COMMITTEE SUBSTITUTE

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Senate Bill No. 324

(By Senators Stollings and Beach)

[Originating in the Committee on Finance;
reported March 28, 2013.]

A BILL to amend and reenact §30-5-1a and §30-5-16 of the Code of West Virginia, 1931, as amended; to amend said code by adding thereto a new section, designated §30-5-16c; to amend and reenact §60A-3-301 of said code; and to amend said code by adding thereto a new section, designated §60A-3-301a, all relating to permits for manufacturing, making, producing, packing, packaging or preparing drugs, medicines, toilet

articles, dentifrices and cosmetics and registration of practitioners dispensing controlled substances; modifying fees associated with the permits; granting rule-making authority to the Board of Pharmacy to establish a fee schedule for obtaining and maintaining the permit; providing that statutory fee schedule will remain in effect until amended, modified, repealed or replaced by legislative rule; clarifying disciplinary action that may be taken if condition or rule relating to permit is violated; modifying registration fees for practitioners dispensing controlled substances; granting rule-making authority to boards, departments and agencies that license or register practitioners dispensing controlled substances; and providing that statutory fee schedule for registering practitioners dispensing controlled substances will remain in effect until amended, modified, repealed or replaced by legislative rule.

Be it enacted by the Legislature of West Virginia:

That §30-5-1a and §30-5-16 of the Code of West Virginia, 1931, as amended, be amended and reenacted; that said code be

amended by adding thereto a new section, designated §30-5-16c; that §60A-3-301 of said code be amended and reenacted; and that said code be amended by adding thereto a new section, designated §60A-3-301a, all to read as follows:

CHAPTER 30. PROFESSIONS AND OCCUPATIONS.

ARTICLE 5. PHARMACISTS, PHARMACY TECHNICIANS, PHARMACY INTERNS AND PHARMACIES.

§30-5-1a. Statement of purpose.

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

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

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

(a) No drugs, ~~or~~ medicines, ~~or~~ toilet articles, dentifrices or cosmetics shall be manufactured, made, produced, packed, packaged or prepared within the state except under the personal supervision of a pharmacist as defined by section one-b of this article or ~~such~~ any other person ~~as may be~~ approved by the Board of Pharmacy after an investigation and determination by the board that ~~they are~~ the person is qualified by scientific or technical training and/or experience to perform ~~such~~ the duties of supervision ~~as may be~~ necessary to protect the public health and safety.

(b) ~~No~~ A person shall not manufacture, make, produce, pack, package or prepare any ~~such~~ of these articles without first obtaining a permit ~~to do so~~ from the Board of Pharmacy. The permit ~~shall be~~ is subject to ~~such~~ rules with respect to sanitation and/or equipment ~~as~~ promulgated by the Board of

Pharmacy ~~may from time to time adopt for the protection of the public health and safety~~.

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

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

~~(e) The following fees shall be charged for a permit to handle controlled substances: For a hospital or clinic, $50; for extended care facilities, $25; for a nursing home, $25; for~~

~~a teaching institution, $25; for a researcher, $25; for a medical examiner, $25; and for a pharmacy or drugstore, $15, which amounts shall also be paid for each annual renewal of such permits.~~

(d) The board may establish, by legislative rule, application and renewal fees for a permit required by this section: *Provided,* That the fee schedule in effect as of July 1, 2013, shall remain in effect until amended, modified, repealed or replaced by any legislative rule promulgated pursuant to this section.

~~(f)~~ (e) ~~Permits~~ A permit issued ~~under the provisions of~~ pursuant to this section shall be posted in a conspicuous place in the factory or place for which it was issued. ~~such permits shall not be~~ A permits is not transferable, ~~and shall expire~~ expires on June 30 following the day of issue and shall be renewed annually. Nothing in this section ~~shall be construed to apply~~ applies to those persons operating registered pharmacies.

~~(g)~~ (f) ~~Any~~ A person, firm, corporation, partnership, company, cooperative society or organization violating any of the provisions of this section ~~and any permittee hereunder who shall violate any of the conditions~~ or a permittee who violates a condition of this permit or ~~any of the rules adopted~~ a rule promulgated by the Board of Pharmacy, ~~shall, upon conviction, be deemed~~ is guilty of a misdemeanor and, upon conviction, shall be fined not more than $50 for each offense ~~Each and every day such violation continues shall constitute a separate and distinct offense. Upon conviction of a permittee, his permit shall also immediately be revoked and become null and void.~~ and shall have his or her permit immediately revoked. Each day a violation continues constitutes a separate offense.

~~(h)~~ (g) ~~Any~~ A person, firm, corporation, partnership, company, cooperative society, organization or ~~any~~ a permittee who is convicted of two or more successive violations of the provisions of this section or of the rules ~~adopted~~ promulgated by the Board of Pharmacy shall, at the discretion of the Board of Pharmacy, have ~~such~~ her or his

permit permanently revoked and the Board of Pharmacy shall refuse to issue further permits to ~~such~~ that person, firm, corporation, partnership, company, cooperative society, organization or permittee.

§30-5-16c. Fee schedule.

Until amended, modified, repealed or replaced by legislative rule, the board shall collect the following fees from any person, firm, corporation, partnership, company, cooperative society or organization seeking a permit pursuant to section sixteen of this article:

(1) Distributor application fee: $150;

(2) Manufacturer application fee: $500;

(3) Distributor annual permit renewal fee: $150; and

(4) Manufacturer annual permit renewal fee: $500.

CHAPTER 60A. UNIFORM CONTROLLED SUBSTANCE ACT.

ARTICLE 3. REGULATION OF MANUFACTURE, DISTRIBUTION AND DISPENSING OF CONTROLLED SUBSTANCES.

§60A-3-301. Rules; fees.

(a) The State Board of Pharmacy shall promulgate rules and charge fees relating to the registration and control of the manufacture and distribution of controlled substances within this state. ~~and~~ Each department, board or agency of this state which licenses or registers practitioners authorized to dispense ~~any~~ a controlled substance shall promulgate rules and charge fees relating to the registration and control of the dispensing of controlled substances within this state by those practitioners licensed or registered by ~~such~~ that department, board or agency.

~~The State Board of Pharmacy or the department, board or agency shall collect the following annual registration fees from persons who manufacture, distribute, dispense or conduct research with controlled substances. For registration of a manufacturer, $50; for registration of a wholesaler, $50; for registration of a retailer $15. for registration of a hospital or clinic, $15; and for registration of a research institution, $5.~~

(b) The fee schedule in effect as of July 1, 2013, shall remain in effect until amended, modified, repealed or replaced by any legislative rule promulgated pursuant to this section.

§60A-3-301a. Fee schedule.

Until amended, modified, repealed or replaced by legislative rule, the State Board of Pharmacy or any department, board or agency shall collect the following annual registration fees from persons who manufacture, distribute, dispense or conduct research with respect to controlled substances:

(1) $50 for registration of a manufacturer;

(2) $50 for registration of a wholesaler;

(3) $50 for registration of a hospital or clinic;

(4) $25 for registration of a medical examiner;

(5) $25 for registration of a teaching or research institution;

(6) $25 for registration of a nursing home or an extended care facility; and

(7) $15 for registration of a dispenser.