SB1150 FULLPCS1 David Derby-AMM
4/5/2016 10:07:12 am

COMMITTEE AMENDMENT

HOUSE OF REPRESENTATIVES
State of Oklahoma

SPEAKER:

CHAIR:

I move to amend SB1150
Of the printed Bill

Page _____ Section _____ Lines _____
Of the Engrossed Bill

By striking the Title, the Enacting Clause, the entire bill, and by inserting in lieu thereof the following language:

AMEND TITLE TO CONFORM TO AMENDMENTS

Amendment submitted by: David Derby

Adopted: _____

_____
Reading Clerk

STATE OF OKLAHOMA

2nd Session of the 55th Legislature (2016)

PROPOSED
COMMITTEE SUBSTITUTE
FOR ENGROSSED
SENATE BILL NO. 1150

By: Standridge of the Senate

and

Cox of the House

PROPOSED COMMITTEE SUBSTITUTE

An Act relating to pharmacy; amending 59 O.S. 2011, Section 353.1, as last amended by Section 1, Chapter 230, O.S.L. 2015 (59 O.S. Supp. 2015, Section 353.1), which relates to definitions; updating statutory references; amending 59 O.S. 2011, Section 353.11, as amended by Section 7, Chapter 230, O.S.L. 2015 (59 O.S. Supp. 2015, Section 353.11), which relates to license renewal; amending Section 8, Chapter 230, O.S.L. 2015 (59 O.S. Supp. 2015, Section 353.11a), which relates to continuing education requirements; amending 59 O.S. 2011, Section 353.18, as amended by Section 11, Chapter 230, O.S.L. 2015 (59 O.S. Supp. 2015, Section 353.18), which relates to the sale, manufacturing, and packaging of dangerous drugs; amending 59 O.S. 2011, Section 353.24, as amended by Section 16, Chapter 230, O.S.L. 2015 (59 O.S. Supp. 2015, Section 353.24), which relates to unlawful acts; amending 59 O.S. 2011, Section 353.26, as amended by Section 17, Chapter 230, O.S.L. 2015 (59 O.S. Supp. 2015, Section 353.26), which relates to revocations or suspensions of licenses; clarifying language; amending Sections 1 and 4, Chapter 263, O.S.L. 2014 (59 O.S. Supp. 2015, Sections 357 and 360), which relate to pharmacy benefit plans; defining term; modifying administrative appeals procedure; repealing 59 O.S. 2011, Sections 353.13, 353.29, 364, and 366, which relate to unlawful acts, supportive personnel, renewal certifications, and

alternative methods of meeting certain requirements; and providing an effective date.

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

SECTION 1. AMENDATORY 59 O.S. 2011, Section 353.1, as last amended by Section 1, Chapter 230, O.S.L. 2015 (59 O.S. Supp. 2015, Section 353.1), is amended to read as follows:

Section 353.1. For the purposes of the Oklahoma Pharmacy Act:

1. "Accredited program" means those seminars, classes, meetings, work projects, and other educational courses approved by the Board for purposes of continuing professional education;

2. "Act" means the Oklahoma Pharmacy Act;

3. "Administer" means the direct application of a drug, whether by injection, inhalation, ingestion or any other means, to the body of a patient;

4. "Assistant pharmacist" means any person presently licensed as an assistant pharmacist in the State of Oklahoma by the Board pursuant to Section 353.10 of this title and for the purposes of the Oklahoma Pharmacy Act shall be considered the same as a pharmacist, except where otherwise specified;

5. "Board" or "State Board" means the State Board of Pharmacy;

6. "Certify" or "certification of a prescription" means the review of a filled prescription by a licensed pharmacist or a licensed practitioner with dispensing authority to confirm that the

medication, labeling and packaging of the filled prescription are accurate and meet all requirements prescribed by state and federal law. For the purposes of this paragraph, "licensed practitioner" shall not include optometrists with dispensing authority;

7. "Chemical" means any medicinal substance, whether simple or compound or obtained through the process of the science and art of chemistry, whether of organic or inorganic origin;

8. "Compounding" means the combining, admixing, mixing, diluting, pooling, reconstituting or otherwise altering of a drug or bulk drug substance to create a drug. Compounding includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns;

9. "Continuing professional education" means professional, pharmaceutical education in the general areas of the socioeconomic and legal aspects of health care; the properties and actions of drugs and dosage forms; and the etiology, characteristics and therapeutics of the diseased state;

10. "Dangerous drug", "legend drug", "prescription drug" or "Rx Only" means a drug:

a. for human use subject to 21 U.S.C. 353(b)(1); or

b. is labeled "Prescription Only", or labeled with the following statement: "Caution: Federal law restricts this drug except for use by or on the order of a licensed veterinarian".

11. "Director" means the Executive Director of the State Board of Pharmacy unless context clearly indicates otherwise;

12. "Dispense" or "dispensing" means the interpretation, evaluation, and implementation of a prescription drug order, including the preparation and delivery of a drug or device to a patient or a patient's agent in a suitable container appropriately labeled for subsequent administration to, or use by, a patient. Dispense includes sell, distribute, leave with, give away, dispose of, deliver or supply;

13. "Dispenser" means a retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distributions of such entities under common ownership and control that do not act as a wholesale distributor. For the purposes of this paragraph, "dispenser" does not mean a person who dispenses only products to be used in animals in accordance with 21 U.S.C. 360b(a)(5);

14. "Distribute" or "distribution" means the sale, purchase, trade, delivery, handling, storage, or receipt of a product, and does not include the dispensing of a product pursuant to a prescription executed in accordance with 21 U.S.C. 353(b)(1) or the dispensing of a product approved under 21 U.S.C. 360b(b);

15. "Doctor of Pharmacy" means a person licensed by the Board to engage in the practice of pharmacy. The terms "pharmacist", "D.Ph.", and "Doctor of Pharmacy" shall be interchangeable and shall have the same meaning wherever they appear in the Oklahoma Statutes and the rules promulgated by the Board;

16. "Drug outlet" means all manufacturers, repackagers, outsourcing facilities, wholesale distributors, third-party logistics providers, pharmacies, and all other facilities which are engaged in dispensing, delivery, distribution or storage of dangerous drugs;

17. "Drugs" means all medicinal substances and preparations recognized by the United States Pharmacopoeia and National Formulary, or any revision thereof, and all substances and preparations intended for external and/or internal use in the cure, diagnosis, mitigation, treatment or prevention of disease in humans or animals and all substances and preparations, other than food, intended to affect the structure or any function of the body of a human or animals;

18. "Drug sample" means a unit of a prescription drug packaged under the authority and responsibility of the manufacturer that is not intended to be sold and is intended to promote the sale of the drug;

19. "Filled prescription" means a packaged prescription medication to which a label has been affixed which contains such information as is required by the Oklahoma Pharmacy Act;

20. "Hospital" means any institution licensed as a hospital by this state for the care and treatment of patients, or a pharmacy operated by the Oklahoma Department of Veterans Affairs;

21. "Licensed practitioner" means an allopathic physician, osteopathic physician, podiatric physician, dentist, veterinarian or optometrist licensed to practice and authorized to prescribe dangerous drugs within the scope of practice of such practitioner;

22. "Manufacturer" or "virtual manufacturer" means with respect to a product:

a. a person that holds an application approved under 21 U.S.C. 355 or a license issued under 42 U.S.C. 262 for such product, or if such product is not the subject of an approved application or license, the person who manufactured the product,

b. a co-licensed partner of the person described in subparagraph a that obtains the product directly from a person described in this subparagraph or subparagraph a, or

c. an affiliate of a person described in subparagraph a or b who receives the product directly from a person

described in this subparagraph or in subparagraph a or b;

23. "Manufacturing" means the production, preparation, propagation, compounding, conversion or processing of a device or a drug, either directly or indirectly by extraction from substances of natural origin or independently by means of chemical or biological synthesis and includes any packaging or repackaging of the substances or labeling or relabeling of its container, and the promotion and marketing of such drugs or devices. The term "manufacturing" also includes the preparation and promotion of commercially available products from bulk compounds for resale by licensed pharmacies, licensed practitioners or other persons;

24. "Medical gas" means those gases including those in liquid state upon which the manufacturer or distributor has placed one of several cautions, such as "Rx Only", in compliance with federal law;

25. "Medical gas order" means an order for medical gas issued by a licensed prescriber;

26. "Medical gas distributor" means a person licensed to distribute, transfer, wholesale, deliver or sell medical gases on drug orders to suppliers or other entities licensed to use, administer or distribute medical gas and may also include a patient or ultimate user;

27. "Medical gas supplier" means a person who dispenses medical gases on drug orders only to a patient or ultimate user;

28. "Medicine" means any drug or combination of drugs which has the property of curing, preventing, treating, diagnosing or mitigating diseases, or which is used for that purpose;

29. "Nonprescription drugs" means medicines or drugs which are sold without a prescription and which are prepackaged for use by the consumer and labeled in accordance with the requirements of the statutes and regulations of this state and the federal government. Such items shall also include medical and dental supplies and bottled or nonbulk chemicals which are sold or offered for sale to the general public if such articles or preparations meet the requirements of the Federal Food, Drug and Cosmetic Act, 21 U.S.C.A., Section 321 et seq.;

30. "Outsourcing facility", including "virtual outsourcing facility" means a facility at one geographic location or address that:

a. is engaged in the compounding of sterile drugs,

b. has elected to register as an outsourcing facility, and

c. complies with all requirements of 21 U.S.C. 353b;

31. "Package" means the smallest individual saleable unit of product for distribution by a manufacturer or repackager that is intended by the manufacturer for ultimate sale to the dispenser of such product. For the purposes of this paragraph, "individual saleable unit" means the smallest container of a product introduced

into commerce by the manufacturer or repackager that is intended by the manufacturer or repackager for individual sale to a dispenser;

32. "Person" means an individual, partnership, limited liability company, corporation or association, unless the context otherwise requires;

33. "Pharmacist-in-charge" or "PIC" means the pharmacist licensed in this state responsible for the management control of a pharmacy and all other aspects of the practice of pharmacy in a licensed pharmacy as defined by Section 353.18 of this title;

34. "Pharmacy" means a place regularly licensed by the Board of Pharmacy in which prescriptions, drugs, medicines, chemicals and poisons are compounded or dispensed or such place where pharmacists practice the profession of pharmacy, or a pharmacy operated by the Oklahoma Department of Veterans Affairs;

35. "Pharmacy technician", "technician", "Rx tech", or "tech" means a person issued a Technician permit by the State Board of Pharmacy to assist the pharmacist and perform nonjudgmental, technical, manipulative, non-discretionary functions in the prescription department under the immediate and direct supervision of a pharmacist;

36. "Poison" means any substance which when introduced into the body, either directly or by absorption, produces violent, morbid or fatal changes, or which destroys living tissue with which such substance comes into contact;

37. "Practice of pharmacy" means:

a. the interpretation and evaluation of prescription orders,

b. the compounding, dispensing, administering and labeling of drugs and devices, except labeling by a manufacturer, repackager or distributor of nonprescription drugs and commercially packaged legend drugs and devices,

c. the participation in drug selection and drug utilization reviews,

d. the proper and safe storage of drugs and devices and the maintenance of proper records thereof,

e. the responsibility for advising by counseling and providing information, where professionally necessary or where regulated, of therapeutic values, content, hazards, and use of drugs and devices,

f. the offering or performing of those acts, services, operations or transactions necessary in the conduct, operation, management and control of a pharmacy, or

g. the provision of those acts or services that are necessary to provide pharmaceutical care;

38. "Preparation" means an article which may or may not contain sterile products compounded in a licensed pharmacy pursuant to the order of a licensed prescriber;

39. "Prescriber" means a person licensed in this state who is authorized to prescribe dangerous drugs within the scope of practice of the person's profession;

40. "Prescription" means and includes any order for drug or medical supplies written or signed, or transmitted by word of mouth, telephone or other means of communication:

a. by a licensed practitioner,

b. under the supervision of an Oklahoma licensed practitioner, an Oklahoma licensed advanced practice registered nurse or an Oklahoma licensed physician assistant, or

c. by an Oklahoma licensed wholesaler or distributor as authorized in Section ~~353.29~~ 353.29.1 of this title;

41. "Product" means a prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing, such as capsules, tablets, and lyophilized products before reconstitution. "Product" does not include blood components intended for transfusion, radioactive drugs or biologics and medical gas;

42. "Repackager", including "virtual repackager", means a person who owns or operates an establishment that repacks and relabels a product or package for further sale or distribution without further transaction;

43. "Sterile drug" means a drug that is intended for parental administration, an ophthalmic or oral inhalation drug in aqueous format, or a drug that is required to be sterile under state and federal law;

44. "Supervising physician" means an individual holding a current license to practice as a physician from the State Board of Medical Licensure and Supervision, pursuant to the provisions of the Oklahoma Allopathic Medical and Surgical Licensure and Supervision Act, or the State Board of Osteopathic Examiners, pursuant to the provisions of the Oklahoma Osteopathic Medicine Act, who supervises an advanced practice registered nurse as defined in Section 567.3a of this title, and who is not in training as an intern, resident, or fellow. To be eligible to supervise an advanced practice registered nurse, such physician shall remain in compliance with the rules promulgated by the State Board of Medical Licensure and Supervision or the State Board of Osteopathic Examiners;

45. "Supportive personnel" means technicians and auxiliary supportive persons who are regularly paid employees of a pharmacy who work and perform tasks in the pharmacy as authorized by Section ~~353.19~~ 353.18A of this title;

46. "Third-party logistics provider", including "virtual third-party logistics provider" means an entity that provides or coordinates warehousing, or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale

distributor, or dispenser of a product but does not take ownership of the product, nor have responsibility to direct the sale or disposition of the product. For the purposes of this paragraph, "third-party logistics provider" does not include shippers and the United States Postal Service; and

47. "Wholesale distributor", including "virtual wholesale distributor" means a person other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or repackager engaged in wholesale distribution as defined by 21 U.S.C 353(e)(4) as amended by the Drug Supply Chain Security Act.

SECTION 2. AMENDATORY 59 O.S. 2011, Section 353.11, as amended by Section 7, Chapter 230, O.S.L. 2015 (59 O.S. Supp. 2015, Section 353.11), is amended to read as follows:

Section 353.11. A. 1. Every licensed pharmacist who desires to continue in the profession of pharmacy in this state shall, on or before the expiration date of the license, complete a renewal form and remit to the State Board of Pharmacy a renewal fee to be fixed by the Board. Upon compliance with the provisions of the Oklahoma Pharmacy Act and payment of such renewal fee by a licensee in good standing with the Board, a renewal certificate of licensure shall be issued.

2. Every licensed pharmacist who fails to complete a renewal form and remit the required renewal fee to the Board by the

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

B. If any pharmacist fails or neglects to procure the renewal of his or her license, as herein required, the Board may, after the expiration of thirty (30) days following the issue of the notice, deprive the person of his or her license and all other privileges conferred by the Oklahoma Pharmacy Act.

C. In order to regain licensure, the pharmacist shall apply in writing to the Board requesting reinstatement. The pharmacist shall pay ~~back~~ all back fees and provide proof of having obtained all delinquent continuing education plus an additional fifteen (15) hours of continuing education. The Board may require the pharmacist to appear before the Board at a regular meeting. The Board may require evidence of competency through examination or impose other requirements for reinstatement.

SECTION 3. AMENDATORY Section 8, Chapter 230, O.S.L. 2015 (59 O.S. Supp. 2015, Section 353.11a), is amended to read as follows:

Section 353.11a. A. No annual renewal certificate shall be issued to a pharmacist until such pharmacist has submitted proof to the State Board of Pharmacy that the pharmacist has satisfactorily completed no less than fifteen (15) clock hours of an accredited or Board-approved program of continuing professional education during the previous calendar year.

B. The Board may grant alternate methods of obtaining continuing education hours to a pharmacist who meets all necessary requirements for licensure except the continuing education requirements.

C. 1. Any pharmacist who does not meet the requirements for continuing education may obtain an inactive renewal certificate of licensure.

2. The holder of an inactive renewal certificate of licensure shall not engage in the practice of pharmacy in this state.

3. The holder of an inactive renewal certificate of licensure may apply to the Board to ~~the~~ be removed from inactive status.

SECTION 4. AMENDATORY 59 O.S. 2011, Section 353.18, as amended by Section 11, Chapter 230, O.S.L. 2015 (59 O.S. Supp. 2015, Section 353.18), is amended to read as follows:

Section 353.18. A. 1. It shall be unlawful for any person, including, but not limited to, Internet, website or online pharmacies, to sell at retail or to offer 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 State Board of Pharmacy. This licensure requirement applies whether such sale, offer for sale or acceptance of prescriptions occurs in this state, or such sale, offer for sale, or acceptance of prescription occurs out of state and the dangerous drug, medicine,

chemical or poison is to be delivered, distributed or dispensed to patients or customers in this state.

2. A pharmacy 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 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 licensed pharmacist or pharmacist-in-charge who shall be licensed as a pharmacist in Oklahoma, and

d. a licensed pharmacist shall be present and on duty at all business hours; provided, however, the provisions of this subparagraph shall not apply to hospital drug rooms.

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

(1) be submitted to the Board in writing,

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

(3) provide other such information deemed relevant by the Board.

b. An application for an initial or renewal license shall be accompanied by a licensing fee not to exceed Three Hundred Dollars ($300.00) for each period of one (1) year. Prior to opening for business, all applicants for an initial license or permit shall be inspected. An initial licensure applicant shall pay an inspection fee not to exceed Two Hundred Dollars ($200.00); provided, however, that no charge shall be made for the licensing of any Federal Veterans Hospital in the State of Oklahoma. Non-resident pharmacies shall reimburse the Board for any actual expenses incurred for inspections.

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 drugs shall obtain a pharmacy license, and shall also obtain a sterile compounding 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 sterile compounding permits.

5. An outsourcing facility desiring to dispense prescriptions to patients must additionally license and meet the requirements of a pharmacy.

B. 1. It shall be unlawful for any person to manufacture, repackage, distribute, outsource, warehouse, or ~~have an outsourcing facility,~~ be a third-party logistics provider~~, or warehouse~~ of any dangerous drugs, medicines, medical gases, chemicals, or poisons for the treatment of disease, excluding agricultural chemicals ~~and drugs, or to sell or offer to sale at retail or wholesale medical gases~~ without first procuring a license from the Board. It shall be unlawful to sell or offer for sale at retail or wholesale dangerous drugs, medicines, medical gases, chemicals or poisons without first procuring a license from the Board. This licensure requirement shall apply when the manufacturing, repackaging, distributing, outsourcing, warehousing, ~~outsourcing facility or third-party logistics provider or facility sale or offer to sell~~ or provision of third-party logistics occurs in this state or ~~when such dangerous drugs, medicines, chemicals or poisons are sold or offered to be sold~~ out of state for delivery, distribution, or dispensing to patients or customers in this state.

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

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

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

c. the place shall be under the management and control of such persons as may be approved by the Board after a review and determination of the persons' qualifications, and

d. an outsourcing facility shall designate in writing on a Board-approved form a person to serve as the pharmacist-in-charge who is a pharmacist licensed by the Board,

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

(1) be submitted to the Board in writing,

(2) contain the name or names of the owners or the applicants, and

(3) provide such other information deemed relevant by the Board,

b. An application for an initial or renewal license shall be accompanied by a licensing fee not to exceed Three Hundred Dollars ($300.00) for each period of one (1) year. Prior to opening for business, all applicants for initial or renewal license shall be inspected. An initial licensure applicant shall pay an inspection fee not to exceed Two Hundred Dollars ($200.00). Non-resident applicants shall reimburse the Board for any actual expenses incurred for inspections.

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

C. A licensee or permit holder 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 provisions for new or renewal application requirements for its licensees and permit holders. Requirements for new and renewal applications may include, but need not be limited to, the following:

a. type of ownership, whether individual, partnership, limited liability company or corporation,

b. names and addresses of principal owners or officers and their Social Security numbers, including applicant's full name, all trade or business names used, full business address, telephone numbers, and email addresses,

c. names of designated representatives and facility managers and their Social Security numbers and dates of birth,

d. evidence of a criminal background check and fingerprinting of the applicant, if a person, and all of the applicant's designated representatives and facility managers,

e. a copy of the license from the applicant's home state, and if applicable, from the federal government,

f. bond requirements, and

g. any other information deemed by the Board to be necessary to protect the public health and safety.

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.

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

SECTION 5. AMENDATORY 59 O.S. 2011, Section 353.24, as amended by Section 16, Chapter 230, O.S.L. 2015 (59 O.S. Supp. 2015, Section 353.24), is amended to read as follows:

Section 353.24. A. It shall be unlawful for any licensee or other person to:

1. Forge or increase the quantity of drug in any prescription, or to present a prescription bearing forged, fictitious or altered information or to possess any drug secured by such forged, fictitious or altered prescription;

2. Sell, offer for sale, barter or give away any unused quantity of drugs obtained by prescription, except through a program pursuant to the Utilization of Unused Prescription Medications Act or as otherwise provided by the State Board of Pharmacy;

3. Sell, offer for sale, barter or give away any drugs damaged by fire, water, or other causes without first obtaining the written approval of the Board or the State Department of Health;

4. Enter into any arrangement whereby prescription orders are received, or prescriptions are delivered at a place other than the pharmacy in which they are filled, compounded or dispensed. However, nothing in this paragraph shall prevent a pharmacist or an employee of the pharmacy from personally receiving a prescription or

delivering a legally filled prescription to a residence, office or place of employment of the patient for whom the prescription was written. Provided further, the provisions of this paragraph shall not apply to any Department of Mental Health and Substance Abuse Services employee or any person whose facility contracts with the Department of Mental Health and Substances Abuse Services whose possession of any dangerous drug, as defined in Section 353.1 of this title, is for the purpose of delivery of a mental health consumer's medicine to the consumer's home or residence. Nothing in this paragraph shall prevent veterinary prescription drugs from being shipped directly from an Oklahoma licensed wholesaler or distributor to a client; provided, such drugs may be dispensed only on prescription of a licensed veterinarian and only when an existing veterinary-client-patient relationship exists;

5. Sell, offer for sale or barter or buy any professional samples except through a program pursuant to the Utilization of Unused Prescription Medications Act;

6. Refuse to permit or otherwise prevent members of the Board or such representatives thereof from entering and inspecting any and all places, including premises, vehicles, equipment, contents, and records, where drugs, medicine, chemicals or poisons are stored, sold, vended, given away, compounded, dispensed, repackaged, transported, or manufactured;

7. Interfere, refuse to participate in, impede or otherwise obstruct any inspection, investigation or disciplinary proceeding authorized by the Oklahoma Pharmacy Act;

8. Possess dangerous drugs without a valid prescription or a valid license to possess such drugs; provided, however, this provision shall not apply to any Department of Mental Health and Substance Abuse Services employee or any person whose facility contracts with the Department of Mental Health and Substances Abuse Services whose possession of any dangerous drug, as defined in Section 353.1 of this title, is for the purpose of delivery of a mental health consumer's medicine to the consumer's home or residence;

9. Fail to establish and maintain effective controls against the diversion of drugs for any other purpose than legitimate medical, scientific or industrial uses as provided by state, and federal, and local law;

10. Fail to have a written drug diversion detection and prevention policy;

11. Possess, sell, offer for sale, barter or give away any quantity of dangerous drugs not listed as a scheduled drug pursuant to Sections 2-201 through 2-212 of Title 63 of the Oklahoma Statutes when obtained by prescription bearing forged, fictitious or altered information.

a. A first violation of this section shall constitute a misdemeanor and upon conviction shall be punishable by imprisonment in the county jail for a term not more than one (1) year and a fine in an amount not more than One Thousand Dollars ($1,000.00).

b. A second violation of this section shall constitute a felony and upon conviction shall be punishable by imprisonment in the Department of Corrections for a term not exceeding five (5) years and a fine in an amount not more than Two Thousand Dollars ($2,000.00);

12. Violate a Board order or agreed order;

13. Compromise the security of licensure examination materials; or

14. Fail to notify the Board, in writing, within ten (10) days of a licensee or permit holder's address change.

B. 1. It shall be unlawful for any person other than a licensed pharmacist or physician to certify a prescription before delivery to the patient or the patient's representative or caregiver.

2. It shall be unlawful for any person to institute or manage a pharmacy unless such person is a licensed pharmacist or has placed a licensed pharmacist in charge of such pharmacy,

3. No licensed pharmacist shall manage, supervise or be in charge of more than one pharmacy.

4. No pharmacist being requested to sell, furnish or compound any drug, medicine, chemical or other pharmaceutical preparation, by prescription or otherwise, shall substitute or cause to be substituted for it, without authority of the prescriber ~~of~~ or purchaser, any like drug, medicine, chemical or pharmaceutical preparation.

5. No pharmacy, pharmacist-in-charge or other person shall permit the practice of pharmacy except by a licensed pharmacist or assistant pharmacist.

6. No person shall subvert the authority of the pharmacist-in-charge of the pharmacy by impeding the management of the prescription department to act in compliance with federal and state law.

C. 1. It shall be unlawful for a pharmacy to resell dangerous drugs to any wholesale distributor.

2. It shall be unlawful for a wholesale distributor to purchase drugs from a pharmacy.

SECTION 6. AMENDATORY 59 O.S. 2011, Section 353.26, as amended by Section 17, Chapter 230, O.S.L. 2015 (59 O.S. Supp. 2015, Section 353.26), is amended to read as follows:

Section 353.26. A. The State Board of Pharmacy may:

1. Revoke permanently or suspend any certificate, license or permit issued pursuant to the Oklahoma Pharmacy Act or reprimand or

place on probation any holder of a certificate, license, or permit who:

a. violates any provision of the Oklahoma Pharmacy Act or any other applicable state or federal law,

b. violates any of the provisions of the Uniform Controlled Dangerous Substances Act,

c. has been convicted of a felony or has pleaded guilty or no contest to a felony,

d. engages in the practice of pharmacy while incapacitated or abuses intoxicating liquors or other chemical substances,

e. conducts himself or herself in a manner likely to lower public esteem for the profession of pharmacy,

f. has been disciplined by another State Board of Pharmacy or by another state or federal entity,

g. has been legally adjudged to be not mentally competent, or

h. exercises conduct and habits inconsistent with the rules of professional conduct established by the Board; and

2. Levy administrative fines not to exceed Three Thousand Dollars ($3,000.00) for each count of which any holder of a certificate, license, or permit has been convicted in Board hearings.

B. 1. The Board, its employees, or other agents of the Board shall keep confidential information obtained during an investigation into violations of the Oklahoma Pharmacy Act; provided, however, such information may be introduced by the state in administrative proceedings before the Board and the information then becomes a public record.

To ensure the confidentiality of such information obtained during the investigation but not introduced in administrative proceedings, this information shall not be deemed to be a record as that term is defined in the Oklahoma Open Records Act, nor shall the information be subject to subpoena or discovery in any civil or criminal proceedings, except that the Board may give such information to law enforcement and other state agencies as necessary and appropriate in the discharge of the duties of that agency and only under circumstances that ensure against unauthorized access to the information.

2. The respondent may acquire information obtained during an investigation, unless the disclosure of the information is otherwise prohibited, except for the investigative report, if the respondent signs a protective order whereby the respondent agrees to use the information solely for the purpose of defense in the Board proceeding and in any appeal therefrom and agrees not to otherwise disclose the information.

C. 1. The Board shall mail by certified mail to respondent at the last address provided by respondent to the Board, postmarked at least ten (10) days before the hearing, the sworn complaint filed with its Executive Director against respondent and notice of the date and place of a hearing thereon. Alternatively, at least ten (10) days before the hearing, the Board may serve respondent personally by any person appointed to make service by the Executive Director of the Board and in any manner authorized by the law of this state for the personal service of summonses in proceedings in a state court. Such service shall be effective upon the personal service or mailing of the complaint and notice, and shall constitute good service. If the Board finds that the allegations of the complaint are supported by the evidence rendered at the hearing, the Board is hereby authorized and empowered to, by written order, revoke permanently or suspend for a designated period, the certificate, license or permit of the respondent and/or reprimand, place on probation and/or fine the respondent.

2. A person whose certificate, license, or permit has been revoked or suspended or who has been reprimanded or placed on probation or fined may appeal such Board order pursuant to the Administrative Procedures Act.

3. The Board's order shall constitute a judgment and may be entered on the judgment docket of the district court in a county in which the respondent has property and ~~execution~~ may be executed

thereon in the same manner as any other judgment of a court of record, unless the fine is paid within thirty days after the appeal time has run.

D. A person, other than a pharmacy technician, whose license or permit has been suspended by the Board or by operation of law shall pay a reinstatement fee not to exceed One Hundred Fifty Dollars ($150.00) as a condition of reinstatement of the license.

SECTION 7. AMENDATORY Section 1, Chapter 263, O.S.L. 2014 (59 O.S. Supp. 2015, Section 357), is amended to read as follows:

Section 357. As used in this act:

1. "Covered entity" means a nonprofit hospital or medical service organization, insurer, health coverage plan or health maintenance organization; a health program administered by the state in the capacity of provider of health coverage; or an employer, labor union, or other entity organized in the state that provides health coverage to covered individuals who are employed or reside in the state. This term does not include a health plan that provides coverage only for accidental injury, specified disease, hospital indemnity, disability income, or other limited benefit health insurance policies and contracts that do not include prescription drug coverage;

2. "Covered individual" means a member, participant, enrollee, contract holder or policy holder or beneficiary of a covered entity

who is provided health coverage by the covered entity. A covered individual includes any dependent or other person provided health coverage through a policy, contract or plan for a covered individual;

3. "Department" means the Oklahoma Insurance Department;

4. "Maximum allowable cost" or "MAC" means the list of drug products delineating the maximum per-unit reimbursement for multiple-source prescription drugs, medical product or device;

5. "Pharmacy benefits management" means a service provided to covered entities to facilitate the provision of prescription drug benefits to covered individuals within the state, including negotiating pricing and other terms with drug manufacturers and providers. Pharmacy benefits management may include any or all of the following services:

a. claims processing, retail network management and payment of claims to pharmacies for prescription drugs dispensed to covered individuals,

b. clinical formulary development and management services,

c. rebate contracting and administration,

d. certain patient compliance, therapeutic intervention and generic substitution programs, or

e. disease management programs;

6. "Pharmacy benefits manager" or "PBM" means a person, business or other entity that performs pharmacy benefits management. The term includes a person or entity acting for a PBM in a contractual or employment relationship in the performance of pharmacy benefits management for a managed care company, nonprofit hospital, medical service organization, insurance company, third-party payor, or a health program administered by an agency of this state;

7. "Plan sponsor" means the employers, insurance companies, unions and health maintenance organizations or any other entity responsible for establishing, maintaining, or administering a health benefit plan on behalf of covered individuals; ~~and~~

8. "Provider" means a pharmacy licensed by the State Board of Pharmacy, or an agent or representative of a pharmacy, including, but not limited to, the pharmacy's contracting agent, which dispenses prescription drugs or devices to covered individuals; and

9. "Reimbursement" means the total amount paid to a pharmacy including the amount paid by patients as determined by a PBM or covered entity for prescription claims.

SECTION 8. AMENDATORY Section 4, Chapter 263, O.S.L. 2014 (59 O.S. Supp. 2015, Section 360), is amended to read as follows:

Section 360. A. The pharmacy benefits manager shall, with respect to contracts between a pharmacy benefits manager and a provider:

1. Include in such contracts the sources utilized to determine the maximum allowable cost (MAC) pricing of the pharmacy, update ~~maximum allowable cost~~ MAC pricing at least every seven (7) calendar days, and establish a process for providers to readily access the MAC list specific to that provider;

2. In order to place a drug on the MAC list, ensure that the drug is listed as "A" or "B" rated in the most recent version of the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book, or has an "NR" or "NA" rating or a similar rating by a nationally recognized reference, and the drug is generally available for purchase by pharmacies in the state from national or regional wholesalers and is not obsolete;

3. Ensure dispensing fees are not included in the calculation of MAC price reimbursement to pharmacy providers;

4. Provide a reasonable administration appeals procedure to allow a provider or a provider's representative to contest ~~maximum allowable cost rates~~ reimbursement amounts within ten (10) business days of the final adjusted payment of the prescription claim ~~date~~. The pharmacy benefits manager must respond to a provider or provider's representative who has contested a ~~maximum allowable cost rate~~ reimbursement amount through this procedure within ten (10)

business days. If a price update is warranted, the pharmacy benefits manager shall make the change in the ~~MAC~~ reimbursement amount, permit the challenging pharmacy to reverse and rebill the claim in question, and make the ~~MAC~~ reimbursement amount change effective for each similarly contracted Oklahoma provider; and

5. If the ~~MAC~~ reimbursement appeal is denied, the PBM shall provide the reason for the denial, including the National Drug Code number from national or regional wholesalers where the drug is generally available for purchase by pharmacies in the state at or below the PBM's ~~Maximum Allowable Cost~~ reimbursement amount.

B. The pharmacy benefits manager may not place a drug on a ~~maximum allowable cost~~ MAC list, unless there are at least two therapeutically equivalent, multiple-source drugs, or at least one generic drug available from only one manufacturer, generally available for purchase by network pharmacies from national or regional wholesalers.

C. The pharmacy benefits manager shall not require accreditation or licensing of providers other than by the State Board of Pharmacy or other state or federal government entity.

SECTION 9. REPEALER 59 O.S. 2011, Sections 353.13, 353.29, 364 and 366, are hereby repealed.

SECTION 10. This act shall become effective November 1, 2016.

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