AN ACT concerning regulation.

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

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

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

(Section scheduled to be repealed on January 1, 2013)

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

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

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

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

Department.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Sec. 50. Inspection powers; access to records.

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

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

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

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

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