ENGROSSED SENATE
BILL NO. 640

By: Shurden of the Senate

and

Nance of the House

[professions and occupations - sale, manufacture or packaging of dangerous drugs - effective date]

BE IT ENACTED BY THE PEOPLE OF THE STATE OF OKLAHOMA:

SECTION 1. AMENDATORY 59 O.S. 2001, Section 353.18, as amended by Section 20, Chapter 523, O.S.L. 2004 (59 O.S. Supp. 2004, Section 353.18), is amended to read as follows:

Section 353.18 A. 1. It shall be unlawful for any person to engage in selling at retail, or offering for sale, dangerous drugs, medicines, chemicals or poisons for the treatment of disease, excluding agricultural chemicals and drugs, or to accept prescriptions for same, without first procuring a license from the Board of Pharmacy. The provisions of this subsection shall not apply to medical gas suppliers or medical gas distributors regulated pursuant to the provisions of subsection B of this section.

2. A license shall be issued to such person as the Board shall deem qualified upon evidence satisfactory to the Board that:

a. the place for which the license is sought will be conducted in full compliance with the law and the rules of the Board,

b. the location, appointments and physical characteristics of the place are reasonably consistent with the maintenance of professional surroundings and constitute no known danger to the public health and safety,

c. the place will be under the management and control of a registered pharmacist, and

d. a registered pharmacist or assistant pharmacist will be present and on duty at all hours the pharmacy is open for business; provided, however, the provisions of this subparagraph shall not apply to a hospital drug room~~,~~.

3. a. An application for a license issued pursuant to the provisions of this subsection shall:

(1) be submitted to the Board in writing, and

(2) contain the name or names of persons owning the pharmacy.

b. An application for each initial or renewal license shall be accompanied by a licensing fee not to exceed One Hundred Fifty Dollars ($150.00) for each period of one (1) year. Prior to opening for business, all applicants for an initial license or permit shall be inspected. Applicants shall pay an inspection fee not to exceed One Hundred Dollars ($100.00); provided however, that no charge shall be made for the licensing of any Federal Veterans Hospital in the State of Oklahoma.

c. A license issued pursuant to the provisions of this subsection shall be valid for a period set by the Board and shall contain the name of the licensee and the address of the place at which such business shall be conducted.

4. A retail pharmacy that prepares sterile therapeutic preparations that shall be free from living microorganisms (aseptic) shall obtain a pharmacy license, and shall also obtain a parenteral permit at a fee set by the Board, not to exceed Seventy-five Dollars

($75.00). Such pharmacy shall meet requirements set by the Board by rule for parenteral permits.

B. 1. It shall be unlawful for any person to manufacture, package, or wholesale any dangerous drugs, or to engage in selling, or offering for sale at retail, medical gases except under the management and control of a registered pharmacist or such other persons as may be approved by the Board after an investigation and determination of such person's qualifications. No person shall sell medical gases, or manufacture, package, or wholesale dangerous drugs offered for sale in this state without first obtaining a permit from the Board.

2. a. An application for an initial or renewal permit issued pursuant to the provisions of this subsection shall be:

(1) made in writing, and

(2) accompanied by a permit fee not to exceed Three Hundred Dollars ($300.00) for each period of one (1) year.

b. Prior to opening for business, all applicants for an initial permit shall be inspected. Applicants shall pay an inspection fee not to exceed One Hundred Dollars ($100.00).

3. A permit issued pursuant to the provisions of this subsection shall be valid for a period determined by the Board and shall contain the name of the permittee and the address of the place at which such business shall be conducted.

4. A registered permittee who fails to complete an application for a renewal permit by the fifteenth day after the expiration of the permit shall pay a late fee to be fixed by the Board.

C. A registrant who, pursuant to the provisions of this section, fails to complete an application for a renewal license or

permit by the fifteenth day after the expiration of the license or permit shall pay a late fee to be fixed by the Board.

D. 1. The Board shall promulgate rules regarding the issuance and renewal of licenses and permits pursuant to the Oklahoma Pharmacy Act which shall include, but need not be limited to:

a. provisions for new or renewal application requirements for both in- and out-of-state wholesale distributors, chain pharmacy warehouses and repackagers that ship into Oklahoma. Requirements for new and renewal applications, if such information has not been previously provided to the Board, shall include, but need not be limited to the following:

(1) type of ownership, whether individual, partnership or corporation,

(2) names of principal owners or officers and their Social Security numbers,

(3) names of designated managers and their Social Security numbers,

(4) applicant's and designated managers' fingerprints,

(5) criminal background check information for the applicants and designated managers as required by rule,

(6) a copy of the license from the applicant's or designated managers' home state, and

(7) bond requirements, and

b. provisions for the establishment of a pedigree or electronic file to be used by wholesale distributors, chain pharmacy warehouses and repackagers for the purpose of ensuring the integrity of drugs owned, purchased, distributed, returned, transferred and sold

when the products leave the normal distribution channel.

2. The Board shall be authorized to use an outside agency, such as the National Association of Boards of Pharmacy (NABP) or the Verified Accredited Wholesale Distributors (VAWD), to accredit wholesale distributors and repackagers.

3. The Board may exempt by rule wholesalers accredited by VAWD from the provisions of subparagraphs a and b of paragraph 1 of this subsection.

4. In promulgating such rules, the Board shall seek input from manufacturers, wholesale distributors, chain pharmacy warehouses and repackagers.

E. The Oklahoma Pharmacy Act shall not be construed to prevent the sale of nonprescription drugs in original packages by any merchant or dealer.

SECTION 2. This act shall become effective November 1, 2005.

Passed the Senate the 16th day of March, 2005.

_____
Presiding Officer of the Senate

Passed the House of Representatives the ____ day of _____, 2005.

_____
Presiding Officer of the House
of Representatives