

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 Acts repealed on December 31, 2002.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8 following Acts are repealed on December 31, 2002: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 Act repealed on January 1, 2013.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19 following Act is repealed on January 1, 2013: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24 (Section scheduled to be repealed on December 31, 2002)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, ~~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.