

E N R O L L E D

COMMITTEE SUBSTITUTE

FOR

Senate Bill No. 588

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

[Passed March 10, 2012; to take effect July 1, 2012.]

AN ACT 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; modifying the definitions of “wholesale distribution” and “manufacturer”; adding definitions of “person”, “key person” and “third-party logistics provider”; 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 a right to hearing; 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That §60A-8-4 of the Code of West Virginia, 1931, as amended, be repealed; that §60A-8-3, §60A-8-5 and §60A-8-7 of said code be amended and reenacted; and that said code be amended by adding thereto three new sections, designated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.

1 The purpose of this article is to protect the health, safety
2 and general welfare of residents of this state and to imple-
3 ment the federal Prescription Drug Marketing Act of 1987
4 (“PDMA”), U. S. Public Law 100-293, 102 Stat. 95, codified
5 at 21 U. S. Code §321; and particularly PDMA requirements
6 that no person or entity may engage in the wholesale distri-
7 bution of human prescription drugs in any state unless such
8 person or entity is licensed by such state in accordance with
9 federally-prescribed minimum standards, terms and condi-
10 tions as set forth in guidelines issued by United States food
11 and drug administration (FDA) regulations pursuant to 21 U.
12 S. Code §353(e)(2)(A) and (B); and such regulations as are set
13 forth in 21 C. F. R. Part 205.

§60A-8-5. Definitions.

1 As used in this article:

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

10 (1) Intracompany sales, being defined as any transaction,
11 transfer or delivery into or within this state between any
12 division, subsidiary, parent and/or affiliated or related

13 company under the common ownership and control of a
14 corporate entity;

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

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

25 (4) The sale, purchase or trade of a drug or an offer to
26 sell, purchase or trade a drug among hospitals or other
27 health care entities that are under common control. For
28 purposes of this article, “common control” means the power
29 to direct or cause the direction of the management and
30 policies of a person or an organization, whether by owner-
31 ship of stock, voting rights, by contract, or otherwise;

32 (5) The sale, purchase or trade of a drug or an offer to
33 sell, purchase or trade a drug for “emergency medical
34 reasons” for purposes of this article includes transfers of
35 prescription drugs by a retail pharmacy to another retail
36 pharmacy to alleviate a temporary shortage, except that the
37 gross dollar value of such transfers shall not exceed five
38 percent of the total prescription drug sales revenue of either
39 the transferor or transferee pharmacy during any twelve
40 consecutive month period;

41 (6) The sale, purchase or trade of a drug, an offer to sell,
42 purchase, or trade a drug or the dispensing of a drug pursu-
43 ant to a prescription;

44 (7) The distribution of drug samples by manufacturers’
45 representatives or distributors’ representatives, if the
46 distribution is permitted under federal law [21 U. S. C.
47 353(d)];

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

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

52 (b) "Wholesale drug distributor" or "wholesale distribu-
53 tor" means any person or entity engaged in wholesale
54 distribution of prescription drugs, including, but not limited
55 to, manufacturers, repackers, own-label distributors,
56 jobbers, private-label distributors, brokers, warehouses,
57 including manufacturers' and distributors' warehouses,
58 chain drug warehouses and wholesale drug warehouses,
59 independent wholesale drug traders, prescription drug
60 repackagers, physicians, dentists, veterinarians, birth control
61 and other clinics, individuals, hospitals, nursing homes
62 and/or their providers, health maintenance organizations
63 and other health care providers, and retail and hospital
64 pharmacies that conduct wholesale distributions, including,
65 but not limited to, any pharmacy distributor as defined in
66 this section. A wholesale drug distributor shall not include
67 any for hire carrier or person or entity hired solely to
68 transport prescription drugs.

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

79 (d) "Manufacturer" means any person who is engaged in
80 manufacturing, preparing, propagating, compounding,
81 processing, packaging, repackaging or labeling of a prescrip-
82 tion drug, whether within or outside this state.

83 (e) "West Virginia Board of Pharmacy", "Board of
84 Pharmacy" or "board" means the agency of this state

85 authorized to license wholesale drug distribution except
86 where otherwise provided.

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

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

95 (h) "Blood component" means that part of blood sepa-
96 rated by physical or mechanical means.

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

100 (j) "Person" means any individual, partnership, associa-
101 tion, limited liability company, corporation or other entity.

102 (k) "Key person" means the person designated by the
103 applicant or license holder from any of the following:

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

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

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

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

124 (5) A managerial employee of a person that has applied
125 for or holds a license under this article or a managerial
126 employee of an affiliate or holding company that has control
127 of a person that has applied for or holds a license under this
128 article who will perform or performs the function of an
129 operations manager or will exercise or exercises manage-
130 ment, supervisory or policy-making authority over the
131 distribution of prescription drugs.

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

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

1 (a) Every applicant for a license under this article shall
2 provide the board with the following as part of the applica-
3 tion for a license and as part of any renewal of such license:

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

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

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

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

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

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

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

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

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

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

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

26 (1) No person or distribution outlet may act as a whole-
27 sale drug distributor without first obtaining a license to do
28 so from the Board of Pharmacy and paying any reasonable
29 fee required by the Board of Pharmacy, such fee not to
30 exceed four hundred dollars per year: *Provided*, That for
31 licenses that are effective on and after July 1, 2012, the
32 annual fee shall be \$750 per license until modified by
33 legislative rule. All fees collected pursuant to this section
34 shall be used for the operation and implementation of the
35 West Virginia Controlled Substances Monitoring Program
36 database or in the same manner as those fees governed by
37 section fourteen-b, article five, chapter thirty of this code.

38 (2) The Board of Pharmacy may grant a temporary
39 license when a wholesale drug distributor first applies to the
40 board for a wholesale drug distributor's license and the
41 temporary license shall remain valid until the Board of
42 Pharmacy finds that the applicant meets or fails to meet the

43 requirements for regular licensure, except that no temporary
44 license shall be valid for more than ninety days from the date
45 of issuance. Any temporary license issued pursuant to this
46 subdivision shall be renewable for a similar period of time
47 not to exceed ninety days pursuant to policies and proce-
48 dures to be prescribed by the Board of Pharmacy.

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

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

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

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

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

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

70 (C) A security system which includes after hours central
71 alarm or comparable entry detection capability, restricted
72 premises access, adequate outside perimeter lighting,
73 comprehensive employment applicant screening and safe-
74 guards against employee theft;

75 (D) An electronic, manual or any other reasonable system
76 of records describing all wholesale distributor activities

77 governed by this article for the two-year period following
78 disposition of each product and being reasonably accessible
79 as defined by Board of Pharmacy regulations during any
80 inspection authorized by the Board of Pharmacy;

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

86 (F) Complete, updated information to be provided to the
87 Board of Pharmacy as a condition for obtaining and retain-
88 ing a license about each wholesale distributor to be licensed
89 under this article including all pertinent licensee ownership
90 and other key personnel and facilities information deter-
91 mined necessary for enforcement of this article;

92 (G) Written policies and procedures which assure
93 reasonable wholesale distributor preparation for protection
94 against and handling of any facility security or operation
95 problems, including, but not limited to, those caused by
96 natural disaster or government emergency, inventory
97 inaccuracies or product shipping and receiving, outdated
98 product or other unauthorized product control, appropriate
99 disposition of returned goods and product recalls;

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

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

104 (2) The board of pharmacy shall consider, at a minimum,
105 the following factors in reviewing the qualifications of
106 persons who apply for a wholesale distributor license under
107 this section or for renewal of that license:

108 (A) Any conviction of the applicant under any federal,
109 state or local laws relating to drug samples, wholesale or
110 retail drug distribution or distribution of controlled sub-
111 stances;

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

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

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

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

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

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

131 (H) Compliance with requirements to maintain and make
132 available to the Board of Pharmacy or to federal, state or
133 local law-enforcement officials those records required by
134 this article; and

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

139 (3) All requirements set forth in this subsection shall
140 conform to wholesale drug distributor licensing guidelines
141 formally adopted by the United States Food and Drug
142 Administration (FDA); and in case of conflict between any
143 wholesale drug distributor licensing requirement imposed by
144 the Board of Pharmacy pursuant to this subsection and any

145 food and drug administration wholesale drug distributor
146 licensing guideline, the latter shall control.

147 (d) An employee of any licensed wholesale drug distribu-
148 tor need not seek licensure under this section and may
149 lawfully possess pharmaceutical drugs when the employee is
150 acting in the usual course of business or employment.

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

155 (f) An applicant who is awarded a license or renewal of
156 a license shall give the board written notification of any
157 material change in the information previously submitted in,
158 or with the application for the license or for renewal thereof,
159 whichever is the most recent document filed with the board,
160 within thirty days after the material change occurs or the
161 licensee becomes aware of the material change, whichever
162 event occurs last. Material changes include, but are not
163 limited to:

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

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

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

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

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

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

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

178 (h) The licensing of any person as a wholesale drug
179 distributor subjects the person and the person's agents and
180 employees to the jurisdiction of the board and to the laws of
181 this state for the purpose of the enforcement of this article,
182 article five, chapter thirty of this code and the rules of the
183 board. However, the filing of an application for a license as
184 a wholesale drug distributor by, or on behalf of, any person
185 or the licensing of any person as a wholesale drug distributor
186 may not, of itself, constitute evidence that the person is doing
187 business within this state.

188 (i) The Board of Pharmacy may adopt rules pursuant to
189 section nine of this article which permit out-of-state whole-
190 sale drug distributors to obtain any license required by this
191 article on the basis of reciprocity to the extent that: (1) An
192 out-of-state wholesale drug distributor possesses a valid
193 license granted by another state pursuant to legal standards
194 comparable to those which must be met by a wholesale drug
195 distributor of this state as prerequisites for obtaining a
196 license under the laws of this state; and (2) such other state
197 would extend reciprocal treatment under its own laws to a
198 wholesale drug distributor of this state.

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

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

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

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

12 (3) Conviction of a felony. For purposes of this subdivi-
13 sion "felony" means a felony or crime punishable as a felony

14 under the laws of this state, any other state or the United
15 States;

16 (4) Ceasing to satisfy the qualifications for licensure
17 under 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
20 the licensing authority of another state, jurisdiction of
21 foreign nation; or

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

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

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

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

1 (a) The Executive Director of the Board of Pharmacy
2 shall maintain a register of the names, addresses and the
3 date the current license was issued or renewed pursuant to
4 this article for license years beginning on and after July 1,
5 2013. The register shall be the property of the board and

6 shall be open for public examination and inspection at all
7 reasonable times, as the board may direct.

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

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

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

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

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

21 (d) A written statement signed and verified by the
22 executive director of the board, in which it is stated that
23 after diligent search of the register no record or entry of the
24 issuance of a license or registration certificate to a person is
25 found, is admissible in evidence and constitutes presumptive
26 evidence of the fact that the person is not a licensed as a
27 wholesale drug distributor under this article.

§60A-8-16. Disposition of fees.

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

The Joint Committee on Enrolled Bills hereby certifies that the foregoing bill is correctly enrolled.

.....
Chairman Senate Committee

.....
Chairman House Committee

Originated in the Senate.

To take effect July 1, 2012.

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Clerk of the Senate

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Clerk of the House of Delegates

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President of the Senate

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Speaker of the House of Delegates

The within this the
Day of, 2012.

.....
Governor