

1 COMMITTEE SUBSTITUTE

2 FOR

3 **H. B. 4514**

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

6 (Originating in the Committee on Finance)

7 [February 24, 2012]

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,
24 be repealed; that §60A-8-3, §60A-8-5 and §60A-8-7 of said code be
25 amended and reenacted; and that said code be amended by adding
26 thereto three new sections, designated §60A-8-14, §60A-8-15 and

1 §60A-8-16, all to read as follows:

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

3 **§60A-8-3. Purpose.**

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

17 **§60A-8-5. Definitions.**

18 As used in this article:

19 (a) "Wholesale distribution" and "wholesale distributions"
20 mean distribution of prescription drugs, including directly or
21 through the use of a third-party logistics provider or any other
22 situation in which title, ownership or control over the
23 prescription drug remains with one person or entity but the
24 prescription drug is brought into this state by another person or
25 entity on his, her or its behalf, to persons other than a consumer

1 or patient, but does not include:

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

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

12 (3) The sale, purchase or trade of a drug or an offer to sell,
13 purchase or trade a drug by a charitable organization described in
14 section 501(c)(3) of the United States Internal Revenue Code of
15 ~~1954~~ 1986 to a nonprofit affiliate of the organization to the
16 extent otherwise permitted by law;

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

24 (5) The sale, purchase or trade of a drug or an offer to sell,
25 purchase or trade a drug for "emergency medical reasons" for
26 purposes of this article includes transfers of prescription drugs

1 by a retail pharmacy to another retail pharmacy to alleviate a
2 temporary shortage, except that the gross dollar value of such
3 transfers shall not exceed five percent of the total prescription
4 drug sales revenue of either the transferor or ~~transferee~~ transferee
5 pharmacy during any twelve consecutive month period;

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

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

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

14 (b) "Wholesale drug distributor" or "wholesale distributor"
15 means any person or entity engaged in wholesale distribution of
16 prescription drugs, including, but not limited to, manufacturers,
17 repackers, own-label distributors, jobbers, private-label
18 distributors, brokers, warehouses, including manufacturers' and
19 distributors' warehouses, chain drug warehouses and wholesale drug
20 warehouses, independent wholesale drug traders, prescription drug
21 repackagers, physicians, dentists, veterinarians, birth control and
22 other clinics, individuals, hospitals, nursing homes and/or their
23 providers, health maintenance organizations and other health care
24 providers, and retail and hospital pharmacies that conduct
25 wholesale distributions, including, but not limited to, any
26 pharmacy distributor as defined in this section. A wholesale drug

1 distributor shall not include any for hire carrier or person or
2 entity hired solely to transport prescription drugs.

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

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

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

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

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

26 (h) "Blood component" means that part of blood separated by

1 physical or mechanical means.

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

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

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

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

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

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

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

26 (5) A managerial employee of a person that has applied for or

1 holds a license under this article or a managerial employee of an
2 affiliate or holding company that has control of a person that has
3 applied for or holds a license under this article who will perform
4 or performs the function of an operations manager or will exercise
5 or exercises management, supervisory or policy-making authority
6 over the distribution of prescription drugs.

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

16 **§60A-8-7. Wholesale drug distributor licensing requirements.**

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

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

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

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

26 (4) The type of ownership or operation (i.e., partnership,

1 corporation, or sole proprietorship);

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

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

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

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

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

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

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

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

23 (b) (2) The Board of Pharmacy may grant a temporary license
24 when a wholesale drug distributor first applies to the board for a
25 wholesale drug distributor's license ~~to operate within this state~~
26 and the temporary license shall remain valid until the Board of

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

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

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

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

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

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

26 (B) Minimum liability and other insurance as may be required

1 under any applicable federal or state law;

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

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

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

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

26 (G) Written policies and procedures which assure reasonable

1 wholesale distributor preparation for protection against and
2 handling of any facility security or operation problems, including,
3 but not limited to, those caused by natural disaster or government
4 emergency, inventory inaccuracies or product shipping and
5 receiving, outdated product or other unauthorized product control,
6 appropriate disposition of returned goods and product recalls;

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

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

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

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

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

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

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

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

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

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

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

15 ~~(H)~~ (I) Any other factors or qualifications the Board of
16 Pharmacy considers relevant to and consistent with the public
17 health and safety, including whether the granting of the license
18 would not be in the public interest.

19 (3) All requirements set forth in this subsection shall
20 conform to wholesale drug distributor licensing guidelines formally
21 adopted by the United States food and drug administration (FDA);
22 and in case of conflict between any wholesale drug distributor
23 licensing requirement imposed by the Board of Pharmacy pursuant to
24 this subsection and any food and drug administration wholesale drug
25 distributor licensing guideline, the latter shall control.

26 (f) An ~~agent~~ or employee of any licensed wholesale drug

1 distributor need not seek licensure under this section and may
2 lawfully possess pharmaceutical drugs when the ~~agent or~~ employee is
3 acting in the usual course of business or employment.

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

7 (h) An applicant who is awarded a license or renewal of a
8 license shall give the board written notification of any material
9 change in the information previously submitted in, or with the
10 application for the license or for renewal thereof, whichever is
11 the most recent document filed with the board, within thirty days
12 after the material change occurs or the licensee becomes aware of
13 the material change, whichever event occurs last. Material changes
14 include, but are not limited to:

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

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

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

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

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

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

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

1 (j) The licensing of any person as a wholesale drug
2 distributor subjects the person and the person's agents and
3 employees to the jurisdiction of the board and to the laws of this
4 state for the purpose of the enforcement of this article, article
5 five, chapter thirty of this code and the rules of the board.
6 However, the filing of an application for a license as a wholesale
7 drug distributor by, or on behalf of, any person or the licensing
8 of any person as a wholesale drug distributor may not, of itself,
9 constitute evidence that the person is doing business within this
10 state.

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

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

1 §60A-8-14. Disciplinary actions - wholesale drug distributor.

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

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

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

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

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

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

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

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

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

14 **§60A-8-15. Maintenance of register and roster of wholesale and**
15 **pharmacy distributors.**

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

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

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

26 (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
24 provision of this code.