

COMMITTEE SUBSTITUTE

FOR

H. B. 4514

(BY DELEGATES WHITE, MORGAN, PERDUE,
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(Originating in the Committee on Finance)
[February 24, 2012]

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

register of wholesale and pharmacy distributors of prescription drugs; and providing for the disposition of fees.

Be it enacted by the Legislature of West Virginia:

That §60A-8-4 of the Code of West Virginia, 1931, as amended, be repealed; that §60A-8-3, §60A-8-5 and §60A-8-7 of said code be amended and reenacted; and that said code be amended by adding thereto three new sections, designated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

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

§60A-8-3. Purpose.

1 The purpose of this article is to protect the health, safety
2 and general welfare of residents of this state and to
3 implement the federal prescription drug marketing act of one
4 thousand nine hundred eighty-seven ("PDMA"), U.S. Pubic
5 Law 100-293, 102 Stat. 95, codified at 21 U.S. Code §321;
6 and particularly PDMA requirements that no person or entity
7 may engage in the wholesale distribution of human
8 prescription drugs in any state unless such person or entity is

9 licensed by such state in accordance with federally-
 10 prescribed minimum standards, terms and conditions as set
 11 forth in guidelines issued by United States food and drug
 12 administration (FDA) regulations pursuant to 21 U.S. Code
 13 §353(e)(2)(A) and (B); and such regulations as are set forth
 14 in 21 C.F.R. Part 205.

§60A-8-5. Definitions.

1 As used in this article:

2 (a) "Wholesale distribution" and "wholesale
 3 distributions" mean distribution of prescription drugs,
 4 including directly or through the use of a third-party logistics
 5 provider or any other situation in which title, ownership or
 6 control over the prescription drug remains with one person or
 7 entity 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 or intercompany deliveries into
 11 this state, being defined as any transaction, ~~or transfer,~~ or
 12 delivery into this state, between any division, subsidiary,

13 parent and/or affiliated or related company under the
14 common ownership and control of a 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
17 purchasing organization of a drug for its own use from the
18 group purchasing organization or from other hospitals or
19 health 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 ~~1954~~ 1986 to a nonprofit affiliate of the
24 organization 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 health
27 care entities that are under common control. For purposes of
28 this article, "common control" means the power to direct or
29 cause the direction of the management and policies of a
30 person or an organization, whether by ownership of stock,
31 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~~ transferee pharmacy during any
40 twelve 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 pursuant
43 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)]; or

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

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

67 (c) "Pharmacy distributor" means any pharmacy licensed
68 in this state or hospital pharmacy which is engaged in the

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

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

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

86 (f) "Prescription drug" means any human drug required
87 by federal law or regulation to be dispensed only by

88 prescription, including finished dosage forms and active
89 ingredients subject to section 503(b) of the federal food, drug
90 and cosmetic act.

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

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

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

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

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

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

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

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

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

123 (5) A managerial employee of a person that has applied
124 for or holds a license under this article or a managerial
125 employee of an affiliate or holding company that has control
126 of a person that has applied for or holds a license under this

127 article who will perform or performs the function of an
128 operations manager or will exercise or exercises
129 management, supervisory or policy-making authority over
130 the distribution of prescription drugs.

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

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

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

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

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

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

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

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

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

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

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

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

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

35 ~~(b)~~ (2) The Board of Pharmacy may grant a temporary
36 license when a wholesale drug distributor first applies to the
37 board for a wholesale drug distributor's license ~~to operate~~
38 ~~within this state~~ and the temporary license shall remain valid
39 until the Board of Pharmacy finds that the applicant meets or
40 fails to meet the requirements for regular licensure, except
41 that no temporary license shall be valid for more than ninety

42 days from the date of issuance. Any temporary license issued
 43 pursuant to this subdivision shall be renewable for a similar
 44 period of time not to exceed ninety days pursuant to policies
 45 and procedures to be prescribed by the Board of Pharmacy.

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

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

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

59 (1) As a condition for receiving and retaining any
 60 wholesale drug distributor license issued pursuant to this

61 article, each applicant shall satisfy the Board of Pharmacy
62 that it has and will continuously maintain:

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

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

67 (C) A security system which includes after hours central
68 alarm or comparable entry detection capability, restricted
69 premises access, adequate outside perimeter lighting,
70 comprehensive employment applicant screening and
71 safeguards against employee theft;

72 (D) An electronic, manual or any other reasonable system
73 of records describing all wholesale distributor activities
74 governed by this article for the two-year period following
75 disposition of each product and being reasonably accessible
76 as defined by Board of Pharmacy regulations during any
77 inspection authorized by the Board of Pharmacy;

78 (E) Officers, directors, managers and other persons in
79 charge of wholesale drug distribution, storage and handling,

80 who must at all times demonstrate and maintain their
81 capability of conducting business according to sound
82 financial practices as well as state and federal law;

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

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 ~~engage in wholesale distribution of prescription~~
107 ~~drugs with this state~~ apply for a wholesale distributor license
108 under this section or for renewal of that license:

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

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

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

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

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

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

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

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

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

140 (3) All requirements set forth in this subsection shall
141 conform to wholesale drug distributor licensing guidelines
142 formally adopted by the United States food and drug
143 administration (FDA); and in case of conflict between any
144 wholesale drug distributor licensing requirement imposed by
145 the Board of Pharmacy pursuant to this subsection and any
146 food and drug administration wholesale drug distributor
147 licensing guideline, the latter shall control.

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

153 (g) The issuance of a license pursuant to this article does
154 not change or affect tax liability imposed by this state's

155 Department of Tax and Revenue on any wholesale drug
156 distributor.

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

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

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

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

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

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

174 and

175 (6) Any other material change that the board may specify

176 by rule.

177 (i) The board may deny a license to an applicant for a

178 license or for renewal of a license if the board determines that

179 the granting of the license would not be in the public interest.

180 (j) The licensing of any person as a wholesale drug

181 distributor subjects the person and the person's agents and

182 employees to the jurisdiction of the board and to the laws of

183 this state for the purpose of the enforcement of this article,

184 article five, chapter thirty of this code and the rules of the

185 board. However, the filing of an application for a license as

186 a wholesale drug distributor by, or on behalf of, any person

187 or the licensing of any person as a wholesale drug distributor

188 may not, of itself, constitute evidence that the person is doing

189 business within this state.

190 ~~(h)~~ (k) The Board of Pharmacy may adopt rules pursuant

191 to section nine of this article which permit out-of-state

192 wholesale drug distributors to obtain any license required by
193 this article on the basis of reciprocity to the extent that: (i) An
194 out-of-state wholesale drug distributor possesses a valid
195 license granted by another state pursuant to legal standards
196 comparable to those which must be met by a wholesale drug
197 distributor of this state as prerequisites for obtaining a license
198 under the laws of this state; and (ii) such other state would
199 extend reciprocal treatment under its own laws to a wholesale
200 drug distributor of this state.

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

§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
8 application for a license or for renewal of a license as a
9 wholesale distributor or pharmacy distributor of prescription
10 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
14 subdivision “felony” means a felony or crime punishable as
15 a felony under the laws of this state, any other state or the
16 United States;

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

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

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

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

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

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

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

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

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

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

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

20 (d) A written statement signed and verified by the
21 executive director of the board, in which it is stated that after
22 diligent search of the register no record or entry of the
23 issuance of a license or registration certificate to a person is
24 found, is admissible in evidence and constitutes presumptive
25 evidence of the fact that the person is not a licensed as a
26 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
6 enforcement of its duties pursuant to this article, articles one
7 and five, chapter thirty of this code, or any other duty of the
8 board prescribed by any other provision of this code.