HOUSE OF REPRESENTATIVES - FLOOR VERSION

STATE OF OKLAHOMA

1st Session of the 56th Legislature (2017)

ENGROSSED SENATE
BILL NO. 784 By: Standridge of the Senate

and

Enns of the House

An Act relating to the State Board of Pharmacy; amending 59 O.S. 2011, Section 353.1, as last amended by Section 1, Chapter 285, O.S.L. 2016 (59 O.S. Supp. 2016, Section 353.1), which relates to definitions; clarifying definition; expanding certain definition; amending 59 O.S. 2011, Section 353.7, as amended by Section 5, Chapter 230, O.S.L. 2015 (59 O.S. Supp. 2016, Section 353.7), which relates to powers of the State Board of Pharmacy; permitting approval of certain projects for certain purposes; approving certain exemptions from rules; amending Section 14, Chapter 230, O.S.L. 2015 (59 O.S. Supp. 2016, Section 353.20.1), which relates to prescription label requirements; providing certain exemption; amending 74 O.S. 2011, Section 3601.1, as last amended by Section 11, Chapter 269, O.S.L. 2016 (74 O.S. Supp. 2016, Section 3601.1), which relates to full-time-equivalent employees; deleting limitation on Board of Pharmacy; 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. 2016, 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)<u>; provided, taking actual physical possession of a product or title shall not be required</u>;

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, or

d. a person who contracts with another to manufacture a product;

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. "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 353.18A 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 353.7, as amended by Section 5, Chapter 230, O.S.L. 2015 (59 O.S. Supp. 2016, Section 353.7), is amended to read as follows:

Section 353.7. The State Board of Pharmacy shall have the power and duty to:

1. Regulate the practice of pharmacy;

2. Regulate the sale and distribution of drugs, medicines, chemicals and poisons;

3. Regulate the dispensing of drugs and medicines in all places where drugs and medicines are compounded and/or dispensed;

4. Examine and issue appropriate certificates of licensure as Doctor of Pharmacy to all applicants whom the Board deems qualified under the provisions of the Oklahoma Pharmacy Act;

5. Issue licenses to manufacturers, repackagers, outsourcing facilities, wholesale distributors, third-party logistics providers,

pharmacies, and other dispensers, medical gas suppliers, and medical gas distributors;

6. Issue sterile compounding and drug supplier permits for pharmacies at the fee set by the Board, with the expiration date of such permits to coincide with the pharmacy license annual expiration date;

7. Prescribe minimum standards with respect to floor space and other physical characteristics of pharmacies and hospital drug rooms as may be reasonably necessary for the maintenance of professional surroundings and for the protection of the safety and welfare of the public, and to refuse the issuance of new or renewal licenses for failure to comply with such standards. Minimum standards for hospital drug rooms shall be consistent with the State Department of Health, Hospital Standards, as defined in OAC 310:667;

8. Authorize its inspectors, compliance officers, and duly authorized representatives to enter and inspect any and all places, including premises, vehicles, equipment, contents and records, where drugs, medicines, chemicals, or poisons are stored, sold, vended, given away, compounded, dispensed, manufactured, repackaged or transported;

9. Employ the number of inspectors and pharmacist compliance officers necessary to carry out the provisions of the Oklahoma Pharmacy Act at an annual salary to be fixed by the Board, and to authorize necessary expenses. Such inspectors shall have the same

powers and authority as that granted to peace officers by the laws of this state for the purpose of enforcing the Oklahoma Pharmacy Act. In addition, such inspectors or pharmacist compliance officers shall have the authority to take and copy records and the duty to confiscate all drugs, medicines, chemicals or poisons found to be stored, sold, vended, given away, compounded, dispensed or manufactured contrary to the provisions of the Oklahoma Pharmacy Act;

10. Investigate complaints, subpoena witnesses and records, initiate prosecution, and hold hearings;

11. Administer oaths in all manners pertaining to the affairs of the Board and to take evidence and compel the attendance of witnesses on questions pertaining to the enforcement of the Oklahoma Pharmacy Act;

12. Reprimand, place on probation, suspend, revoke or take other disciplinary action and/or levy fines not to exceed Three Thousand Dollars ($3,000.00) for each count for which any holder of a certificate, license or permit has been convicted in Board hearings. The Board may impose as part of any disciplinary action the payment of costs expended by the Board for any legal fees and costs, including, but not limited to, staff time, salary and travel expense, witness fees and attorney fees. The Board may also require additional continuing education, including attendance at a live continuing education program, and may require participation in a

rehabilitation program for the impaired. The Board may take such actions singly or in combination, as the nature of the violation requires;

13. Adopt and establish rules of professional conduct appropriate to the establishment and maintenance of a high standard of integrity and dignity in the profession of pharmacy. Such rules shall be subject to amendment or repeal by the Board as the need may arise;

14. Make and publish rules such as may be necessary for carrying out and enforcing the provisions of the Oklahoma Pharmacy Act, Oklahoma drug laws and rules, federal drug laws and regulations, and make such other rules as in its discretion may be necessary to protect the health, safety, and welfare of the public;

15. Establish and collect appropriate fees for licenses, permits, inspections, and services provided; and such fees shall be nonrefundable. Such fees shall be promulgated to implement the provisions of the Oklahoma Pharmacy Act under the provisions of the Administrative Procedures Act;

16. Regulate:

a. personnel working in a pharmacy, such as interns and supportive personnel, including technicians, and issue pharmacy technician permits and intern licenses,

b. interns, preceptors and training areas through which the training of applicants occurs for licensure as a pharmacist, and

c. such persons regarding all aspects relating to the handling of drugs, medicines, chemicals, and poisons;

17. Acquire by purchase, lease, gift, solicitation of gift or by any other manner, and to maintain, use and operate or to contract for the maintenance, use and operation of or lease of any and all property of any kind, real, personal or mixed or any interest therein unless otherwise provided by the Oklahoma Pharmacy Act; provided, all contracts for real property shall be subject to the provisions of Section 63 of Title 74 of the Oklahoma Statutes; ~~and~~

18. Perform other such duties, exercise other such powers and employ such personnel as the provisions and enforcement of the Oklahoma Pharmacy Act may require; and

19. Approve pilot projects designed to utilize new or expanded technology or processes and provide patients with better pharmacy products or provide pharmacy services in a more safe and efficient manner. Such approvals may include provisions granting exemptions to any rule adopted by the Board.

SECTION 3. AMENDATORY Section 14, Chapter 230, O.S.L. 2015 (59 O.S. Supp. 2016, Section 353.20.1), is amended to read as follows:

Section 353.20.1. A. Prescriptions received by other than written communication shall be promptly recorded in writing by the pharmacist. The record made by the pharmacist shall constitute the original prescription to be filled by the pharmacist.

B. A filled prescription label shall include the name and address of the pharmacy of origin, date of filling, name of patient, name of prescriber, directions for administration, and prescription number. The symptom or purpose for which the drug is prescribed may appear on the label if provided by the practitioner and requested by the patient or the patient's authorized representative. If the symptom or purpose for which a drug is prescribed is not provided by the practitioner, the pharmacist may fill the prescription without contacting the practitioner, patient, or patient's representative. The label shall also include the trade or generic name, prescribed quantity, and prescription strength of the drug therein contained, except when otherwise directed by the prescriber. This requirement shall not apply to prescriptions or medicines and drugs supplied or delivered directly to patients for consumption on the premises of any hospital or mental institution. <u>This requirement shall not apply to dialysate sold, dispensed or delivered in their original, sealed packaging upon receipt of a prescriber's order.</u>

C. No prescription shall be written in any characters, figures, or ciphers other than in the English or Latin language generally in use among medical and pharmaceutical practitioners.

SECTION 4. AMENDATORY 74 O.S. 2011, Section 3601.1, as last amended by Section 11, Chapter 269, O.S.L. 2016 (74 O.S. Supp. 2016, Section 3601.1), is amended to read as follows:

Section 3601.1. A. For purposes of Sections 3601.1 through 3603 of this title, the term "employee" means a full-time employee or any number of part-time employees whose combined weekly hours of employment equal those of a full-time employee, but shall not include temporary employees working on a seasonal basis between May 1 and October 31.

B. Beginning July 1, 2008, the maximum number of full-time-equivalent employees for each of the following agencies, boards, commissions, departments, or programs shall not exceed the numbers specified in this section, except as may be authorized pursuant to the provisions of Section 3603 of this title.

	MAXIMUM NUMBER OF FULL-TIME-EQUIVALENT EMPLOYEES
Oklahoma Employment Security Commission	1150
Oklahoma Accountancy Board	11
Board of Governors of the Licensed Architects, Landscape Architects and Interior Designers of Oklahoma	4
Board of Chiropractic Examiners	3
State Board of Cosmetology	16

Board of Dentistry	10
Oklahoma State Board of Embalmers and Funeral Directors	5
State Board of Registration for Professional Engineers and Land Surveyors	10
State Board of Medical Licensure and Supervision/ Board of Podiatric Medical Examiners/State Board of Examiners of Perfusionists	29
Commission on Marginally Producing Oil and Gas Wells	5
Oklahoma Motor Vehicle Commission	6
Oklahoma Board of Nursing	30
Oklahoma State Board of Examiners for Nursing Home Administrators	4
Board of Examiners in Optometry	3
State Board of Osteopathic Examiners	7
~~Oklahoma State Board of Pharmacy~~	~~10~~
State Board of Examiners of Psychologists	2
Oklahoma Real Estate Commission	26
Board of Examiners for Speech-Language Pathology and Audiology	2
Oklahoma Used Motor Vehicle and Parts Commission	12
State Board of Veterinary Medical Examiners	6

Oklahoma Firefighters Pension and Retirement System	13
Oklahoma Police Pension and Retirement System	12
Teachers' Retirement System of Oklahoma	52
Oklahoma Public Employees Retirement System	63
Oklahoma Student Loan Authority	85
Oklahoma Industrial Finance Authority/Oklahoma Development Finance Authority	10
State and Education Employees Group Insurance Board	178
Oklahoma Capital Investment Board	4
State Board of Licensed Social Workers	1
Oklahoma State Employees Benefits Council	38
Oklahoma State Banking Department	46
Liquefied Petroleum Gas Administration	10

C. The duties and compensation of employees, not otherwise prescribed by law, necessary to perform the duties imposed upon the Oklahoma Public Employees Retirement System Board of Trustees by law shall be set by the Board of Trustees.

D. Temporary employees of the Oklahoma Used Motor Vehicle and Parts Commission between the dates of November 1 and January 31 annually shall not be counted toward the maximum number of full-time-equivalent employees provided for in this section.

SECTION 5. This act shall become effective November 1, 2017.

COMMITTEE REPORT BY: COMMITTEE ON PUBLIC HEALTH, dated 04/04/2017 - DO PASS.