

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7 (Section scheduled to be repealed on January 1, 2013)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