



94TH GENERAL ASSEMBLY
State of Illinois
2005 and 2006
SB2909

Introduced 1/20/2006, by Sen. Ira I. Silverstein

SYNOPSIS AS INTRODUCED:

225 ILCS 120/25
225 ILCS 120/50

from Ch. 111, par. 8301-25
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Amends the Wholesale Drug Distribution Act. Provides that an applicant for temporary licensure must meet the inspection requirements for regular licensure before the temporary license shall be granted. Removes a provision that requires the Department of Financial and Professional Regulation to employ an Assistant Drug Compliance Coordinator to assist the Drug Compliance Coordinator in administering and enforcing the Act.

LRB094 18023 RAS 53328 b

FISCAL NOTE ACT
MAY APPLY

1 AN ACT concerning regulation.

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

4 Section 5. The Wholesale Drug Distribution Licensing Act is
5 amended by changing Sections 25 and 50 as follows:

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

7 (Section scheduled to be repealed on January 1, 2013)

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 subject
12 to the following requirements:

13 (a) No person or distribution outlet shall act as a
14 wholesale drug distributor without first obtaining a license to
15 do so from the Department and paying any reasonable fee
16 required by the Department.

17 (b) The Department may grant a temporary license when a
18 wholesale drug distributor first applies for a license to
19 operate within this State. A temporary license shall only be
20 granted after the applicant meets the inspection requirements
21 for regular licensure and shall remain valid until the
22 Department finds that the applicant meets or fails to meet the
23 requirements for regular licensure. Nevertheless, no temporary
24 license shall be valid for more than 90 days from the date of
25 issuance. Any temporary license issued under this subsection
26 shall be renewable for a similar period of time not to exceed
27 90 days under policies and procedures prescribed by the
28 Department.

29 (c) No license shall be issued or renewed for a wholesale
30 drug distributor to operate unless the wholesale drug
31 distributor shall operate in a manner prescribed by law and
32 according to the rules and regulations promulgated by the

1 Department.

2 (d) The Department may require a separate license for each
3 facility directly or indirectly owned or operated by the same
4 business entity within this State, or for a parent entity with
5 divisions, subsidiaries, and affiliate companies within this
6 State when operations are conducted at more than one location
7 and there exists joint ownership and control among all the
8 entities.

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

13 (1) acceptable storage and handling conditions plus
14 facilities standards;

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

17 (3) a security system that includes after hours,
18 central alarm or comparable entry detection capability;
19 restricted premises access; adequate outside perimeter
20 lighting; comprehensive employment applicant screening;
21 and safeguards against employee theft;

22 (4) an electronic, manual, or any other reasonable
23 system of records, describing all wholesale distributor
24 activities governed by this Act for the 2 year period
25 following disposition of each product and reasonably
26 accessible during regular business hours as defined by the
27 Department's rules in any inspection authorized by the
28 Department;

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

34 (6) complete, updated information, to be provided the
35 Department as a condition for obtaining and renewing a
36 license, about each wholesale distributor to be licensed

1 under this Act, including all pertinent licensee ownership
2 and other key personnel and facilities information deemed
3 necessary for enforcement of this Act. Any changes in this
4 information shall be submitted at the time of license
5 renewal or within 45 days from the date of the change;

6 (7) written policies and procedures that assure
7 reasonable wholesale distributor preparation for,
8 protection against and handling of any facility security or
9 operation problems, including, but not limited to, those
10 caused by natural disaster or government emergency;
11 inventory inaccuracies or product shipping and receiving;
12 outdated product or other unauthorized product control;
13 appropriate disposition of returned goods; and product
14 recalls;

15 (8) sufficient inspection procedures for all incoming
16 and outgoing product shipments; and

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

19 (f) The Department shall consider, at a minimum, the
20 following factors in reviewing the qualifications of persons
21 who engage in wholesale distribution of prescription drugs in
22 this State:

23 (1) any conviction of the applicant under any federal,
24 State, or local laws relating to drug samples, wholesale or
25 retail drug distribution, or distribution of controlled
26 substances;

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

29 (3) the applicant's past experience in the manufacture
30 or distribution of prescription drugs, including
31 controlled substances;

32 (4) the furnishing by the applicant of false or
33 fraudulent material in any application made in connection
34 with drug manufacturing or distribution;

35 (5) suspension or revocation by federal, State, or
36 local government of any license currently or previously

1 held by the applicant for the manufacture or distribution
2 of any drug, including controlled substances;

3 (6) compliance with licensing requirements under
4 previously granted licenses, if any;

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

9 (8) any other factors or qualifications the Department
10 considers relevant to and consistent with the public health
11 and safety, including whether the granting of the license
12 would not be in the public interest.

13 (9) All requirements set forth in this subsection shall
14 conform to wholesale drug distributor licensing guidelines
15 formally adopted by the U.S. Food and Drug Administration
16 (FDA). In case of conflict between any wholesale drug
17 distributor licensing requirement imposed by the
18 Department and any FDA wholesale drug distributor
19 licensing guideline, the FDA guideline shall control.

20 (g) An agent or employee of any licensed wholesale drug
21 distributor need not seek licensure under this Section and may
22 lawfully possess pharmaceutical drugs when the agent or
23 employee is acting in the usual course of business or
24 employment.

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

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

30 (Source: P.A. 92-586, eff. 6-26-02.)

31 (225 ILCS 120/50) (from Ch. 111, par. 8301-50)

32 (Section scheduled to be repealed on January 1, 2013)

33 Sec. 50. Inspection powers; access to records.

34 (a) Any pharmacy investigator authorized by the Department
35 has the right of entry for inspection during normal business

1 hours of premises purporting or appearing to be used by a
2 wholesale drug distributor in this State. The duly authorized
3 investigators shall be required to show appropriate
4 identification before given access to a wholesale drug
5 distributor's premises and delivery vehicles. Any wholesale
6 drug distributor providing adequate documentation of the most
7 recent satisfactory inspection less than 3 years old of the
8 distributor's wholesale drug distribution activities and
9 facilities by either the U.S. FDA, a State agency, or any
10 person or entity lawfully designated by a State agency to
11 perform an inspection determined to be comparable by the
12 Department shall be exempt from further inspection for a period
13 of time to be determined by the Department. The exemption shall
14 not bar the Department from initiating an investigation of a
15 public or governmental complaint received by the Department
16 regarding a wholesale drug distributor. Wholesale drug
17 distributors shall be given an opportunity to correct minor
18 violations determined by these investigations.

19 (b) Wholesale drug distributors may keep records regarding
20 purchase and sales transactions at a central location apart
21 from the principal office of the wholesale drug distributor or
22 the location at which the drugs were stored and from which they
23 were shipped, provided that the records shall be made available
24 for inspection within 2 working days of a request by the
25 Department. The records may be kept in any form permissible
26 under federal law applicable to prescription drugs record
27 keeping.

28 (c) (Blank). ~~The Department shall employ a person whose~~
29 ~~title shall be Assistant Drug Compliance Coordinator to assist~~
30 ~~the Drug Compliance Coordinator in administering and enforcing~~
31 ~~this Act.~~

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