

1 AMENDMENT TO SENATE BILL 1685

2 AMENDMENT NO. _____. Amend Senate Bill 1685 on page 1,
3 immediately below line 20, by inserting the following:

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

6 (225 ILCS 120/25) (from Ch. 111, par. 8301-25)

7 (Section scheduled to be repealed on December 31, 2002)

8 Sec. 25. Wholesale drug distributor licensing
9 requirements. All wholesale distributors and pharmacy
10 distributors, wherever located, who engage in wholesale
11 distribution into, out of, or within the State shall be
12 subject to the following requirements:

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

18 (b) The Department may grant a temporary license when a
19 wholesale drug distributor first applies for a license to
20 operate within this State. A temporary license shall remain
21 valid until the Department finds that the applicant meets or
22 fails to meet the requirements for regular licensure.

1 Nevertheless, no temporary license shall be valid for more
2 than 90 days from the date of issuance. Any temporary
3 license issued under this subsection shall be renewable for a
4 similar period of time not to exceed 90 days under policies
5 and procedures prescribed by the Department.

6 (c) No license shall be issued or renewed for a
7 wholesale drug distributor to operate unless the wholesale
8 drug distributor shall operate in a manner prescribed by law
9 and according to the rules and regulations promulgated by the
10 Department.

11 (d) The Department may require a separate license for
12 each facility directly or indirectly owned or operated by the
13 same business entity within this State, or for a parent
14 entity with divisions, subsidiaries, and affiliate companies
15 within this State when operations are conducted at more than
16 one location and there exists joint ownership and control
17 among all the entities.

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

22 (1) acceptable storage and handling conditions plus
23 facilities standards;

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

26 (3) a security system that includes after hours,
27 central alarm or comparable entry detection capability;
28 restricted premises access; adequate outside perimeter
29 lighting; comprehensive employment applicant screening;
30 and safeguards against employee theft;

31 (4) an electronic, manual, or any other reasonable
32 system of records, describing all wholesale distributor
33 activities governed by this Act for the 2 year period
34 following disposition of each product and reasonably

1 accessible during regular business hours as defined by
2 the Department's rules in any inspection authorized by
3 the Department;

4 (5) officers, directors, managers, and other
5 persons in charge of wholesale drug distribution,
6 storage, and handling who must at all times demonstrate
7 and maintain their capability of conducting business
8 according to sound financial practices as well as State
9 and federal law;

10 (6) complete, updated information, to be provided
11 the Department as a condition for obtaining and renewing
12 a license, about each wholesale distributor to be
13 licensed under this Act, including all pertinent licensee
14 ownership and other key personnel and facilities
15 information deemed necessary for enforcement of this Act.
16 Any changes in this information shall be submitted at the
17 time of license renewal or within 45 days from the date
18 of the change;

19 (7) written policies and procedures that assure
20 reasonable wholesale distributor preparation for,
21 protection against and handling of any facility security
22 or operation problems, including, but not limited to,
23 those caused by natural disaster or government emergency;
24 inventory inaccuracies or product shipping and receiving;
25 outdated product or other unauthorized product control;
26 appropriate disposition of returned goods; and product
27 recalls;

28 (8) sufficient inspection procedures for all
29 incoming and outgoing product shipments; and

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

32 (f) The Department shall consider, at a minimum, the
33 following factors in reviewing the qualifications of persons
34 who engage in wholesale distribution of prescription drugs in

1 this State:

2 (1) any conviction of the applicant under any
3 federal, State, or local laws relating to drug samples,
4 wholesale or retail drug distribution, or distribution of
5 controlled substances;

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

8 (3) the applicant's past experience in the
9 manufacture or distribution of prescription drugs,
10 including controlled substances;

11 (4) the furnishing by the applicant of false or
12 fraudulent material in any application made in connection
13 with drug manufacturing or distribution;

14 (5) suspension or revocation by federal, State, or
15 local government of any license currently or previously
16 held by the applicant for the manufacture or distribution
17 of any drug, including controlled substances;

18 (6) compliance with licensing requirements under
19 previously granted licenses, if any;

20 (7) compliance with requirements to maintain and
21 make available to the Department or to federal, State, or
22 local law enforcement officials those records required by
23 this Act; and

24 (8) any other factors or qualifications the
25 Department considers relevant to and consistent with the
26 public health and safety, including whether the granting
27 of the license would not be in the public interest.

28 (9) All requirements set forth in this subsection
29 shall conform to wholesale drug distributor licensing
30 guidelines formally adopted by the U.S. Food and Drug
31 Administration (FDA). In case of conflict between any
32 wholesale drug distributor licensing requirement imposed
33 by the Department and any FDA wholesale drug distributor
34 licensing guideline, the FDA guideline shall control.

1 (g) An agent or employee of any licensed wholesale drug
 2 distributor need not seek licensure under this Section and
 3 may lawfully possess pharmaceutical drugs when the agent or
 4 employee is acting in the usual course of business or
 5 employment.

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

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

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

12 (225 ILCS 120/35) (from Ch. 111, par. 8301-35)
 13 (Section scheduled to be repealed on December 31, 2002)
 14 Sec. 35. Fees; Illinois State Pharmacy Disciplinary Fund.

15 (a) The Department shall provide by rule for a schedule
 16 of fees for the administration and enforcement of this Act,
 17 including but not limited to original licensure, renewal, and
 18 restoration. The fees shall be nonrefundable. The--following
 19 fees---shall--be--imposed--by--the--Department--and--are--not
 20 refundable-

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

23 (2)--The--fee--for--the--renewal-of-a-certificate-of
 24 registration-as-a-wholesale-drug-distributor-is-\$200--per
 25 year-

26 (3)--The--fee--for--the-change-of-person-responsible
 27 for-drugs-is-\$50-

28 (4)--The-fee-for-the-issuance-of-a-duplicate-license
 29 to-replace-a-license-that-has-been-lost-or--destroyed--is
 30 \$25-

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

33 (6)--The-fee-for-a-roster-of-licensed-wholesale-drug

1 distributors shall be the actual cost of producing the
2 roster.

3 (7) The fee for wholesale drug distributor
4 licensing, disciplinary, or investigative records
5 obtained under subpoena is \$1 per page.

6 (b) All fees collected under this Act shall be deposited
7 into the Illinois State Pharmacy Disciplinary Fund and shall
8 be appropriated to the Department for the ordinary and
9 contingent expenses of the Department in the administration
10 of this Act. All moneys received by the Department under this
11 Act shall be deposited into the Illinois State Pharmacy
12 Disciplinary Fund in the State Treasury and shall be used
13 only for the following purposes: (i) by the State Board of
14 Pharmacy in the exercise of its powers and performance of its
15 duties, as such use is made by the Department upon the
16 recommendations of the State Board of Pharmacy; (ii) for
17 costs directly related to license renewal of persons licensed
18 under this Act; and (iii) for direct and allocable indirect
19 costs related to the public purposes of the Department of
20 Professional Regulation. Moneys in the Fund may be
21 transferred to the Professions Indirect Cost Fund as
22 authorized by Section 2105-300 of the Department of
23 Professional Regulation Law (20 ILCS 2105/2105-300).

24 The moneys deposited into the Illinois State Pharmacy
25 Disciplinary Fund shall be invested to earn interest which
26 shall accrue to the Fund.

27 The Department shall present to the Board for its review
28 and comment all appropriation requests from the Illinois
29 State Pharmacy Disciplinary Fund. The Department shall give
30 due consideration to any comments of the Board in making
31 appropriation requests.

32 (c) Any person who delivers a check or other payment to
33 the Department that is returned to the Department unpaid by
34 the financial institution upon which it is drawn shall pay to

1 the Department, in addition to the amount already owed to the
2 Department, a fine of \$50. The fines imposed by this
3 Section are in addition to any other discipline provided
4 under this Act for unlicensed practice or practice on a
5 nonrenewed license. The Department shall notify the person
6 that payment of fees and fines shall be paid to the
7 Department by certified check or money order within 30
8 calendar days of the notification. If, after the expiration
9 of 30 days from the date of the notification, the person has
10 failed to submit the necessary remittance, the Department
11 shall automatically terminate the license or certificate or
12 deny the application, without hearing. If, after termination
13 or denial, the person seeks a license or certificate, he or
14 she shall apply to the Department for restoration or issuance
15 of the license or certificate and pay all fees and fines due
16 to the Department. The Department may establish a fee for
17 the processing of an application for restoration of a license
18 or certificate to pay all expenses of processing this
19 application. The Director may waive the fines due under this
20 Section in individual cases where the Director finds that the
21 fines would be unreasonable or unnecessarily burdensome.

22 (d) The Department shall maintain a roster of the names
23 and addresses of all registrants and of all persons whose
24 licenses have been suspended or revoked. This roster shall
25 be available upon written request and payment of the required
26 fee.

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