AMENDMENT TO HOUSE BILL 4003

AMENDMENT NO. _____. Amend House Bill 4003 on page 1, immediately below line 20, by inserting the following:

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

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

(Section scheduled to be repealed on December 31, 2002)

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~~, the fee not to exceed $200 per year~~.

(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 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. 87-594.)

(225 ILCS 120/35) (from Ch. 111, par. 8301-35)

(Section scheduled to be repealed on December 31, 2002)

Sec. 35. Fees; Illinois State Pharmacy Disciplinary Fund.

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

~~(1) The fee for application for a certificate of registration as a wholesale drug distributor is $200.~~

~~(2) The fee for the renewal of a certificate of registration as a wholesale drug distributor is $200 per year.~~

~~(3) The fee for the change of person responsible for drugs is $50.~~

~~(4) The fee for the issuance of a duplicate license to replace a license that has been lost or destroyed is $25.~~

~~(5) The fee for certification of a registrant's record for any purpose is $25.~~

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

~~distributors shall be the actual cost of producing the roster.~~

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

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

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

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

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

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

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

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