

1 **H. B. 4514**

2  
3 (By Delegates White, Morgan, Perdue, T. Campbell  
4 and Manypenny)

5 [Introduced February 14, 2012; referred to the  
6 Committee on Government Organization then Finance.]

7  
8  
9  
10 A BILL to repeal §60A-8-4 of the Code of West Virginia, 1931, as  
11 amended; to amend and reenact §60A-8-3, §60A-8-5 and §60A-8-7  
12 of said code; and to amend said article by adding thereto  
13 three new sections, designated §60A-8-14, §60A-8-15 and §60A-  
14 8-16, all relating generally to wholesale drug distributors  
15 licensed by Board of Pharmacy; specifying purpose of article;  
16 defining terms; specifying wholesale drug distributor  
17 licensing requirements; specifying powers of Board of  
18 Pharmacy; authorizing board to take certain disciplinary  
19 action against licensees, including civil penalties; providing  
20 for register of wholesale and pharmacy distributors of  
21 prescription drugs; and providing for the disposition of fees.

22 *Be it enacted by the Legislature of West Virginia:*

23 That §60A-8-4 of the Code of West Virginia, 1931, as amended,

1 be repealed; that §60A-8-3, §60A-8-5 and §60A-8-7 of said code be  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

5 **ARTICLE 8. WHOLESALE DRUG DISTRIBUTION LICENSING ACT OF 1991.**

6 **§60A-8-3. Purpose.**

7       The purpose of this article is to protect the health, safety  
8 and general welfare of residents of this state and to implement the  
9 federal prescription drug marketing act of one thousand nine  
10 hundred eighty-seven ("PDMA"), U.S. Pubic Law 100-293, 102 Stat.  
11 95, codified at 21 U.S. Code §321; and particularly PDMA  
12 requirements that no person or entity may engage in the wholesale  
13 distribution of human prescription drugs in any state unless such  
14 person or entity is licensed by such state in accordance with  
15 federally-prescribed minimum standards, terms and conditions as set  
16 forth in guidelines issued by United States food and drug  
17 administration (FDA) regulations pursuant to 21 U.S. Code  
18 §353(e) (2) (A) and (B); and such regulations as are set forth in 21  
19 C.F.R. Part 205.

20 **§60A-8-5. Definitions.**

21       As used in this article:

22       (a) "Wholesale distribution" and "wholesale distributions"  
23 mean distribution of prescription drugs, including directly or

1 through the use of a third-party logistics provider or any other  
2 situation in which title, ownership or control over the  
3 prescription drug remains with one person or entity but the  
4 prescription drug is brought into this state by another person or  
5 entity on his, her or its behalf, to persons other than a consumer  
6 or patient, but does not include:

7       (1) Intracompany sales, being defined as any transaction or  
8 transfer between any division, subsidiary, parent and/or affiliated  
9 or related company under the common ownership and control of a  
10 corporate entity;

11       (2) The purchase or other acquisition by a hospital or other  
12 health care entity that is a member of a group purchasing  
13 organization of a drug for its own use from the group purchasing  
14 organization or from other hospitals or health care entities that  
15 are members of such organizations;

16       (3) The sale, purchase or trade of a drug or an offer to sell,  
17 purchase or trade a drug by a charitable organization described in  
18 section 501(c)(3) of the United States Internal Revenue Code of  
19 ~~1954~~ 1986 to a nonprofit affiliate of the organization to the  
20 extent otherwise permitted by law;

21       (4) The sale, purchase or trade of a drug or an offer to sell,  
22 purchase or trade a drug among hospitals or other health care  
23 entities that are under common control. For purposes of this

1 article, "common control" means the power to direct or cause the  
2 direction of the management and policies of a person or an  
3 organization, whether by ownership of stock, voting rights, by  
4 contract, or otherwise;

5 (5) The sale, purchase or trade of a drug or an offer to sell,  
6 purchase or trade a drug for "emergency medical reasons" for  
7 purposes of this article includes transfers of prescription drugs  
8 by a retail pharmacy to another retail pharmacy to alleviate a  
9 temporary shortage, except that the gross dollar value of such  
10 transfers shall not exceed five percent of the total prescription  
11 drug sales revenue of either the transferor or ~~transferee~~ transferee  
12 pharmacy during any twelve consecutive month period;

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

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

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

21 (b) "Wholesale drug distributor" or "wholesale distributor"  
22 means any person or entity engaged in wholesale distribution of  
23 prescription drugs, including, but not limited to, manufacturers,

1 repackers, own-label distributors, jobbers, private-label  
2 distributors, brokers, warehouses, including manufacturers' and  
3 distributors' warehouses, chain drug warehouses and wholesale drug  
4 warehouses, independent wholesale drug traders, prescription drug  
5 repackagers, physicians, dentists, veterinarians, birth control and  
6 other clinics, individuals, hospitals, nursing homes and/or their  
7 providers, health maintenance organizations and other health care  
8 providers, and retail and hospital pharmacies that conduct  
9 wholesale distributions, including, but not limited to, any  
10 pharmacy distributor as defined in this section. A wholesale drug  
11 distributor shall not include any for hire carrier or person or  
12 entity hired solely to transport prescription drugs.

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

23 (d) "Manufacturer" means ~~anyone~~ any person who is engaged in

1 manufacturing, preparing, propagating, compounding, processing,  
2 packaging, repackaging or labeling of a prescription drug, whether  
3 within or outside this state.

4 (e) "West Virginia Board of Pharmacy", "Board of Pharmacy" or  
5 "board" means the agency of this state authorized to license  
6 wholesale drug distribution except where otherwise provided.

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

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

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

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

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

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

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

1 has control of a person that has applied for or holds a license  
2 under this article.

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

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

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

16 (5) A managerial employee of a person that has applied for or  
17 holds a license under this article or a managerial employee of an  
18 affiliate or holding company that has control of a person that has  
19 applied for or holds a license under this article who will perform  
20 or performs the function of an operations manager or will exercise  
21 or exercises management, supervisory or policy-making authority  
22 over the distribution of prescription drugs.

23 (1) "Third-party logistics provider" means a person who

1 contracts with a prescription drug manufacturer to provide or  
2 coordinate warehousing, distribution or other services on behalf of  
3 a manufacturer, but does not take title to the prescription drug or  
4 have general responsibility to direct the prescription drug's sale  
5 or disposition. A third-party logistics provider must be licensed  
6 as a wholesale distributor under this article and, in order to be  
7 considered part of the normal distribution channel, must also be an  
8 authorized distributor of record.

9 **§60A-8-7. Wholesale drug distributor licensing requirements.**

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

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

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

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

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

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

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



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

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

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

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

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

12       ~~(a)~~ (1) No person or distribution outlet may act as a  
13 wholesale drug distributor without first obtaining a license to do  
14 so from the Board of Pharmacy and paying any reasonable fee  
15 required by the Board of Pharmacy, such fee not to exceed four  
16 hundred dollars per year: Provided, That for licenses that are  
17 effective on and after July 1, 2012, the annual fee shall be \$750  
18 a license until modified by legislative rule.

19       ~~(b)~~ (2) The Board of Pharmacy may grant a temporary license  
20 when a wholesale drug distributor first applies to the board for a  
21 wholesale drug distributor's license ~~to operate within this state~~  
22 and the temporary license shall remain valid until the Board of  
23 Pharmacy finds that the applicant meets or fails to meet the

1 requirements for regular licensure, except that no temporary  
2 license shall be valid for more than ninety days from the date of  
3 issuance. Any temporary license issued pursuant to this subdivision  
4 shall be renewable for a similar period of time not to exceed  
5 ninety days pursuant to policies and procedures to be prescribed by  
6 the Board of Pharmacy.

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

11       ~~(d)~~ (4) The Board of Pharmacy may require a separate license  
12 for each facility directly or indirectly owned or operated by the  
13 same business entity within this state, or for a parent entity with  
14 divisions, subsidiaries, or affiliate companies within this state  
15 when operations are conducted at more than one location and there  
16 exists joint ownership and control among all the entities.

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

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

23       (A) Acceptable storage and handling conditions plus facilities

1 standards;

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

4 (C) A security system which includes after hours central alarm  
5 or comparable entry detection capability, restricted premises  
6 access, adequate outside perimeter lighting, comprehensive  
7 employment applicant screening and safeguards against employee  
8 theft;

9 (D) An electronic, manual or any other reasonable system of  
10 records describing all wholesale distributor activities governed by  
11 this article for the two-year period following disposition of each  
12 product and being reasonably accessible as defined by Board of  
13 Pharmacy regulations during any inspection authorized by the Board  
14 of Pharmacy;

15 (E) Officers, directors, managers and other persons in charge  
16 of wholesale drug distribution, storage and handling, who must at  
17 all times demonstrate and maintain their capability of conducting  
18 business according to sound financial practices as well as state  
19 and federal law;

20 (F) Complete, updated information to be provided to the Board  
21 of Pharmacy as a condition for obtaining and retaining a license  
22 about each wholesale distributor to be licensed under this article  
23 including all pertinent licensee ownership and other key personnel

1 and facilities information determined necessary for enforcement of  
2 this article; ~~with any changes in the information to be submitted~~  
3 ~~at the time of license renewal or within twelve months from the~~  
4 ~~date of the change, whichever occurs first;~~

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

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

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

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

21 (A) Any conviction of the applicant under any federal, state  
22 or local laws relating to drug samples, wholesale or retail drug  
23 distribution or distribution of controlled substances;

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

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

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

9 (E) Suspension or revocation by federal, state or local  
10 government of any license currently or previously held by the  
11 applicant for the manufacture or distribution of any drug,  
12 including, but not limited to, controlled substances;

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

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

19 ~~(G)~~ (H) Compliance with requirements to maintain and make  
20 available to the Board of Pharmacy or to federal, state or local  
21 law-enforcement officials those records required by this article;  
22 and

23 ~~(H)~~ (I) Any other factors or qualifications the Board of

1 Pharmacy considers relevant to and consistent with the public  
2 health and safety, including whether the granting of the license  
3 would not be in the public interest.

4 (3) All requirements set forth in this subsection shall  
5 conform to wholesale drug distributor licensing guidelines formally  
6 adopted by the United States food and drug administration (FDA);  
7 and in case of conflict between any wholesale drug distributor  
8 licensing requirement imposed by the Board of Pharmacy pursuant to  
9 this subsection and any food and drug administration wholesale drug  
10 distributor licensing guideline, the latter shall control.

11 (f) An ~~agent or~~ employee of any licensed wholesale drug  
12 distributor need not seek licensure under this section and may  
13 lawfully possess pharmaceutical drugs when the ~~agent or~~ employee is  
14 acting in the usual course of business or employment.

15 ~~(g) The issuance of a license pursuant to this article does~~  
16 ~~not change or affect tax liability imposed by this state's~~  
17 ~~Department of Tax and Revenue on any wholesale drug distributor.~~

18 (g) An applicant who is awarded a license or renewal of a  
19 license shall give the board written notification of any material  
20 change in the information previously submitted in, or with the  
21 application for the license or for renewal thereof, whichever is  
22 the most recent document filed with the board, within thirty days  
23 after the material change occurs or the licensee becomes aware of

1 the material change, whichever event occurs last. Material changes  
2 include, but are not limited to:

3 (1) A change of the physical and mailing, or both, address;

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

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

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

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

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

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

15 (i) The licensing of any person as a wholesale drug  
16 distributor subjects the person and the person's agents and  
17 employees to the jurisdiction of the board and to the laws of this  
18 state for the purpose of the enforcement of this article, article  
19 five, chapter thirty of this code and the rules of the board.

20 However, the filing of an application for a license as a wholesale  
21 drug distributor by, or on behalf of, any person or the licensing  
22 of any person as a wholesale drug distributor may not, of itself,  
23 constitute evidence that the person is doing business within this

1 state.

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

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

18 **§60A-8-14. Disciplinary actions - wholesale drug distributor.**

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



1 following causes:

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

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

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

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

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

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

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

21 (c) If the board suspends, revokes or refuses to renew any  
22 license issued to a wholesale distributor of prescription drugs and  
23 determines that there is clear and convincing evidence of a danger

1 of immediate and serious harm to any person, the board may place  
2 under seal all drugs owned by or in the possession, custody or  
3 control of the affected wholesale distributor. Except as provided  
4 in this article, the board may not dispose of the drugs sealed  
5 under this subsection until the distributor exhausts all of his or  
6 her appeal rights under this article or article five, chapter  
7 thirty of this code. The court involved in the appeal may order the  
8 board, during the pendency of the appeal, to sell sealed dangerous  
9 drugs that are perishable. The board shall deposit the proceeds of  
10 the sale with the court.

11 **§60A-8-15. Maintenance of register and roster of wholesale and**  
12 **pharmacy distributors.**

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

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

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

23 (2) Those persons whose licenses have been suspended, revoked,

1 or surrendered during the current license year or during the two  
2 preceding license years; and

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

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

9 (d) A written statement signed and verified by the executive  
10 director of the board, in which it is stated that after diligent  
11 search of the register no record or entry of the issuance of a  
12 license or registration certificate to a person is found, is  
13 admissible in evidence and constitutes presumptive evidence of the  
14 fact that the person is not a licensed as a wholesale drug  
15 distributor under this article.

16 **§60A-8-16. Disposition of fees.**

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

1 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, they have been completely underscored.