

1 **HOUSE OF REPRESENTATIVES - FLOOR VERSION**

2 STATE OF OKLAHOMA

3 2nd Session of the 59th Legislature (2024)

4 COMMITTEE SUBSTITUTE
5 FOR ENGROSSED
6 SENATE BILL NO. 232

By: Garvin of the Senate

and

McEntire of the House

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10 COMMITTEE SUBSTITUTE

11 An Act relating to the practice of pharmacy; allowing
12 pharmacist to test or screen for and initiate drug
13 therapy for minor, nonchronic health conditions;
14 specifying allowed tests; allowing pharmacist to
15 dispense certain products under certain protocol;
16 directing adoption of rules; amending 59 O.S. 2021,
17 Section 353.1, as amended by Section 6, Chapter 288,
18 O.S.L. 2022 (59 O.S. Supp. 2023, Section 353.1),
19 which relates to definitions used in the Oklahoma
20 Pharmacy Act; modifying and adding definitions;
21 amending 59 O.S. 2021, Section 353.18A, which relates
22 to pharmacy technicians; establishing certain
23 pharmacy ratio; updating statutory language and
24 references; providing for codification; providing an
effective date; and declaring an emergency.

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

SECTION 1. 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:

1 A. A pharmacist may test or screen for and initiate drug
2 therapy for minor, nonchronic health conditions as defined in
3 Section 353.1 of Title 59 of the Oklahoma Statutes.

4 B. To test for minor, nonchronic health conditions under this
5 section, the pharmacist may use any test that may guide clinical
6 decision-making and that is:

7 1. Approved by, cleared by, or authorized under an emergency
8 use authorization by the United States Food and Drug Administration;
9 and

10 2. Waived under the federal Clinical Laboratory Improvement
11 Amendments of 1988 (CLIA) or deemed to be CLIA-waived for use in
12 patient care settings operating under a CLIA certificate.

13 C. A pharmacist may dispense self-administered hormonal
14 contraceptives under the protocol established pursuant to subsection
15 D of this section, regardless of whether the patient has obtained a
16 prescription.

17 D. A pharmacist may not test or screen for streptococcus and
18 initiate drug therapy for streptococcus to individuals under six (6)
19 years of age.

20 E. The State Board of Pharmacy shall adopt rules establishing a
21 protocol for dispensing self-administered hormonal contraceptives by
22 January 1, 2025.

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1 SECTION 2. AMENDATORY 59 O.S. 2021, Section 353.1, as
2 amended by Section 6, Chapter 288, O.S.L. 2022 (59 O.S. Supp. 2023,
3 Section 353.1), is amended to read as follows:

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

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

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

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

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

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

19 6. "Certify" or "certification of a prescription" means the
20 review of a filled prescription by a licensed pharmacist or a
21 licensed practitioner with dispensing authority to confirm that the
22 medication, labeling and packaging of the filled prescription are
23 accurate and meet all requirements prescribed by state and federal
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1 law. For the purposes of this paragraph, "licensed practitioner"
2 shall not include optometrists with dispensing authority;

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

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

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

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

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

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

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

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

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

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

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1 360b(b); provided, taking actual physical possession of a product or
2 title shall not be required;

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

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

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

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

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

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

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

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

13 23. "Manufacturer" or "virtual manufacturer" means with respect
14 to a product:

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

20 b. a co-licensed partner of the person described in
21 subparagraph a of this paragraph that obtains the
22 product directly from a person described in this
23 subparagraph or subparagraph a of this paragraph,
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- 1 c. an affiliate of a person described in subparagraph a
2 or b of this paragraph who receives the product
3 directly from a person described in this subparagraph
4 or in subparagraph a or b of this paragraph, or
5 d. a person who contracts with another to manufacture a
6 product;

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

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

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

23 27. "Medical gas distributor" means a person licensed to
24 distribute, transfer, wholesale, deliver or sell medical gases on

1 drug orders to suppliers or other entities licensed to use,
2 administer or distribute medical gas and may also include a patient
3 or ultimate user;

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

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

9 30. "Minor, nonchronic health condition" means a typically
10 short-term health condition that is generally managed with
11 noncontrolled drug therapies, minimal treatment, or self-care, and
12 is limited to the following:

- 13 a. influenzas,
- 14 b. streptococcus,
- 15 c. SARS-CoV-2,
- 16 d. lice, and
- 17 e. other emerging and existing public health threats
18 identified by the State Department of Health if
19 permitted by an order, rule, or regulation;

20 31. "Nonprescription drugs" means medicines or drugs which are
21 sold without a prescription and which are prepackaged for use by the
22 consumer and labeled in accordance with the requirements of the
23 statutes and regulations of this state and the federal government.
24 Such items shall also include medical and dental supplies and

1 bottled or nonbulk chemicals which are sold or offered for sale to
2 the general public if such articles or preparations meet the
3 requirements of the Federal Food, Drug and Cosmetic Act, 21
4 U.S.C.A., Section 321 et seq.;

5 ~~31.~~ 32. "Outsourcing facility" including "virtual outsourcing
6 facility" means a facility at one geographic location or address
7 that:

- 8 a. is engaged in the compounding of sterile drugs,
- 9 b. has elected to register as an outsourcing facility,
- 10 and
- 11 c. complies with all requirements of 21 U.S.C. Section
12 353b;

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

20 ~~33.~~ 34. "Person" means an individual, partnership, limited
21 liability company, corporation or association, unless the context
22 otherwise requires;

23 ~~34.~~ 35. "Pharmacist-in-charge" or "PIC" means the pharmacist
24 licensed in this state responsible for the management control of a

1 pharmacy and all other aspects of the practice of pharmacy in a
2 licensed pharmacy as defined by Section 353.18 of this title;

3 ~~35.~~ 36. "Pharmacy" means a place regularly licensed by the
4 State Board of Pharmacy in which prescriptions, drugs, medicines,
5 chemicals and poisons are compounded or dispensed or such place
6 where pharmacists practice the profession of pharmacy, or a pharmacy
7 operated by the Oklahoma Department of Veterans Affairs;

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

14 ~~37.~~ 38. "Poison" means any substance which when introduced into
15 the body, either directly or by absorption, produces violent, morbid
16 or fatal changes, or which destroys living tissue with which such
17 substance comes into contact;

18 ~~38.~~ 39. "Practice of pharmacy" means:

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

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

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

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

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

14 g. the ordering, performing, and interpreting of tests
15 for minor, nonchronic health conditions that meet the
16 requirements of Section 1 of this act and the
17 initiation of drug therapy for minor, nonchronic
18 health conditions,

19 h. the dispensing of self-administered hormonal
20 contraceptives as provided by Section 1 of this act,
21 or

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

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1 ~~39.~~ 40. "Preparation" means an article which may or may not
2 contain sterile products compounded in a licensed pharmacy pursuant
3 to the order of a licensed prescriber;

4 ~~40.~~ 41. "Prescriber" means a person licensed in this state who
5 is authorized to prescribe dangerous drugs within the scope of
6 practice of the person's profession;

7 ~~41.~~ 42. "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~~ Advanced Practice Registered Nurse or
14 an Oklahoma licensed physician assistant, or
- 15 c. by an Oklahoma licensed wholesaler or distributor as
16 authorized in Section 353.29.1 of this title;

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

23 ~~43.~~ 44. "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 ~~44.~~ 45. "Sterile drug" means a drug that is intended for
4 parenteral administration, an ophthalmic or oral inhalation drug in
5 aqueous format, or a drug that is required to be sterile under state
6 and federal law;

7 ~~45.~~ 46. "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~~ Advanced Practice Registered
14 Nurse as defined in Section 567.3a of this title, and who is not in
15 training as an intern, resident, or fellow. To be eligible to
16 supervise an ~~advanced practice registered nurse~~ Advanced Practice
17 Registered Nurse, such physician shall remain in compliance with the
18 rules promulgated by the State Board of Medical Licensure and
19 Supervision or the State Board of Osteopathic Examiners;

20 ~~46.~~ 47. "Supportive personnel" means technicians and auxiliary
21 supportive persons who are regularly paid employees of a pharmacy
22 who work and perform tasks in the pharmacy as authorized by Section
23 353.18A of this title;

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1 ~~47.~~ 48. "Third-party logistics provider" including "virtual
2 third-party logistics provider" means an entity that provides or
3 coordinates warehousing, or other logistics services of a product in
4 interstate commerce on behalf of a manufacturer, wholesale
5 distributor, or dispenser of a product but does not take ownership
6 of the product, nor have responsibility to direct the sale or
7 disposition of the product. For the purposes of this paragraph,
8 ~~"third party logistics provider"~~ third-party logistics provider does
9 not include shippers and the United States Postal Service;

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

16 ~~49.~~ 50. "County jail" means a facility operated by a county for
17 the physical detention and correction of persons charged with, or
18 convicted of, criminal offenses or ordinance violations or persons
19 found guilty of civil or criminal contempt;

20 ~~50.~~ 51. "State correctional facility" means a facility or
21 institution that houses a prisoner population under the jurisdiction
22 of the Department of Corrections;

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1 ~~51.~~ 52. "Unit dose package" means a package that contains a
2 single dose drug with the name, strength, control number, and
3 expiration date of that drug on the label; and

4 ~~52.~~ 53. "Unit of issue package" means a package that provides
5 multiple doses of the same drug, but each drug is individually
6 separated and includes the name, lot number, and expiration date.

7 SECTION 3. AMENDATORY 59 O.S. 2021, Section 353.18A, is
8 amended to read as follows:

9 Section 353.18A A. Supportive personnel may perform certain
10 tasks in the practice of pharmacy if such personnel perform the
11 tasks in compliance with rules promulgated by the State Board of
12 Pharmacy.

13 B. 1. No person shall serve as a pharmacy technician without
14 first procuring a permit from the Board.

15 2. An application for an initial or renewal pharmacy technician
16 permit issued pursuant to the provisions of this subsection shall be
17 submitted to the Board and provide any other information deemed
18 relevant by the Board.

19 3. An application for an initial or renewal permit shall be
20 accompanied by a permit fee not to exceed ~~Seventy-Five~~ Seventy-five
21 Dollars (\$75.00) for each period of one (1) year. A permit issued
22 pursuant to this subsection shall be valid for a period to be
23 determined by the Board.

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1 4. Every permitted pharmacy technician who fails to complete a
2 renewal form and remit the required renewal fee to the Board by the
3 fifteenth day after the expiration of the permit shall pay a late
4 fee to be fixed by the Board.

5 5. A pharmacy technician permit shall be ~~cancelled~~ canceled
6 thirty (30) days after expiration.

7 6. A person may obtain reinstatement of a ~~cancelled~~ canceled
8 pharmacy technician permit by making application, paying a
9 reinstatement fee, and satisfactorily completing other requirements
10 set by the Board.

11 C. A licensed pharmacy shall maintain a pharmacy technician-to-
12 pharmacist ratio of not more than three pharmacy technicians for
13 every one licensed pharmacist.

14 SECTION 4. This act shall become effective July 1, 2024.

15 SECTION 5. It being immediately necessary for the preservation
16 of the public peace, health or safety, an emergency is hereby
17 declared to exist, by reason whereof this act shall take effect and
18 be in full force from and after its passage and approval.

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20 COMMITTEE REPORT BY: COMMITTEE ON BUSINESS AND COMMERCE, dated
21 04/10/2024 - DO PASS, As Amended.
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