

1 STATE OF OKLAHOMA

2 1st Session of the 52nd Legislature (2009)

3 HOUSE BILL 1849

By: McMullen

4
5
6 AS INTRODUCED

7 An Act relating to professions and occupations;
8 amending 59 O.S. 2001, Section 353.18, as last
9 amended by Section 2, Chapter 285, O.S.L. 2005 (59
10 O.S. Supp. 2008, Section 353.18), which relates to
11 limitations on the sale of certain drugs and other
12 items; prohibiting the use of prescription
13 information for certain purposes; defining term;
14 providing exceptions; and providing an effective
15 date.

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

17 SECTION 1. AMENDATORY 59 O.S. 2001, Section 353.18, as
18 last amended by Section 2, Chapter 285, O.S.L. 2005 (59 O.S. Supp.
19 2008, Section 353.18), is amended to read as follows:

20 Section 353.18 A. 1. It shall be unlawful for any person to
21 engage in selling at retail, or offering for sale, dangerous drugs,
22 medicines, chemicals or poisons for the treatment of disease,
23 excluding agricultural chemicals and drugs, or to accept
24 prescriptions for same, without first procuring a license from the
Board of Pharmacy. The provisions of this subsection shall not

1 apply to medical gas suppliers or medical gas distributors regulated
2 pursuant to the provisions of subsection B of this section.

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

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

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

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

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

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

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

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

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

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

16 4. A retail pharmacy that prepares sterile therapeutic
17 preparations that shall be free from living microorganisms (aseptic)
18 shall obtain a pharmacy license, and shall also obtain a parenteral
19 permit at a fee set by the Board, not to exceed Seventy-five Dollars
20 (\$75.00). Such pharmacy shall meet requirements set by the Board by
21 rule for parenteral permits.

22 B. 1. It shall be unlawful for any person to manufacture,
23 package, or wholesale any dangerous drugs, or to engage in selling,
24 or offering for sale at retail, medical gases except under the

1 management and control of a registered pharmacist or such other
2 persons as may be approved by the Board after an investigation and
3 determination of such person's qualifications. No person shall sell
4 medical gases, or manufacture, package, or wholesale dangerous drugs
5 offered for sale in this state without first obtaining a permit from
6 the Board.

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

10 (1) made in writing, and

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

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

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

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

1 C. A registrant who, pursuant to the provisions of this
2 section, fails to complete an application for a renewal license or
3 permit by the fifteenth day after the expiration of the license or
4 permit shall pay a late fee to be fixed by the Board.

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

- 8 a. provisions for new or renewal application requirements
9 for both in- and out-of-state wholesale distributors,
10 chain pharmacy warehouses and repackagers that ship
11 into Oklahoma. Requirements for new and renewal
12 applications, if such information has not been
13 previously provided to the Board, shall include, but
14 need not be limited to, the following:
- 15 (1) type of ownership, whether individual,
16 partnership or corporation,
 - 17 (2) names of principal owners or officers and their
18 Social Security numbers,
 - 19 (3) names of designated managers and their Social
20 Security numbers,
 - 21 (4) applicant's and designated managers'
22 fingerprints,
- 23
24

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

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

6 (7) bond requirements, and

7 b. provisions for the establishment of a pedigree or
8 electronic file to be used by wholesale distributors,
9 chain pharmacy warehouses and repackagers for the
10 purpose of ensuring the integrity of drugs owned,
11 purchased, distributed, returned, transferred and sold
12 when the products leave the normal distribution
13 channel.

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

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

21 4. The Board shall exempt from the provisions of this
22 subsection logistics providers that receive prescription drugs from
23 original sponsors or manufacturers, deliver the drug products in
24 commerce at the direction of the original sponsor or manufacturer,

1 and do not purchase, sell, trade, or take title to any prescription
2 drug.

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

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

17 F. Records pertaining to prescription information containing
18 patient-identifiable and prescriber-identifiable data shall not be
19 transferred, used, or sold by any pharmacy benefits manager,
20 insurance company, electronic transmission intermediary, retail,
21 mail order, or Internet pharmacy or other similar entity, for any
22 commercial purpose, except for the limited purposes of pharmacy
23 reimbursement, formulary compliance, care management, utilization
24 review by a health care provider, the patient's insurance provider

1 or the agent of either, health care research, or as otherwise
2 provided by law. Commercial purpose includes, but is not limited
3 to, advertising, marketing, promotion, or any activity that could be
4 used to influence sales or market share of a pharmaceutical product,
5 influence or evaluate the prescribing behavior of an individual
6 health care professional, or evaluate the effectiveness of a
7 professional pharmaceutical detailing sales force. Nothing in this
8 section shall prohibit the dispensing of prescription information
9 between an authorized prescriber and a licensed pharmacy; the
10 transfer of prescription information between licensed pharmacies;
11 the transfer of prescription records that may occur in the event a
12 pharmacy ownership is changed or transferred; care management
13 educational communications provided to a patient about the patient's
14 health condition, adherence to a prescribed course of therapy or
15 other information about the drug being dispensed, treatment options
16 or clinical trials. Nothing in this section shall prohibit the
17 collection, use, transfer, or sale of patient and prescriber data
18 identified by zip code, geographic region, or medical specialty for
19 commercial purposes.

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

23

24

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24

SECTION 2. This act shall become effective November 1, 2009.

52-1-6410 SDR 01/03/09