

1 **Senate Bill No. 324**

2 (By Senators Stollings and Beach)

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4 [Introduced February 20, 2013; referred to the Committee on
5 Government Organization; and then to the Committee on Finance.]

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10 A BILL to amend and reenact §30-5-1a and §30-5-16 of the Code of
11 West Virginia, 1931, as amended; and to amend and reenact
12 §60A-3-301 of said code, all relating to permits for
13 manufacture, distribution and dispensing of controlled
14 substances; and providing boards which license persons who
15 engage in manufacture, distribution or dispensing of
16 controlled substances with legislative rule-making authority
17 to set fees.

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

19 That §30-5-1a and §30-5-16 of the Code of West Virginia, 1931,
20 as amended, be amended and reenacted; and that §60A-3-301 of said
21 code be amended and reenacted, all to read as follows:

22 **CHAPTER 30. PROFESSIONS AND OCCUPATIONS.**

23 **ARTICLE 5. PHARMACISTS, PHARMACY TECHNICIANS, PHARMACY INTERNS AND**
24 **PHARMACIES.**

1 **§30-5-1a. Statement of purpose.**

2 (a) It is the purpose of this article to promote, preserve and
3 protect the public health, safety and welfare by the effective
4 regulation of the practice of pharmacy; the licensure of
5 pharmacists; the licensure, and regulation of all sites or persons
6 who distribute, manufacture or sell drugs or devices used in the
7 dispensing and administration of drugs or devices within this
8 state.

9 (b) A person, firm, corporation, partnership, company,
10 cooperative society or organization who offers for sale, sells,
11 offers or exposes for sale through the method of distribution any
12 legend drugs are subject to this article.

13 **§30-5-16. Permit for manufacture and packaging of drugs,**
14 **medicines, cosmetics; distribution of legend drugs;**
15 **regulations as to sanitation and equipment;**
16 **penalties; revocation of permit.**

17 (a) No drugs, ~~or~~ medicines, ~~or~~ toilet articles, dentifrices,
18 or cosmetics shall be manufactured, made, produced, packed,
19 packaged or prepared within the state except under the personal
20 supervision of a pharmacist as defined by section one-b of this
21 article or ~~such~~ other person as ~~may be~~ approved by the Board of
22 Pharmacy after an investigation and determination by the board that
23 ~~they are~~ the person is qualified by scientific or technical

1 training and/or experience to perform ~~such~~ the duties of
2 supervision as ~~may be~~ necessary to protect the public health and
3 safety.

4 (b) No person shall manufacture, make, produce, pack, package
5 or prepare any such articles without first obtaining a permit ~~to do~~
6 ~~so~~ from the Board of Pharmacy. The permit ~~shall be~~ is subject to
7 such rules with respect to sanitation and/or equipment as the Board
8 of Pharmacy may ~~from time to time adopt for the protection of the~~
9 ~~public health and safety~~ promulgate.

10 ~~(c) Any person, firm, corporation, partnership, company,~~
11 ~~cooperative society or organization who offers for sale, sells,~~
12 ~~offers or exposes for sale through the method of distribution any~~
13 ~~legend drugs shall be subject to this article.~~

14 ~~(d)~~ (c) The application for ~~any~~ a permit required by this
15 section shall be made on a form to be prescribed in legislative
16 rule, and furnished by the Board of Pharmacy and ~~shall be~~
17 accompanied by the following fees: For a distributor, \$150, for a
18 manufacturer, \$500, which amounts ~~shall also be~~ are also paid as
19 ~~the~~ fees for each annual renewal of ~~such~~ the permits. Separate
20 applications shall be made and separate permits issued for each
21 separate place of manufacture, distribution, making, producing,
22 packing, packaging or preparation.

23 (d) On and after the effective date of the reenactment of this
24 section during the Regular Session of the Legislature in 2013, the

1 Board of Pharmacy and each department, board or agency may
2 establish by legislative rule annual fees for a permit required in
3 subsection (c) of this section. The fees set forth in subsection
4 (c) of this section remain in effect until modified by a
5 legislative rule promulgated pursuant to this subsection.

6 ~~(e) The following fees shall be charged for a permit to handle~~
7 ~~controlled substances: For a hospital or clinic, \$50; for extended~~
8 ~~care facilities, \$25; for a nursing home, \$25; for a teaching~~
9 ~~institution, \$25; for a researcher, \$25; for a medical examiner,~~
10 ~~\$25; and for a pharmacy or drugstore, \$15, which amounts shall also~~
11 ~~be paid for each annual renewal of such permits.~~

12 ~~(f) (e) Permits issued under the provisions of~~ pursuant to
13 this section shall be posted in a conspicuous place in the factory
14 or place for which issued. such permits shall not be Permits are
15 not transferable, and shall expire on June 30 following the day of
16 issue and shall be renewed annually. Nothing in this section ~~shall~~
17 ~~be construed to apply~~ applies to those operating registered
18 pharmacies.

19 ~~(g) (f) Any A~~ person, firm, corporation, partnership, company,
20 cooperative society or organization violating any of the provisions
21 of this section and any permittee hereunder who shall violate any
22 of the conditions a permittee who violates a condition of this
23 permit or any of the rules adopted a rule promulgated by the Board
24 of Pharmacy, ~~shall, upon conviction, be deemed~~ shall be guilty of

1 a misdemeanor and, upon conviction, be fined not more than \$50 for
2 each offense and shall have his or her permit immediately revoked.
3 ~~Each and every day such violation continues shall constitute a~~
4 ~~separate and distinct offense. Upon conviction of a permittee, his~~
5 ~~or her permit shall also immediately be revoked and become null and~~
6 ~~void. Each day a violation continues constitutes a separate~~
7 ~~offense.~~

8 ~~(h)~~ (g) ~~Any~~ A person, firm, corporation, partnership, company,
9 cooperative society, organization or ~~any~~ a permittee who is
10 convicted of two or more successive violations of the provisions of
11 this section or of the rules ~~adopted~~ promulgated by the Board of
12 Pharmacy shall, at the discretion of the Board of Pharmacy, have
13 ~~such~~ her or his permit permanently revoked and the Board of
14 Pharmacy shall refuse to issue further permits to ~~such~~ the person,
15 firm, corporation, partnership, company, cooperative society,
16 organization or permittee.

17 **CHAPTER 60A. UNIFORM CONTROLLED SUBSTANCE ACT.**

18 **ARTICLE 3. REGULATION OF MANUFACTURE, DISTRIBUTION AND DISPENSING**

19 **OF CONTROLLED SUBSTANCES.**

20 **§60A-3-301. Rules; fees.**

21 (a) The State Board of Pharmacy shall promulgate rules and
22 charge fees relating to the registration and control of the
23 manufacture and distribution of controlled substances within this
24 state. ~~and~~ Each department, board or agency of this state which

1 licenses or registers practitioners authorized to dispense ~~any a~~
2 controlled substance shall promulgate rules and charge fees
3 relating to the registration and control of the dispensing of
4 controlled substances within this state by those practitioners
5 licensed or registered by ~~such~~ the department, board or agency.

6 (b) The State Board of Pharmacy or the department, board or
7 agency shall collect the following annual registration fees from
8 persons who manufacture, distribute, dispense or conduct research
9 with controlled substances: For registration of a manufacturer,
10 \$50; for registration of a wholesaler, \$50; for registration of a
11 hospital or clinic, \$50; for registration of a medical examiner,
12 \$25; for registration of a teaching or research institution, \$25;
13 for registration of nursing home or an extended care facility, \$25;
14 and for registration of a ~~retailer \$15. for registration of a~~
15 ~~hospital or clinic, \$15; and for registration of a research~~
16 ~~institution, \$5. dispenser, \$15.~~

17 (c) On and after the effective date of the reenactment of this
18 section during the Regular Session of the Legislature in 2013, the
19 Board of Pharmacy and each department, board or agency may
20 establish by legislative rule, annual fees for a registration as
21 set forth in this section. The fees set forth in subsection (b) of
22 this section remain in effect until modified by a legislative rule
promulgated pursuant to this subsection.

NOTE: The purpose of this bill is to remove fees for the manufacture, distribution and dispensing of controlled substances from code and to allow the boards which license persons who engage in manufacture, distribution or dispensing to set appropriate fees by legislative rule.

Strike-throughs indicate language that would be stricken from the present law and underscoring indicates new language that would be added.