

ENROLLED HOUSE
BILL NO. 1347

By: Terrill, Kiesel, Calvey, Cooksey,
Cox, DeWitt, Martin, Nance,
Peterson (Pam), Shelton,
Wesselhoft and Worthen of the
House

and

Paddack, Eason McIntyre, Garrison
and Coates of the Senate

An Act relating to public health and safety; amending 63 O.S. 2001, Section 1-1918.2, as last amended by Section 3, Chapter 374, O.S.L. 2004, and as renumbered by Section 9, Chapter 374, O.S.L. 2004 (59 O.S. Supp. 2004, Section 367.3), which relates to unused prescription medications; deleting reference to certain pilot program; expanding program for certain facilities; amending 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), which relates to the sale, manufacturing or packaging of dangerous drugs; clarifying certain responsibilities of the Board of Pharmacy; specifying contents of rules promulgated by the Board; specifying responsibilities of wholesale distributors; amending 59 O.S. 2001, Section 3003, as amended by Section 13, Chapter 523, O.S.L. 2004 (59 O.S. Supp. 2004, Section 3003), which relates to the Orthotics and Prosthetics Practice Act; adding certain persons who are exempt from provisions of the act; and providing an effective date.

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

SECTION 1. AMENDATORY 63 O.S. 2001, Section 1-1918.2, as last amended by Section 3, Chapter 374, O.S.L. 2004, and as renumbered by Section 9, Chapter 374, O.S.L. 2004 (59 O.S. Supp. 2004, Section 367.3), is amended to read as follows:

~~Section 367.3 A. 1. The State Board of Health, the Board of Pharmacy and the Oklahoma Health Care Authority shall jointly develop and implement a pilot program consistent with public health and safety through which unused prescription drugs, other than prescription drugs defined as controlled dangerous substances by Section 2-101 of Title 63 of the Oklahoma Statutes, may be transferred from nursing facilities to pharmacies operated by city-county health departments or county pharmacies for the purpose of distributing the medication to Oklahoma residents who are medically indigent.~~

~~2. The pilot program established pursuant to the provisions of paragraph 1 of this subsection shall conform to the requirements established in rules promulgated by the State Board of Health, the Board of Pharmacy and the Oklahoma Health Care Authority prior to~~

~~the effective date of this act, and shall remain in effect until January 1, 2005.~~

~~B. The State Board of Health, the Board of Pharmacy, the Oklahoma Health Care Authority, the State Board of Medical Licensure and Supervision, and the State Board of Osteopathic Examiners shall review and evaluate the pilot program and shall submit a report and any recommendations to the Governor, the Speaker of the Oklahoma House of Representatives, the President Pro Tempore of the State Senate, and the Chairs of the appropriate legislative committees on or before January 1, 2005.~~

~~C. 1.~~ Beginning January 1, 2005, the Board of Pharmacy shall implement statewide a program consistent with public health and safety through which unused prescription drugs, other than prescription drugs defined as controlled dangerous substances in Section 2-101 of Title 63 of the Oklahoma Statutes, may be transferred from nursing facilities, assisted living centers, public intermediate care facilities for people with mental retardation (ICF/MR) or pharmaceutical manufacturers to pharmacies operated by a county. If no county pharmacy exists, or if a county pharmacy chooses not to participate, such unused prescription medications may be transferred to a pharmacy operated by a city-county health department or a pharmacy under contract with a city-county health department, a pharmacy operated by the Department of Mental Health and Substance Abuse Services or a charitable clinic for the purpose of distributing the unused prescription medications to Oklahoma residents who are medically indigent.

~~2. B.~~ The Board of Pharmacy shall promulgate rules and establish procedures necessary to implement the program established by the Utilization of Unused Prescription Medications Act.

~~3. C.~~ The Board of Pharmacy shall provide technical assistance to entities who may wish to participate in the program.

SECTION 2. 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_{7.}
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. The Board shall exempt from the provisions of this subsection logistics providers that receive prescription drugs from original sponsors or manufacturers, deliver the drug products in commerce at the direction of the original sponsor or manufacturer, and do not purchase, sell, trade, or take title to any prescription drug.

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

E. A wholesale distributor shall accept prescription drug returns pursuant to the terms and conditions of the agreement between the wholesale distributor and a hospital, pharmacy, chain pharmacy warehouse or other healthcare entity and these returns shall not be subject to any pedigree or electronic file requirement unless the returns are greater than the purchases from the wholesale distributor. Wholesale distributors shall be held accountable for maintaining their return process and ensuring that items returned originated from their operations, that the return process is secure, and that the return process does not permit the entry of adulterated and counterfeit product.

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

SECTION 3. AMENDATORY 59 O.S. 2001, Section 3003, as amended by Section 13, Chapter 523, O.S.L. 2004 (59 O.S. Supp. 2004, Section 3003), is amended to read as follows:

Section 3003. The Orthotics and Prosthetics Practice Act shall not apply to:

1. Persons licensed by this state as practitioners of the healing arts when engaging in the practice or practices for which licensed;

2. A person who is employed by the government of the United States or any entity thereof while in the discharge of the employee's assigned duties;

3. A student enrolled in a school of orthotics or prosthetics recognized by the State Board of Medical Licensure and Supervision or a resident as defined by Section 3002 of this title who is continuing clinical education;

4. A person licensed by this state as a physical therapist, occupational therapist, or physician assistant when engaging in the practice for which licensed; ~~or~~

5. A person certified by the Board for Certification in Pedorthics when practicing pedorthics at the ankle or below; or

6. Persons engaged in the practice of orthotics as an employee or authorized representative of an orthotics manufacturer with employment responsibilities that include, but are not limited to, evaluating, measuring, designing, fabricating, assembling, fitting, adjusting, servicing, training, repairing, replacing or delivering an orthotic device under order, direction or prescription of a physician or health-care provider operating within the licensed scope of practice of such physician or health-care provider.

SECTION 4. This act shall become effective November 1, 2005.

Passed the House of Representatives the 24th day of May, 2005.

Presiding Officer of the House of
Representatives

Passed the Senate the 25th day of May, 2005.

Presiding Officer of the Senate