

1 **SENATE FLOOR VERSION**

2 February 9, 2023

3 COMMITTEE SUBSTITUTE
4 FOR

5 SENATE BILL NO. 931

6 By: Garvin

7 An Act relating to the practice of pharmacy; amending
8 59 O.S. 2021, Section 353.1, as amended by Section 6,
9 Chapter 288, O.S.L. 2022 (59 O.S. Supp. 2022, Section
10 353.1), which relates to definitions used in the
11 Oklahoma Pharmacy Act; modifying and adding
12 definitions; allowing pharmacist to test for, screen
13 for, or treat minor, nonchronic health conditions;
14 specifying permitted tests and screening procedures;
15 allowing pharmacist to dispense certain products
16 under certain protocol; directing promulgation of
17 rules; updating statutory language; updating
18 statutory reference; providing for codification;
19 providing an effective date; and declaring an
20 emergency.

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

22 SECTION 1. AMENDATORY 59 O.S. 2021, Section 353.1, as
23 amended by Section 6, Chapter 288, O.S.L. 2022 (59 O.S. Supp. 2022,
24 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~~ State Board of Pharmacy for purposes of continuing
professional education;

1 2. "Act" means the Oklahoma Pharmacy Act;

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

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

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

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

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

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

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

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

- 10 a. for human use subject to 21 U.S.C. 353(b)(1), or
11 b. is labeled "Prescription Only", or labeled with the
12 following statement: "Caution: Federal law restricts
13 this drug ~~except for~~ to use by or on the order of a
14 licensed veterinarian.";

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

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

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

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

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

22 16. "Drug outlet" means all manufacturers, repackagers,
23 outsourcing facilities, wholesale distributors, third-party
24 logistics providers, pharmacies, and all other facilities which are

1 engaged in dispensing, delivery, distribution or storage of
2 dangerous drugs;

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

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

15 19. "Durable medical equipment" has the same meaning as
16 provided by Section ~~2 of this act~~ 375.2 of this title;

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

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

23 22. "Licensed practitioner" means an allopathic physician,
24 osteopathic physician, podiatric physician, dentist, veterinarian or

1 optometrist licensed to practice and authorized to prescribe
2 dangerous drugs within the scope of practice of such practitioner;

3 23. "Manufacturer" or "virtual manufacturer" means with respect
4 to a product:

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

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

14 c. an affiliate of a person described in subparagraph a
15 or b of this paragraph who receives the product
16 directly from a person described in this subparagraph
17 or in subparagraph a or b of this paragraph, or

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

20 24. "Manufacturing" means the production, preparation,
21 propagation, compounding, conversion or processing of a device or a
22 drug, either directly or indirectly by extraction from substances of
23 natural origin or independently by means of chemical or biological
24 synthesis and includes any packaging or repackaging of the

1 substances or labeling or relabeling of its container, and the
2 promotion and marketing of such drugs or devices. The term
3 ~~"manufacturing"~~ manufacturing also includes the preparation and
4 promotion of commercially available products from bulk compounds for
5 resale by licensed pharmacies, licensed practitioners or other
6 persons;

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

10 26. "Medical gas order" means an order for medical gas issued
11 by a licensed prescriber;

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

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

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

22 30. "Minor, nonchronic health condition" means a typically
23 short-term health condition that is generally managed with

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- 1 noncontrolled drug therapies, minimal treatment, or self-care, which
2 includes the following:
- 3 a. influenzas,
 - 4 b. streptococcus,
 - 5 c. SARS-COV-2 or other respiratory illness, condition, or
6 disease,
 - 7 d. lice,
 - 8 e. urinary tract infections,
 - 9 f. skin conditions, such as ringworm and athlete's foot,
10 and
 - 11 g. other emerging and existing public health threats
12 identified by the State Department of Health if
13 permitted by an order, rule, or regulation.

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

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1 ~~31.~~ 32. "Outsourcing facility" including "virtual outsourcing
2 facility" means a facility at one geographic location or address
3 that:

4 a. is engaged in the compounding of sterile drugs,

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

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

8 ~~32.~~ 33. "Package" means the smallest individual saleable unit
9 of product for distribution by a manufacturer or repackager that is
10 intended by the manufacturer for ultimate sale to the dispenser of
11 such product. For the purposes of this paragraph, "individual
12 saleable unit" means the smallest container of a product introduced
13 into commerce by the manufacturer or repackager that is intended by
14 the manufacturer or repackager for individual sale to a dispenser;

15 ~~33.~~ 34. "Person" means an individual, partnership, limited
16 liability company, corporation or association, unless the context
17 otherwise requires;

18 ~~34.~~ 35. "Pharmacist-in-charge" or "PIC" means the pharmacist
19 licensed in this state responsible for the management control of a
20 pharmacy and all other aspects of the practice of pharmacy in a
21 licensed pharmacy as defined by Section 353.18 of this title;

22 ~~35.~~ 36. "Pharmacy" means a place regularly licensed by the
23 State Board of Pharmacy in which prescriptions, drugs, medicines,
24 chemicals and poisons are compounded or dispensed or such place

1 where pharmacists practice the profession of pharmacy, or a pharmacy
2 operated by the Oklahoma Department of Veterans Affairs;

3 ~~36.~~ 37. "Pharmacy technician", "technician", "Rx tech", or
4 "tech" means a person issued a Technician permit by the State Board
5 of Pharmacy to assist the pharmacist and perform nonjudgmental,
6 technical, manipulative, non-discretionary functions in the
7 prescription department under the immediate and direct supervision
8 of a pharmacist;

9 ~~37.~~ 38. "Poison" means any substance which when introduced into
10 the body, either directly or by absorption, produces violent, morbid
11 or fatal changes, or which destroys living tissue with which such
12 substance comes into contact;

13 ~~38.~~ 39. "Practice of pharmacy" means:

- 14 a. the interpretation and evaluation of prescription
15 orders,
- 16 b. the compounding, dispensing, administering and
17 labeling of drugs and devices, except labeling by a
18 manufacturer, repackager or distributor of
19 nonprescription drugs and commercially packaged legend
20 drugs and devices,
- 21 c. the participation in drug selection and drug
22 utilization reviews,
- 23 d. the proper and safe storage of drugs and devices and
24 the maintenance of proper records thereof,

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

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

8 g. the ordering, performing, and interpreting of tests
9 authorized by the United States Food and Drug
10 Administration and waived under the federal Clinical
11 Laboratory Improvement Amendments of 1988, and
12 initiating drug therapy for minor, nonchronic health
13 conditions,

14 h. the dispensing of self-administered hormonal
15 contraceptives and any nicotine replacement therapy
16 product that is approved by the United States Food and
17 Drug Administration, or

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

20 ~~39.~~ 40. "Preparation" means an article which may or may not
21 contain sterile products compounded in a licensed pharmacy pursuant
22 to the order of a licensed prescriber;
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1 ~~40.~~ 41. "Prescriber" means a person licensed in this state who
2 is authorized to prescribe dangerous drugs within the scope of
3 practice of the person's profession;

4 ~~41.~~ 42. "Prescription" means and includes any order for drug or
5 medical supplies written or signed, or transmitted by word of mouth,
6 telephone or other means of communication:

- 7 a. by a licensed prescriber,
- 8 b. under the supervision of an Oklahoma licensed
9 practitioner, an Oklahoma licensed ~~advanced practice~~
10 ~~registered nurse~~ Advanced Practice Registered Nurse or
11 an Oklahoma licensed physician assistant, or
- 12 c. by an Oklahoma licensed wholesaler or distributor as
13 authorized in Section 353.29.1 of this title;

14 ~~42.~~ 43. "Product" means a prescription drug in a finished
15 dosage form for administration to a patient without substantial
16 further manufacturing, such as capsules, tablets, and lyophilized
17 products before reconstitution. ~~"Product"~~ Product does not include
18 blood components intended for transfusion, radioactive drugs or
19 biologics and medical gas;

20 ~~43.~~ 44. "Repackager", including "virtual repackager", means a
21 person who owns or operates an establishment that repacks and
22 relabels a product or package for further sale or distribution
23 without further transaction;

1 ~~44.~~ 45. "Sterile drug" means a drug that is intended for
2 parenteral administration, an ophthalmic or oral inhalation drug in
3 aqueous format, or a drug that is required to be sterile under state
4 and federal law;

5 ~~45.~~ 46. "Supervising physician" means an individual holding a
6 current license to practice as a physician from the State Board of
7 Medical Licensure and Supervision, pursuant to the provisions of the
8 Oklahoma Allopathic Medical and Surgical Licensure and Supervision
9 Act, or the State Board of Osteopathic Examiners, pursuant to the
10 provisions of the Oklahoma Osteopathic Medicine Act, who supervises
11 an ~~advanced practice registered nurse~~ Advanced Practice Registered
12 Nurse as defined in Section 567.3a of this title, and who is not in
13 training as an intern, resident, or fellow. To be eligible to
14 supervise an ~~advanced practice registered nurse~~ Advanced Practice
15 Registered Nurse, such physician shall remain in compliance with the
16 rules promulgated by the State Board of Medical Licensure and
17 Supervision or the State Board of Osteopathic Examiners;

18 ~~46.~~ 47. "Supportive personnel" means technicians and auxiliary
19 supportive persons who are regularly paid employees of a pharmacy
20 who work and perform tasks in the pharmacy as authorized by Section
21 353.18A of this title;

22 ~~47.~~ 48. "Third-party logistics provider" including "virtual
23 third-party logistics provider" means an entity that provides or
24 coordinates warehousing, or other logistics services of a product in

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

7 ~~48.~~ 49. “Wholesale distributor” including “virtual wholesale
8 distributor” means a person other than a manufacturer, a
9 manufacturer’s co-licensed partner, a third-party logistics
10 provider, or repackager engaged in wholesale distribution as defined
11 by 21 U.S.C. 353(e) (4) as amended by the Drug Supply Chain Security
12 Act;

13 ~~49.~~ 50. “County jail” means a facility operated by a county for
14 the physical detention and correction of persons charged with, or
15 convicted of, criminal offenses or ordinance violations or persons
16 found guilty of civil or criminal contempt;

17 ~~50.~~ 51. “State correctional facility” means a facility or
18 institution that houses a prisoner population under the jurisdiction
19 of the Department of Corrections;

20 ~~51.~~ 52. “Unit dose package” means a package that contains a
21 single dose drug with the name, strength, control number, and
22 expiration date of that drug on the label; and
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1 ~~52.~~ 53. "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 353.31 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 administer treatment
8 for minor, nonchronic health conditions.

9 B. A pharmacist who tests or screens for and treats minor,
10 nonchronic health conditions provided by this section may use any
11 test that may guide clinical decision-making, which the Centers for
12 Medicare and Medicaid Services has determined qualifies for a waiver
13 under the federal Clinical Laboratory Improvement Amendments of
14 1988, or the federal rules adopted thereunder, or any established
15 screening procedures that can safely be performed by a pharmacist.

16 C. A pharmacist may dispense self-administered hormonal
17 contraceptives and nicotine replacement therapy products under the
18 protocol established pursuant to subsection D of this section,
19 regardless of whether the patient has obtained a prescription.

20 D. The State Board of Pharmacy shall adopt rules establishing a
21 protocol for dispensing self-administered hormonal contraceptives
22 and nicotine replacement therapy products by January 1, 2024.

23 SECTION 3. This act shall become effective July 1, 2023.

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

5 COMMITTEE REPORT BY: COMMITTEE ON HEALTH AND HUMAN SERVICES
6 February 9, 2023 - DO PASS AS AMENDED BY CS
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