

1 ENGROSSED SENATE
2 BILL NO. 931

By: Garvin of the Senate

and

Marti of the House

3
4
5
6 An Act relating to the practice of pharmacy; allowing
7 pharmacist to test or screen for and initiate drug
8 therapy for minor, nonchronic health conditions;
9 specifying allowed tests; allowing pharmacist to
10 dispense certain products under certain protocol;
11 directing promulgation of rules; amending 59 O.S.
12 2021, Section 353.1, as amended by Section 6, Chapter
13 288, O.S.L. 2022 (59 O.S. Supp. 2022, Section 353.1),
14 which relates to definitions used in the Oklahoma
15 Pharmacy Act; modifying and adding definitions;
16 updating statutory language and references; providing
17 for codification; providing an effective date; and
18 declaring an emergency.

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

20 SECTION 1. NEW LAW A new section of law to be codified
21 in the Oklahoma Statutes as Section 353.31 of Title 59, unless there
22 is created a duplication in numbering, reads as follows:

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

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

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

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

7 C. A pharmacist may dispense self-administered hormonal
8 contraceptives under the protocol established pursuant to subsection
9 D of this section, regardless of whether the patient has obtained a
10 prescription.

11 D. The State Board of Pharmacy shall adopt rules establishing a
12 protocol for dispensing self-administered hormonal contraceptives by
13 January 1, 2024.

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

17 Section 353.1. For the purposes of the Oklahoma Pharmacy Act:

18 1. "Accredited program" means those seminars, classes,
19 meetings, work projects, and other educational courses approved by
20 the ~~Board~~ State Board of Pharmacy for purposes of continuing
21 professional education;

22 2. "Act" means the Oklahoma Pharmacy Act;
23
24

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~~ this state by
6 the Board pursuant to Section 353.10 of this title and for the
7 purposes of the Oklahoma Pharmacy Act shall be considered the same
8 as a pharmacist, 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~~ to 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"~~ dispenser does not
5 mean a 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;

24

1 17. "Drugs" means all medicinal substances and preparations
2 recognized by the United States ~~Pharmacopoeia~~ Pharmacopeia and
3 National 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. "Durable medical equipment" has the same meaning as
14 provided by Section ~~2 of this act~~ 375.2 of this title;

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

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

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

1 23. "Manufacturer" or "virtual manufacturer" means with respect
2 to a product:

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

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

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

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

18 24. "Manufacturing" means the production, preparation,
19 propagation, compounding, conversion or processing of a device or a
20 drug, either directly or indirectly by extraction from substances of
21 natural origin or independently by means of chemical or biological
22 synthesis and includes any packaging or repackaging of the
23 substances or labeling or relabeling of its container, and the
24 promotion and marketing of such drugs or devices. The term

1 ~~"manufacturing"~~ manufacturing also includes the preparation and
2 promotion of commercially available products from bulk compounds for
3 resale by licensed pharmacies, licensed practitioners or other
4 persons;

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

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

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

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

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

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

24 a. influenzas,

- b. streptococcus,
- c. SARS-CoV-2,
- d. lice, and
- e. other emerging and existing public health threats identified by the State Department of Health if permitted by an order, rule, or regulation;

31. "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.;

~~31.~~ 32. "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;

~~32.~~ 33. "Package" means the smallest individual saleable unit of product for distribution by a manufacturer or repackager that is

1 intended by the manufacturer for ultimate sale to the dispenser of
2 such product. For the purposes of this paragraph, "individual
3 saleable unit" means the smallest container of a product introduced
4 into commerce by the manufacturer or repackager that is intended by
5 the manufacturer or repackager for individual sale to a dispenser;

6 ~~33.~~ 34. "Person" means an individual, partnership, limited
7 liability company, corporation or association, unless the context
8 otherwise requires;

9 ~~34.~~ 35. "Pharmacist-in-charge" or "PIC" means the pharmacist
10 licensed in this state responsible for the management control of a
11 pharmacy and all other aspects of the practice of pharmacy in a
12 licensed pharmacy as defined by Section 353.18 of this title;

13 ~~35.~~ 36. "Pharmacy" means a place regularly licensed by the
14 State Board of Pharmacy in which prescriptions, drugs, medicines,
15 chemicals and poisons are compounded or dispensed or such place
16 where pharmacists practice the profession of pharmacy, or a pharmacy
17 operated by the Oklahoma Department of Veterans Affairs;

18 ~~36.~~ 37. "Pharmacy technician", "technician", "Rx tech", or
19 "tech" means a person issued a Technician permit by the State Board
20 of Pharmacy to assist the pharmacist and perform nonjudgmental,
21 technical, manipulative, non-discretionary functions in the
22 prescription department under the immediate and direct supervision
23 of a pharmacist;

24

1 ~~37.~~ 38. "Poison" means any substance which when introduced into
2 the body, either directly or by absorption, produces violent, morbid
3 or fatal changes, or which destroys living tissue with which such
4 substance comes into contact;

5 ~~38.~~ 39. "Practice of pharmacy" means:

- 6 a. the interpretation and evaluation of prescription
7 orders,
- 8 b. the compounding, dispensing, administering and
9 labeling of drugs and devices, except labeling by a
10 manufacturer, repackager or distributor of
11 nonprescription drugs and commercially packaged legend
12 drugs and devices,
- 13 c. the participation in drug selection and drug
14 utilization reviews,
- 15 d. the proper and safe storage of drugs and devices and
16 the maintenance of proper records thereof,
- 17 e. the responsibility for advising by counseling and
18 providing information, where professionally necessary
19 or where regulated, of therapeutic values, content,
20 hazards and use of drugs and devices,
- 21 f. the offering or performing of those acts, services,
22 operations or transactions necessary in the conduct,
23 operation, management and control of a pharmacy, ~~or~~

1 g. the ordering, performing, and interpreting of tests
2 for minor, nonchronic health conditions that meet the
3 requirements of Section 1 of this act and the
4 initiation of drug therapy for minor, nonchronic
5 health conditions,

6 h. the dispensing of self-administered hormonal
7 contraceptives as provided by Section 1 of this act,
8 or

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

11 ~~39.~~ 40. "Preparation" means an article which may or may not
12 contain sterile products compounded in a licensed pharmacy pursuant
13 to the order of a licensed prescriber;

14 ~~40.~~ 41. "Prescriber" means a person licensed in this state who
15 is authorized to prescribe dangerous drugs within the scope of
16 practice of the person's profession;

17 ~~41.~~ 42. "Prescription" means and includes any order for drug or
18 medical supplies written or signed, or transmitted by word of mouth,
19 telephone or other means of communication:

20 a. by a licensed prescriber,

21 b. under the supervision of an Oklahoma licensed
22 practitioner, an Oklahoma licensed ~~advanced practice~~
23 ~~registered nurse~~ Advanced Practice Registered Nurse or
24 an Oklahoma licensed physician assistant, or

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

3 ~~42.~~ 43. "Product" means a prescription drug in a finished
4 dosage form for administration to a patient without substantial
5 further manufacturing, such as capsules, tablets, and lyophilized
6 products before reconstitution. ~~"Product"~~ Product does not include
7 blood components intended for transfusion, radioactive drugs or
8 biologics and medical gas;

9 ~~43.~~ 44. "Repackager", including "virtual repackager", means a
10 person who owns or operates an establishment that repacks and
11 relabels a product or package for further sale or distribution
12 without further transaction;

13 ~~44.~~ 45. "Sterile drug" means a drug that is intended for
14 parenteral administration, an ophthalmic or oral inhalation drug in
15 aqueous format, or a drug that is required to be sterile under state
16 and federal law;

17 ~~45.~~ 46. "Supervising physician" means an individual holding a
18 current license to practice as a physician from the State Board of
19 Medical Licensure and Supervision, pursuant to the provisions of the
20 Oklahoma Allopathic Medical and Surgical Licensure and Supervision
21 Act, or the State Board of Osteopathic Examiners, pursuant to the
22 provisions of the Oklahoma Osteopathic Medicine Act, who supervises
23 an ~~advanced practice registered nurse~~ Advanced Practice Registered
24 Nurse as defined in Section 567.3a of this title, and who is not in

1 training as an intern, resident, or fellow. To be eligible to
2 supervise an ~~advanced practice registered nurse~~ Advanced Practice
3 Registered Nurse, such physician shall remain in compliance with the
4 rules promulgated by the State Board of Medical Licensure and
5 Supervision or the State Board of Osteopathic Examiners;

6 ~~46.~~ 47. "Supportive personnel" means technicians and auxiliary
7 supportive persons who are regularly paid employees of a pharmacy
8 who work and perform tasks in the pharmacy as authorized by Section
9 353.18A of this title;

10 ~~47.~~ 48. "Third-party logistics provider" including "virtual
11 third-party logistics provider" means an entity that provides or
12 coordinates warehousing, or other logistics services of a product in
13 interstate commerce on behalf of a manufacturer, wholesale
14 distributor, or dispenser of a product but does not take ownership
15 of the product, nor have responsibility to direct the sale or
16 disposition of the product. For the purposes of this paragraph,
17 ~~"third-party logistics provider"~~ third-party logistics provider does
18 not include shippers and the United States Postal Service;

19 ~~48.~~ 49. "Wholesale distributor" including "virtual wholesale
20 distributor" means a person other than a manufacturer, a
21 manufacturer's co-licensed partner, a third-party logistics
22 provider, or repackager engaged in wholesale distribution as defined
23 by 21 U.S.C. 353(e) (4) as amended by the Drug Supply Chain Security
24 Act;

1 ~~49.~~ 50. "County jail" means a facility operated by a county for
2 the physical detention and correction of persons charged with, or
3 convicted of, criminal offenses or ordinance violations or persons
4 found guilty of civil or criminal contempt;

5 ~~50.~~ 51. "State correctional facility" means a facility or
6 institution that houses a prisoner population under the jurisdiction
7 of the Department of Corrections;

8 ~~51.~~ 52. "Unit dose package" means a package that contains a
9 single dose drug with the name, strength, control number, and
10 expiration date of that drug on the label; and

11 ~~52.~~ 53. "Unit of issue package" means a package that provides
12 multiple doses of the same drug, but each drug is individually
13 separated and includes the name, lot number, and expiration date.

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

15 SECTION 4. 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.

1 Passed the Senate the 22nd day of March, 2023.

2
3 _____
4 Presiding Officer of the Senate

5 Passed the House of Representatives the ____ day of _____,
6 2023.

7
8 _____
9 Presiding Officer of the House
10 of Representatives