

STATE OF OKLAHOMA

2nd Session of the 58th Legislature (2022)

COMMITTEE SUBSTITUTE
FOR

HOUSE BILL NO. 3497

By: McEntire

COMMITTEE SUBSTITUTE

An Act relating to pharmacists; amending 59 O.S. 2021, Section 353.1, which relates to definitions; modifying definitions; modifying pharmacists scope of practice; allowing for testing or screening of certain medical conditions; providing conditions; providing guidelines; allowing for dispensing certain drugs; directing the Board of Pharmacy to adopt certain regulations; providing for codification; providing an effective date; and declaring an emergency.

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

SECTION 1. AMENDATORY 59 O.S. 2021, 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;

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

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

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

10 6. "Certify" or "certification of a prescription" means the
11 review of a filled prescription by a licensed pharmacist or a
12 licensed practitioner with dispensing authority to confirm that the
13 medication, labeling and packaging of the filled prescription are
14 accurate and meet all requirements prescribed by state and federal
15 law. For the purposes of this paragraph, "licensed practitioner"
16 shall not include optometrists with dispensing authority;

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

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

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

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

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

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

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

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

22 13. "Dispenser" means a retail pharmacy, hospital pharmacy, a
23 group of chain pharmacies under common ownership and control that do
24 not act as a wholesale distributor, or any other person authorized

1 by law to dispense or administer prescription drugs, and the
2 affiliated warehouses or distributions of such entities under common
3 ownership and control that do not act as a wholesale distributor.
4 For the purposes of this paragraph, "dispenser" does not mean a
5 person who dispenses only products to be used in animals in
6 accordance with 21 U.S.C. 360b(a)(5);

7 14. "Distribute" or "distribution" means the sale, purchase,
8 trade, delivery, handling, storage, or receipt of a product, and
9 does not include the dispensing of a product pursuant to a
10 prescription executed in accordance with 21 U.S.C. 353(b)(1) or the
11 dispensing of a product approved under 21 U.S.C. 360b(b); provided,
12 taking actual physical possession of a product or title shall not be
13 required;

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

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

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

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

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

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

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

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

- 1 a. a person that holds an application approved under 21
2 U.S.C. 355 or a license issued under 42 U.S.C. 262 for
3 such product, or if such product is not the subject of
4 an approved application or license, the person who
5 manufactured the product,
- 6 b. a co-licensed partner of the person described in
7 subparagraph a that obtains the product directly from
8 a person described in this subparagraph or
9 subparagraph a,
- 10 c. an affiliate of a person described in subparagraph a
11 or b who receives the product directly from a person
12 described in this subparagraph or in subparagraph a or
13 b; or
- 14 d. a person who contracts with another to manufacture a
15 product;

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

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

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

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

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

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

18 29. "Nonprescription drugs" means medicines or drugs which are
19 sold without a prescription and which are prepackaged for use by the
20 consumer and labeled in accordance with the requirements of the
21 statutes and regulations of this state and the federal government.
22 Such items shall also include medical and dental supplies and
23 bottled or nonbulk chemicals which are sold or offered for sale to
24 the general public if such articles or preparations meet the

1 requirements of the Federal Food, Drug and Cosmetic Act, 21
2 U.S.C.A., Section 321 et seq.;

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

- 6 a. is engaged in the compounding of sterile drugs,
- 7 b. has elected to register as an outsourcing facility,
- 8 and
- 9 c. complies with all requirements of 21 U.S.C. 353b;

10 31. "Package" means the smallest individual saleable unit of
11 product for distribution by a manufacturer or repackager that is
12 intended by the manufacturer for ultimate sale to the dispenser of
13 such product. For the purposes of this paragraph, "individual
14 saleable unit" means the smallest container of a product introduced
15 into commerce by the manufacturer or repackager that is intended by
16 the manufacturer or repackager for individual sale to a dispenser;

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

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

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

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

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

16 37. "Practice of pharmacy" means:

- 17 a. the interpretation and evaluation of prescription
18 orders,
- 19 b. the compounding, dispensing, administering and
20 labeling of drugs and devices, except labeling by a
21 manufacturer, repackager or distributor of
22 nonprescription drugs and commercially packaged legend
23 drugs and devices,

- 1 c. the participation in drug selection and drug
2 utilization reviews,
- 3 d. the proper and safe storage of drugs and devices and
4 the maintenance of proper records thereof,
- 5 e. the responsibility for advising by counseling and
6 providing information, where professionally necessary
7 or where regulated, of therapeutic values, content,
8 hazards and use of drugs and devices,
- 9 f. the offering or performing of those acts, services,
10 operations or transactions necessary in the conduct,
11 operation, management and control of a pharmacy, ~~or~~
- 12 g. ~~the provision of those acts or services that are~~
13 ~~necessary to provide pharmaceutical care~~ ordering,
14 performing, and evaluating laboratory and clinical
15 drug therapy related tests and initiating drug therapy
16 for minor, nonchronic health conditions,
- 17 h. the prescribing and dispensing of self-administered
18 hormonal contraceptives and any nicotine replacement
19 therapy product that is approved by the U.S. Food and
20 Drug Administration, or
- 21 i. the provision of those acts or services that are
22 necessary to provide pharmaceutical care;
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1 38. "Preparation" means an article which may or may not contain
2 sterile products compounded in a licensed pharmacy pursuant to the
3 order of a licensed prescriber;

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

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

10 a. by a licensed prescriber,

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

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

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

23 42. "Repackager", including "virtual repackager", means a
24 person who owns or operates an establishment that repacks and

1 relabels a product or package for further sale or distribution
2 without further transaction;

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

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

19 45. "Supportive personnel" means technicians and auxiliary
20 supportive persons who are regularly paid employees of a pharmacy
21 who work and perform tasks in the pharmacy as authorized by Section
22 353.18A of this title;

23 46. "Third-party logistics provider", including "virtual third-
24 party logistics provider" means an entity that provides or

1 coordinates warehousing, or other logistics services of a product in
2 interstate commerce on behalf of a manufacturer, wholesale
3 distributor, or dispenser of a product but does not take ownership
4 of the product, nor have responsibility to direct the sale or
5 disposition of the product. For the purposes of this paragraph,
6 "third-party logistics provider" does not include shippers and the
7 United States Postal Service;

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

14 48. "County jail" means a facility operated by a county for the
15 physical detention and correction of persons charged with, or
16 convicted of, criminal offenses or ordinance violations or persons
17 found guilty of civil or criminal contempt;

18 49. "State correctional facility" means a facility or
19 institution that houses a prisoner population under the jurisdiction
20 of the Department of Corrections;

21 50. "Unit dose package" means a package that contains a single
22 dose drug with the name, strength, control number, and expiration
23 date of that drug on the label; and
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1 51. "Unit of issue package" means a package that provides
2 multiple doses of the same drug, but each drug is individually
3 separated and includes the name, lot number, and expiration date.

4 SECTION 2. NEW LAW A new section of law to be codified
5 in the Oklahoma Statutes as Section 353.40 of Title 59, unless there
6 is created a duplication in numbering, reads as follows:

7 A. A pharmacist may test or screen for and treat minor,
8 nonchronic health conditions. For purposes of this section, a
9 minor, nonchronic health condition is typically a short-term
10 condition that is generally managed with minimal treatment or self-
11 care, and includes:

- 12 1. Influenza;
- 13 2. Streptococcus;
- 14 3. SARS-COV-2 or other respiratory illness, condition, or
15 disease;
- 16 4. Lice;
- 17 5. Urinary tract infection;
- 18 6. Skin conditions, such as ringworm and athlete's foot; and
- 19 7. Minor, uncomplicated infections.

20 B. A pharmacist who tests or screens for and treats minor,
21 nonchronic health conditions under this section may use any test
22 that may guide clinical decision making which the Centers for
23 Medicare and Medicaid Services has determined qualifies for a waiver
24 under the federal Clinical Laboratory Improvement Amendments of

1 1988, or the federal rules adopted thereunder, or any established
2 screening procedures that can safely be performed by a pharmacist.

3 C. A pharmacist may dispense a self-administered hormonal
4 contraceptive and nicotine replacement therapy products under the
5 protocol established pursuant to this section, regardless of whether
6 the patient has obtained a prescription.

7 D. The Board of Pharmacy shall adopt regulations establishing a
8 protocol for dispensing self-administered hormonal contraceptives
9 and nicotine replacement therapy products.

10 SECTION 3. This act shall become effective July 1, 2022.

11 SECTION 4. It being immediately necessary for the preservation
12 of the public peace, health or safety, an emergency is hereby
13 declared to exist, by reason whereof this act shall take effect and
14 be in full force from and after its passage and approval.

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