directors, managers, and other
16 persons in charge of wholesale drug distribution,
17 storage, and handling who must at all times demonstrate
18 and maintain their capability of conducting business
19 according to sound financial practices as well as State
20 and federal law;

21 (6) complete, updated information, to be provided
22 the Department as a condition for obtaining and renewing
23 a license, about each wholesale distributor to be
24 licensed under this Act, including all pertinent licensee
25 ownership and other key personnel and facilities
26 information deemed necessary for enforcement of this Act.
27 Any changes in this information shall be submitted at the
28 time of license renewal or within 45 days from the date
29 of the change;

30 (7) written policies and procedures that assure
31 reasonable wholesale distributor preparation for,
32 protection against and handling of any facility security
33 or operation problems, including, but not limited to,
34 those caused by natural disaster or government emergency;

1 inventory inaccuracies or product shipping and receiving;
2 outdated product or other unauthorized product control;
3 appropriate disposition of returned goods; and product
4 recalls;

5 (8) sufficient inspection procedures for all
6 incoming and outgoing product shipments; and

7 (9) operations in compliance with all federal legal
8 requirements applicable to wholesale drug distribution.

9 (f) The Department shall consider, at a minimum, the
10 following factors in reviewing the qualifications of persons
11 who engage in wholesale distribution of prescription drugs in
12 this State:

13 (1) any conviction of the applicant under any
14 federal, State, or local laws relating to drug samples,
15 wholesale or retail drug distribution, or distribution of
16 controlled substances;

17 (2) any felony convictions of the applicant under
18 federal, State, or local laws;

19 (3) the applicant's past experience in the
20 manufacture or distribution of prescription drugs,
21 including controlled substances;

22 (4) the furnishing by the applicant of false or
23 fraudulent material in any application made in connection
24 with drug manufacturing or distribution;

25 (5) suspension or revocation by federal, State, or
26 local government of any license currently or previously
27 held by the applicant for the manufacture or distribution
28 of any drug, including controlled substances;

29 (6) compliance with licensing requirements under
30 previously granted licenses, if any;

31 (7) compliance with requirements to maintain and
32 make available to the Department or to federal, State, or
33 local law enforcement officials those records required by
34 this Act; and

1 (8) any other factors or qualifications the
 2 Department considers relevant to and consistent with the
 3 public health and safety, including whether the granting
 4 of the license would not be in the public interest.

5 (9) All requirements set forth in this subsection
 6 shall conform to wholesale drug distributor licensing
 7 guidelines formally adopted by the U.S. Food and Drug
 8 Administration (FDA). In case of conflict between any
 9 wholesale drug distributor licensing requirement imposed
 10 by the Department and any FDA wholesale drug distributor
 11 licensing guideline, the FDA guideline shall control.

12 (g) An agent or employee of any licensed wholesale drug
 13 distributor need not seek licensure under this Section and
 14 may lawfully possess pharmaceutical drugs when the agent or
 15 employee is acting in the usual course of business or
 16 employment.

17 (h) The issuance of a license under this Act shall not
 18 change or affect tax liability imposed by the State on any
 19 wholesale drug distributor.

20 (i) A license issued under this Act shall not be sold,
 21 transferred, or assigned in any manner.

22 (Source: P.A. 87-594.)

23 (225 ILCS 120/35) (from Ch. 111, par. 8301-35)
 24 (Section scheduled to be repealed on December 31, 2002)
 25 Sec. 35. Fees; Illinois State Pharmacy Disciplinary Fund.

26 (a) The Department shall provide by rule for a schedule
 27 of fees for the administration and enforcement of this Act,
 28 including but not limited to original licensure, renewal, and
 29 restoration. The fees shall be nonrefundable. The--following
 30 fees---shall--be--imposed--by--the--Department--and--are--not
 31 refundable-

32 ~~(1)--The-fee-for-application-for--a--certificate--of~~
 33 ~~registration-as-a-wholesale-drug-distributor-is-\$200-~~

1 (2)--The--fee--for--the--renewal--of--a--certificate--of
2 registration--as--a--wholesale--drug--distributor--is--\$200--per
3 year.

4 (3)--The--fee--for--the--change--of--person--responsible
5 for--drugs--is--\$50.

6 (4)--The--fee--for--the--issuance--of--a--duplicate--license
7 to--replace--a--license--that--has--been--lost--or--destroyed--is
8 \$25.

9 (5)--The--fee--for--certification--of--a--registrant's
10 record--for--any--purpose--is--\$25.

11 (6)--The--fee--for--a--roster--of--licensed--wholesale--drug
12 distributors--shall--be--the--actual--cost--of--producing--the
13 roster.

14 (7)--The--fee--for--wholesale--drug--distributor
15 licensing,--disciplinary,--or--investigative--records
16 obtained--under--subpoena--is--\$1--per--page.

17 (b) All fees collected under this Act shall be deposited
18 into the Illinois State Pharmacy Disciplinary Fund and shall
19 be appropriated to the Department for the ordinary and
20 contingent expenses of the Department in the administration
21 of this Act. All moneys received by the Department under this
22 Act--shall--be--deposited--into--the--Illinois--State--Pharmacy
23 Disciplinary--Fund--in--the--State--Treasury--and--shall--be--used
24 only--for--the--following--purposes:--(i)--by--the--State--Board--of
25 Pharmacy--in--the--exercise--of--its--powers--and--performance--of--its
26 duties,--as--such--use--is--made--by--the--Department--upon--the
27 recommendations--of--the--State--Board--of--Pharmacy,--(ii)--for
28 costs--directly--related--to--license--renewal--of--persons--licensed
29 under--this--Act,--and--(iii)--for--direct--and--allocable--indirect
30 costs--related--to--the--public--purposes--of--the--Department--of
31 Professional--Regulation. Moneys in the Fund may be
32 transferred to the Professions Indirect Cost Fund as
33 authorized by Section 2105-300 of the Department of
34 Professional Regulation Law (20 ILCS 2105/2105-300).

1 The moneys deposited into the Illinois State Pharmacy
2 Disciplinary Fund shall be invested to earn interest which
3 shall accrue to the Fund.

4 The Department shall present to the Board for its review
5 and comment all appropriation requests from the Illinois
6 State Pharmacy Disciplinary Fund. The Department shall give
7 due consideration to any comments of the Board in making
8 appropriation requests.

9 (c) Any person who delivers a check or other payment to
10 the Department that is returned to the Department unpaid by
11 the financial institution upon which it is drawn shall pay to
12 the Department, in addition to the amount already owed to the
13 Department, a fine of \$50. The fines imposed by this
14 Section are in addition to any other discipline provided
15 under this Act for unlicensed practice or practice on a
16 nonrenewed license. The Department shall notify the person
17 that payment of fees and fines shall be paid to the
18 Department by certified check or money order within 30
19 calendar days of the notification. If, after the expiration
20 of 30 days from the date of the notification, the person has
21 failed to submit the necessary remittance, the Department
22 shall automatically terminate the license or certificate or
23 deny the application, without hearing. If, after termination
24 or denial, the person seeks a license or certificate, he or
25 she shall apply to the Department for restoration or issuance
26 of the license or certificate and pay all fees and fines due
27 to the Department. The Department may establish a fee for
28 the processing of an application for restoration of a license
29 or certificate to pay all expenses of processing this
30 application. The Director may waive the fines due under this
31 Section in individual cases where the Director finds that the
32 fines would be unreasonable or unnecessarily burdensome.

33 (d) The Department shall maintain a roster of the names
34 and addresses of all registrants and of all persons whose

1 licenses have been suspended or revoked. This roster shall
2 be available upon written request and payment of the required
3 fee.

4 (Source: P.A. 91-239, eff. 1-1-00; 92-146, eff. 1-1-02.)

5 Section 99. Effective date. This Act takes effect upon
6 becoming law.