

1 **ENROLLED**

2 COMMITTEE SUBSTITUTE

3 FOR

4 **Senate Bill No. 588**

5 (SENATORS PALUMBO, STOLLINGS, PLYMALE, JENKINS AND BARNES, *original*
6 *sponsors*)

7 _____
8 [Passed March 10, 2012; to take effect July 1, 2012.]
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11
12 AN ACT to repeal §60A-8-4 of the Code of West Virginia, 1931, as
13 amended; to amend and reenact §60A-8-3, §60A-8-5 and §60A-8-7
14 of said code; and to amend said code by adding thereto three
15 new sections, designated §60A-8-14, §60A-8-15 and §60A-8-16,
16 all relating generally to wholesale drug distributors licensed
17 by Board of Pharmacy; specifying purpose of article; modifying
18 the definitions of "wholesale distribution" and
19 "manufacturer"; adding definitions of "person", "key person"
20 and "third-party logistics provider"; specifying wholesale
21 drug distributor licensing requirements; specifying powers of
22 Board of Pharmacy; increasing licensing fees; requiring
23 updates when material changes occur to a licensee; authorizing
24 board to take certain disciplinary action against licensees,

1 including revocation or suspension of licenses, refusal to
2 renew license and civil penalties; providing a right to
3 hearing; providing for register of wholesale and pharmacy
4 distributors of prescription drugs; and providing for the
5 disposition of fees.

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

7 That §60A-8-4 of the Code of West Virginia, 1931, as amended,
8 be repealed; that §60A-8-3, §60A-8-5 and §60A-8-7 of said code be
9 amended and reenacted; and that said code be amended by adding
10 thereto three new sections, designated §60A-8-14, §60A-8-15 and
11 §60A-8-16, all to read as follows:

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

13 **§60A-8-3. Purpose.**

14 The purpose of this article is to protect the health, safety
15 and general welfare of residents of this state and to implement the
16 federal Prescription Drug Marketing Act of 1987 ("PDMA"), U. S.
17 Public Law 100-293, 102 Stat. 95, codified at 21 U. S. Code §321;
18 and particularly PDMA requirements that no person or entity may
19 engage in the wholesale distribution of human prescription drugs in
20 any state unless such person or entity is licensed by such state in
21 accordance with federally-prescribed minimum standards, terms and
22 conditions as set forth in guidelines issued by United States Food
23 and Drug Administration (FDA) regulations pursuant to 21 U. S. Code
24 §353(e) (2) (A) and (B); and such regulations as are set forth in 21

1 C. F. R. Part 205.

2 **§60A-8-5. Definitions.**

3 As used in this article:

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

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

16 (2) The purchase or other acquisition by a hospital or other
17 health care entity that is a member of a group purchasing
18 organization of a drug for its own use from the group purchasing
19 organization or from other hospitals or health care entities that
20 are members of such organizations;

21 (3) The sale, purchase or trade of a drug or an offer to sell,
22 purchase or trade a drug by a charitable organization described in
23 section 501(c)(3) of the United States Internal Revenue Code of
24 1986 to a nonprofit affiliate of the organization to the extent

1 otherwise permitted by law;

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

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

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

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

23 (8) Drug returns by a pharmacy or chain drug warehouse to
24 wholesale drug distributor or the drug's manufacturer; or

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

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

18 (c) "Pharmacy distributor" means any pharmacy licensed in this
19 state or hospital pharmacy which is engaged in the delivery or
20 distribution of prescription drugs either to any other pharmacy
21 licensed in this state or to any other person or entity, including,
22 but not limited to, a wholesale drug distributor as defined in
23 subdivision (b) of this section engaged in the delivery or
24 distribution of prescription drugs and who is involved in the

1 actual, constructive or attempted transfer of a drug in this state
2 to other than the ultimate consumer except as otherwise provided
3 for by law.

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

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

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

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

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

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

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

24 (k) "Key person" means the person designated by the applicant

1 or license holder from any of the following:

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

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

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

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

20 (5) 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 will perform
24 or performs the function of an operations manager or will exercise

1 or exercises management, supervisory or policy-making authority
2 over the distribution of prescription drugs.

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

12 **§60A-8-7. Wholesale drug distributor licensing requirements.**

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

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

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

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

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

24 (5) The name(s) of the owner and operator, or both, of the

1 licensee, including:

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

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

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

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

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

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

14 (1) No person or distribution outlet may act as a wholesale
15 drug distributor without first obtaining a license to do so from
16 the Board of Pharmacy and paying any reasonable fee required by the
17 Board of Pharmacy, such fee not to exceed four hundred dollars per
18 year: *Provided*, That for licenses that are effective on and after
19 July 1, 2012, the annual fee shall be \$750 per license until
20 modified by legislative rule. All fees collected pursuant to this
21 section shall be used for the operation and implementation of the
22 West Virginia Controlled Substances Monitoring Program database or
23 in the same manner as those fees governed by section fourteen-b,
24 article five, chapter thirty of this code.

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

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

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

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

23 (1) As a condition for receiving and retaining any wholesale
24 drug distributor license issued pursuant to this article, each

1 applicant shall satisfy the Board of Pharmacy that it has and will
2 continuously maintain:

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

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

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

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

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

23 (F) Complete, updated information to be provided to the Board
24 of Pharmacy as a condition for obtaining and retaining a license

1 about each wholesale distributor to be licensed under this article
2 including all pertinent licensee ownership and other key personnel
3 and facilities information determined necessary for enforcement of
4 this article;

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 apply for a wholesale distributor license under this section or for
19 renewal of that license:

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

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

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

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

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

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

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

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

21 (I) Any other factors or qualifications the Board of Pharmacy
22 considers relevant to and consistent with the public health and
23 safety, including whether the granting of the license would not be
24 in the public interest.

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

8 (d) An employee of any licensed wholesale drug distributor
9 need not seek licensure under this section and may lawfully possess
10 pharmaceutical drugs when the employee is acting in the usual
11 course of business or employment.

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

15 (f) An applicant who is awarded a license or renewal of a
16 license shall give the board written notification of any material
17 change in the information previously submitted in, or with the
18 application for the license or for renewal thereof, whichever is
19 the most recent document filed with the board, within thirty days
20 after the material change occurs or the licensee becomes aware of
21 the material change, whichever event occurs last. Material changes
22 include, but are not limited to:

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

24 (2) A change of the responsible individual, compliance officer

1 or other executive officers or board members;

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

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

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

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

8 (g) Before denial of a license or application for renewal of
9 a license, the applicant shall be entitled to a hearing in
10 accordance with subsection (h), section eight, article one, chapter
11 thirty of this code.

12 (h) The licensing of any person as a wholesale drug
13 distributor subjects the person and the person's agents and
14 employees to the jurisdiction of the board and to the laws of this
15 state for the purpose of the enforcement of this article, article
16 five, chapter thirty of this code and the rules of the board.
17 However, the filing of an application for a license as a wholesale
18 drug distributor by, or on behalf of, any person or the licensing
19 of any person as a wholesale drug distributor may not, of itself,
20 constitute evidence that the person is doing business within this
21 state.

22 (i) The Board of Pharmacy may adopt rules pursuant to section
23 nine of this article which permit out-of-state wholesale drug
24 distributors to obtain any license required by this article on the

1 basis of reciprocity to the extent that: (1) An out-of-state
2 wholesale drug distributor possesses a valid license granted by
3 another state pursuant to legal standards comparable to those which
4 must be met by a wholesale drug distributor of this state as
5 prerequisites for obtaining a license under the laws of this state;
6 and (2) such other state would extend reciprocal treatment under
7 its own laws to a wholesale drug distributor of this state.

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

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

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

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

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

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

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

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

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

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

23 **§60A-8-15. Maintenance of register and roster of wholesale and**
24 **pharmacy distributors.**

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

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

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

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

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

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

20 (d) A written statement signed and verified by the executive
21 director of the board, in which it is stated that after diligent
22 search of the register no record or entry of the issuance of a
23 license or registration certificate to a person is found, is
24 admissible in evidence and constitutes presumptive evidence of the

1 fact that the person is not a licensed as a wholesale drug
2 distributor under this article.

3 **§60A-8-16. Disposition of fees.**

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