COMMITTEE SUBSTITUTE

FOR

Senate Bill No. 588

(By Senators Palumbo, Stollings, Plymale, Jenkins and Barnes)

[Originating in the Committee on the Judiciary;

reported February 24, 2012.]

A BILL to repeal §60A-8-4 of the Code of West Virginia, 1931, as amended; to amend and reenact §60A-8-3, §60A-8-5 and §60A-8-7 of said code; and to amend said code by adding thereto three new sections, designated §60A-8-14, §60A-8-15 and §60A-8-16, all relating generally to wholesale drug distributors licensed by Board of Pharmacy; specifying purpose of article; defining terms; specifying wholesale drug distributor licensing requirements; specifying powers of Board of Pharmacy; increasing licensing fees; requiring updates when material changes occur to a licensee; authorizing board to take certain disciplinary action against licensees, including revocation or

suspension of licenses, refusal to renew license and civil penalties; providing for register of wholesale and pharmacy distributors of prescription drugs; and providing for the disposition of fees.

Be it enacted by the Legislature of West Virginia:

That §60A-8-4 of the Code of West Virginia, 1931, as amended, be repealed; that §60A-8-3, §60A-8-5 and §60A-8-7 of said code be amended and reenacted; and that said code be amended by adding thereto three new sections, designated §60A-8-14, §60A-8-15 and §60A-8-16, all to read as follows:

ARTICLE 8. WHOLESALE DRUG DISTRIBUTION LICENSING ACT OF 1991.

§60A-8-3. Purpose.

The purpose of this article is <u>to protect the health, safety and general welfare of residents of this state and</u> to implement the federal Prescription Drug Marketing Act of 1987 ("PDMA"), U. S. Public Law 100-293, 102 Stat. 95, codified at 21 U. S. Code §321; and particularly PDMA requirements that no person or entity may engage in the wholesale distribution of human prescription drugs in any state unless such person or entity is licensed by such state in accordance with federally-prescribed minimum standards, terms and condi-

tions as set forth in guidelines issued by United States food and drug administration (FDA) regulations pursuant to 21 U. S. Code §353(e)(2)(A) and (B); and such regulations as are set forth in 21 C. F. R. Part 205.

§60A-8-5. Definitions.

As used in this article:

(a) "Wholesale distribution" and "wholesale distributions" mean distribution of prescription drugs, including directly or through the use of a third-party logistics provider or any other situation in which title, ownership or control over the prescription drug remains with one person or entity but the prescription drug is brought into this state by another person or entity on his, her or its behalf, to persons other than a consumer or patient, but does not include:

(1) Intracompany sales, being defined as any transaction, ~~or~~ transfer or delivery into or within this state between any division, subsidiary, parent and/or affiliated or related company under the common ownership and control of a corporate entity;

(2) The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for its own use from the group

purchasing organization or from other hospitals or health care entities that are members of such organizations;

(3) The sale, purchase or trade of a drug or an offer to sell, purchase or trade a drug by a charitable organization described in section 501(c)(3) of the United States Internal Revenue Code of ~~1954~~ 1986 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(4) The sale, purchase or trade of a drug or an offer to sell, purchase or trade a drug among hospitals or other health care entities that are under common control. For purposes of this article, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, by contract, or otherwise;

(5) The sale, purchase or trade of a drug or an offer to sell, purchase or trade a drug for "emergency medical reasons" for purposes of this article includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage, except that the gross dollar value of such transfers shall not exceed five percent of the total prescription drug sales revenue of either

the transferor or ~~tranferee~~ transferee pharmacy during any twelve consecutive month period;

(6) The sale, purchase or trade of a drug, an offer to sell, purchase, or trade a drug or the dispensing of a drug pursuant to a prescription;

(7) The distribution of drug samples by manufacturers' representatives or distributors' representatives, if the distribution is permitted under federal law [21 U. S. C. 353(d)]; or

(8) The sale, purchase or trade of blood and blood components intended for transfusion.

(b) "Wholesale drug distributor" or "wholesale distributor" means any person or entity engaged in wholesale distribution of prescription drugs, including, but not limited to, manufacturers, repackers, own-label distributors, jobbers, private-label distributors, brokers, warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses and wholesale drug warehouses, independent wholesale drug traders, prescription drug repackagers, physicians, dentists, veterinarians, birth control and other clinics, individuals, hospitals, nursing homes and/or their providers, health maintenance organizations

and other health care providers, and retail and hospital pharmacies that conduct wholesale distributions, including, but not limited to, any pharmacy distributor as defined in this section. A wholesale drug distributor shall not include any for hire carrier or person or entity hired solely to transport prescription drugs.

(c) "Pharmacy distributor" means any pharmacy licensed in this state or hospital pharmacy which is engaged in the delivery or distribution of prescription drugs either to any other pharmacy licensed in this state or to any other person or entity, including, but not limited to, a wholesale drug distributor as defined in subdivision (b) of this section engaged in the delivery or distribution of prescription drugs and who is involved in the actual, constructive or attempted transfer of a drug in this state to other than the ultimate consumer except as otherwise provided for by law.

(d) "Manufacturer" means ~~anyone~~ any person who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging or labeling of a prescription drug, whether within or outside this state.

(e) "West Virginia board of pharmacy", "board of pharmacy" or "board" means the agency of this state

authorized to license wholesale drug distribution except where otherwise provided.

(f) "Prescription drug" means any human drug required by federal law or regulation to be dispensed only by prescription, including finished dosage forms and active ingredients subject to section 503(b) of the federal food, drug and cosmetic act.

(g) "Blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

(h) "Blood component" means that part of blood separated by physical or mechanical means.

(i) "Drug sample" means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

(j) "Person" means any individual, partnership, association, limited liability company, corporation or other entity.

(k) "Key person" means any of the following:

(1) An officer, director, trustee, partner, principal or proprietor of a person that has applied for or holds a license issued under this article or an affiliate or holding company that has control of a person that has applied for or holds a

license under this article.

(2) A person who holds a combined direct, indirect or attributed debt or equity interest of more than five percent in a person who has applied for or holds a license under this article;

(3) A person who holds a combined direct, indirect or attributed equity interest of more than five percent in a person who has a controlling interest in a person who has applied for or holds license under this article;

(4) A managerial employee of a person who has applied for or holds a license under this article or a managerial employee of an affiliate or holding company that has control of a person who has applied for or holds a license under this article, who performs the function of principal executive officer, principal operating officer, principal accounting officer or an equivalent officer;

(5) A managerial employee of a person who has applied for or holds a license under this article or a managerial employee of an affiliate or holding company that has control of a person who has applied for or holds a license under this article who will perform or performs the function of an operations manager or will exercise or exercises manage-

ment, supervisory or policy-making authority over the distribution of prescription drugs.

(l) "Third-party logistics provider" means a person who contracts with a prescription drug manufacturer to provide or coordinate warehousing, distribution or other services on behalf of a manufacturer, but does not take title to the prescription drug or have general responsibility to direct the prescription drug's sale or disposition. A third-party logistics provider must be licensed as a wholesale distributor under this article and, in order to be considered part of the normal distribution channel, must also be an authorized distributor of record.

§60A-8-7. Wholesale drug distributor licensing requirements.

(a) Every applicant for a license under this article shall provide the board with the following as part of the application for a license and as part of any renewal of such license:

(1) The name, full business address and telephone number of the licensee;

(2) All trade or business names used by the licensee;

(3) Addresses, telephone numbers and the names of contact persons for all facilities used by the licensee for the storage, handling, and distribution of prescription drugs;

(4) The type of ownership or operation (i.e., partnership, corporation or sole proprietorship);

(5) The name(s) of the owner and operator, or both, of the licensee, including:

(A) If a person, the name of the person;

(B) If a partnership, the name of each partner and the name of the partnership;

(C) If a corporation, the name and title of each corporate officer and director, the corporate names and the name of the state of incorporation; and

(D) If a sole proprietorship, the full name of the sole proprietor and the name of the business entity; and

(6) Any other information or documentation that the board may require.

(b) All wholesale distributors and pharmacy distributors shall be subject to the following requirements:

(~~a~~) (1) No person or distribution outlet may act as a wholesale drug distributor without first obtaining a license to do so from the board of pharmacy and paying any reasonable fee required by the board of pharmacy, such fee not to exceed four hundred dollars per year: *Provided*, That for licenses that are effective on and after July 1, 2012, the

annual fee shall be $750 a license until modified by legislative rule.

(~~b~~) (2) The Board of Pharmacy may grant a temporary license when a wholesale drug distributor first applies to the board for a wholesale drug distributor's license ~~to operate within this state~~ and the temporary license shall remain valid until the board of pharmacy finds that the applicant meets or fails to meet the requirements for regular licensure, except that no temporary license shall be valid for more than ninety days from the date of issuance. Any temporary license issued pursuant to this subdivision shall be renewable for a similar period of time not to exceed ninety days pursuant to policies and procedures to be prescribed by the board of pharmacy.

~~(c)~~ (3) No license may be issued or renewed for a wholesale drug distributor to operate unless the distributor operates in a manner prescribed by law and according to the rules promulgated by the board of pharmacy with respect thereto.

~~(d)~~ (4) The board of pharmacy 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, or 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.

~~(c)~~ (c) The minimum qualifications for licensure are set forth in this section as follows:

(1) As a condition for receiving and retaining any wholesale drug distributor license issued pursuant to this article, each applicant shall satisfy the board of pharmacy that it has and will continuously maintain:

(A) Acceptable storage and handling conditions plus facilities standards;

(B) Minimum liability and other insurance as may be required under any applicable federal or state law;

(C) A security system which 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;

(D) An electronic, manual or any other reasonable system of records describing all wholesale distributor activities governed by this article for the two-year period following

disposition of each product and being reasonably accessible as defined by board of pharmacy regulations during any inspection authorized by the board of pharmacy;

(E) 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;

(F) Complete, updated information to be provided to the board of pharmacy as a condition for obtaining and retaining a license about each wholesale distributor to be licensed under this article including all pertinent licensee ownership and other key personnel and facilities information determined necessary for enforcement of this article; ~~with any changes in the information to be submitted at the time of license renewal or within twelve months from the date of the change, whichever occurs first;~~

(G) Written policies and procedures which 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;

(H) Sufficient inspection procedures for all incoming and outgoing product shipments; and

(I) Operations in compliance with all federal legal requirements applicable to wholesale drug distribution.

(2) The board of pharmacy shall consider, at a minimum, the following factors in reviewing the qualifications of persons who ~~engage in wholesale distribution of prescription drugs with this state~~ apply for a wholesale distributor license under this section or for renewal of that license:

(A) 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;

(B) Any felony convictions of the applicant or any key person under federal, state or local laws;

(C) The applicant's past experience in the manufacture or distribution of prescription drugs, including, but not limited to, controlled substances;

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

(E) 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, but not limited to, controlled substances;

(F) Compliance with licensing requirements under previously granted licenses, if any;

(G) Whether personnel employed by the applicant in wholesale drug distribution have appropriate education or experience, or both education and experience, to assume responsibility for positions related to compliance with the requirements of this article;

~~(G)~~ (H) Compliance with requirements to maintain and make available to the board of pharmacy or to federal, state or local law-enforcement officials those records required by this article; and

~~(H)~~ (I) Any other factors or qualifications the board of pharmacy 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.

(3) All requirements set forth in this subsection shall conform to wholesale drug distributor licensing guidelines formally adopted by the United States food and drug administration (FDA); and in case of conflict between any wholesale drug distributor licensing requirement imposed by the board of pharmacy pursuant to this subsection and any food and drug administration wholesale drug distributor licensing guideline, the latter shall control.

~~(f)~~ (d) 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.

~~(g)~~ (e) The issuance of a license pursuant to this article does not change or affect tax liability imposed by this state's department of tax and revenue on any wholesale drug distributor.

~~(h)~~ (f) An applicant who is awarded a license or renewal of a license shall give the board written notification of any material change in the information previously submitted in, or with the application for the license or for renewal thereof, whichever is the most recent document filed with the board,

within thirty days after the material change occurs or the licensee becomes aware of the material change, whichever event occurs last. Material changes include, but are not limited to:

(1) A change of the physical address or mailing address;

(2) A change of the responsible individual, compliance officer or other executive officers or board members;

(3) A change of the licensee's name or trade name;

(4) A change in the location where the records of the licensee are retained;

(5) The felony conviction of a key person of the licensee; and

(6) Any other material change that the board may specify by rule.

(g) The board may deny a license to an applicant for a license or for renewal of a license if the board determines that the granting of the license would not be in the public interest.

(h) The licensing of any person as a wholesale drug distributor subjects the person and the person's agents and employees to the jurisdiction of the board and to the laws of this state for the purpose of the enforcement of this article,

article five, chapter thirty of this code and the rules of the board. However, the filing of an application for a license as a wholesale drug distributor by, or on behalf of, any person or the licensing of any person as a wholesale drug distributor may not, of itself, constitute evidence that the person is doing business within this state.

~~(h)~~ (i) The Board of Pharmacy may adopt rules pursuant to section nine of this article which permit out-of-state wholesale drug distributors to obtain any license required by this article on the basis of reciprocity to the extent that: (i) An out-of-state wholesale drug distributor possesses a valid license granted by another state pursuant to legal standards comparable to those which must be met by a wholesale drug distributor of this state as prerequisites for obtaining a license under the laws of this state; and (ii) such other state would extend reciprocal treatment under its own laws to a wholesale drug distributor of this state.

(j) Notwithstanding the provisions of section four, article thirteen, chapter eight of this code to the contrary, municipalities may not impose the license fees imposed by this article on manufacturers of prescription drugs, wholesale distributors of prescription drugs or pharmacy distributors of prescription drugs.

§60A-8-14. Disciplinary actions - wholesale drug distributor.

(a) In accordance with article five, chapter thirty of this code, the Board of Pharmacy may suspend, revoke or refuse to renew any license issued to a wholesale distributor of prescription drugs pursuant to this article or may impose a civil money penalty not to exceed $1,000, in the discretion of the board for any of the following causes:

(1) Making any false material statements in an application for a license or for renewal of a license as a wholesale distributor or pharmacy distributor of prescription drugs;

(2) Violating any federal, state or local drug law, any provision of this article or any rule of the board;

(3) Conviction of a felony. For purposes of this subdivision "felony" means a felony or crime punishable as a felony under the laws of this state, any other state or the United States;

(4) Ceasing to satisfy the qualifications for licensure under section seven of this article or the rules of the board;

(5) The license or registration of a wholesale drug distributor licensed under this article has been revoked by the licensing authority of another state, jurisdiction of foreign nation; or

(6) Any reason for which the board may impose disciplinary sanctions under the provisions of chapter thirty of this code.

(b) Upon the suspension or revocation of the license of any wholesale distributor of prescription drugs, the distributor shall immediately surrender the license to the board.

(c) If the board suspends, revokes or refuses to renew any license issued to a wholesale distributor of prescription drugs and determines that there is clear and convincing evidence of a danger of immediate and serious harm to any person, the board may place under seal all drugs owned by or in the possession, custody or control of the affected wholesale distributor. Except as provided in this article, the board may not dispose of the drugs sealed under this subsection until the distributor exhausts all of his or her appeal rights under this article or article five, chapter thirty of this code. The court involved in the appeal may order the board, during the pendency of the appeal, to sell sealed dangerous drugs that are perishable. The board shall deposit the proceeds of the sale with the court.

§60A-8-15. Maintenance of register and roster of wholesale and pharmacy distributors.

(a) The Executive Director of the Board of Pharmacy shall maintain a register of the names, addresses and the date the current license was issued or renewed pursuant to this article for license years beginning on and after July 1, 2013. The register shall be the property of the board and shall be open for public examination and inspection at all reasonable times, as the board may direct.

(b) The register shall set forth the names and addresses of:

(1) Those persons who are or have been licensed under this article for the current license year;

(2) Those persons whose licenses have been suspended, revoked or surrendered during the current license year or during the two preceding license years; and

(3) Those persons whose licenses have not been renewed for the current license year.

(c) In lieu of annually publishing a typed or printed register providing the information required by this subsection, the board may make the information required to be published available at its website.

(d) A written statement signed and verified by the executive director of the board, in which it is stated that

after diligent search of the register no record or entry of the issuance of a license or registration certificate to a person is found, is admissible in evidence and constitutes presumptive evidence of the fact that the person is not a licensed as a wholesale drug distributor under this article.

§60A-8-16. Disposition of fees.

The board shall pay all fees it collects under this article into the separate fund created in the State Treasury for the board pursuant to section ten, article one, chapter thirty of this code. The money in this fund shall be used exclusively by the board for the purposes of administering and enforcement of its duties pursuant to this article, articles one and five, chapter thirty of this code, or any other duty of the board prescribed by any other provision of this code.

(NOTE: The purpose of this bill is to update the Wholesale Drug Distribution Act of 1991, including specifying additional purpose of article and definition of terms. The bill specifies wholesale drug distributor licensing requirements and powers of the Board of Pharmacy. It authorizes the board to take certain disciplinary action against licensees, including civil penalty fines. It provides for the register of wholesale and pharmacy distributors of prescription drugs. And, it provides for the disposition of fees.

Strike-throughs indicate language that would be stricken from the present law, and underscoring indicates new language that would be added.

§60A-8-14, §60A-8-15 and §60A-8-16 are new; therefore, strike-throughs and underscoring have been omitted.)