STATE OF OKLAHOMA

2nd Session of the 56th Legislature (2018)

SENATE BILL 1511 By: Standridge

AS INTRODUCED

An Act relating to Oklahoma Pharmacy Act; amending 59 O.S. 2011, Section 353.1, as last amended by Section 1, Chapter 285, O.S.L. 2016 (59 O.s. Supp. 2017, Section 353.1), which relates to definitions; inserting definitions; providing for accreditation of specialty pharmacies; providing that specialty pharmacies may exist only as specialty pharmacies and may not dispense other drugs beside specialty drugs; requiring specialty pharmacies to obtain certain license; directing State Board of Pharmacy to promulgate certain rules; providing for codification; 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 285, O.S.L. 2016 (59 O.S. Supp. 2017, 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 353.29.1 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. "Specialty drug" means a product used to treat chronic, high-cost or rare diseases and may be injectable, infusible, oral or inhaled medications. Specialty drugs are more complex to maintain, administer and monitor than traditional drugs, and key characteristics are as follows:

a. frequent dosage adjustments,

b. dosage administration of injectable and infusible,

c. more-severe side effects than traditional drugs,

d. special storage, handling or administration,

e. narrow therapeutic range,

f. periodic laboratory or diagnostic testing,

g. higher costs than traditional products, typically between Ten Thousand Dollars ($10,000.00) and One Hundred Thousand Dollars ($100,000.00) annually,

h. small numbers of patients,

i. patient registration,

j. patient training and clinical call center,

k. compliance management, and

l. clinical data reporting and analysis;

44. "Specialty pharmacy" means the service created to manage the handling and service requirements of specialty drugs as defined in this section, including dispensing, distribution, reimbursement, case management and other services specific to patients with rare or chronic diseases;

~~43.~~ 45. "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.~~ 46. "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.~~ 47. "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 353.18A of this title;

~~46.~~ 48. "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.~~ 49. "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. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 353.31 of Title 59, unless there is created a duplication in numbering, reads as follows:

A. A specialty pharmacy, as defined in Section 1 of this act:

1. Shall be accredited by either the Utilization Review Accreditation Commission or the Accreditation Commission for Health Care;

2. Shall exist solely as a specialty pharmacy and shall only dispense and ship specialty drugs as defined in Section 1 of this act;

3. May ship specialty drugs to retail pharmacies; and

4. Shall be licensed by the State Board of Pharmacy pursuant to this section.

B. The State Board of Pharmacy shall promulgate rules to create a license for specialty pharmacy pursuant to this act.

SECTION 3. This act shall become effective November 1, 2018.

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