1	STATE OF OKLAHOMA
2	2nd Session of the 59th Legislature (2024)
3	COMMITTEE SUBSTITUTE FOR ENGROSSED
4	SENATE BILL NO. 232 By: Garvin of the Senate
5	and
6	McEntire of the House
7	
8	
9	COMMITTEE SUBSTITUTE
10	An Act relating to the practice of pharmacy; allowing pharmacist to test or screen for and initiate drug
11	therapy for minor, nonchronic health conditions; specifying allowed tests; allowing pharmacist to
12	dispense certain products under certain protocol; directing adoption of rules; amending 59 O.S. 2021,
13	Section 353.1, as amended by Section 6, Chapter 288, O.S.L. 2022 (59 O.S. Supp. 2023, Section 353.1),
14	which relates to definitions used in the Oklahoma Pharmacy Act; modifying and adding definitions;
15	amending 59 O.S. 2021, Section 353.18A, which relates to pharmacy technicians; establishing certain
16	pharmacy ratio; updating statutory language and references; providing for codification; providing an
17	effective date; and declaring an emergency.
18	
19	
20	BE IT ENACTED BY THE PEOPLE OF THE STATE OF OKLAHOMA:
21	SECTION 1. NEW LAW A new section of law to be codified
22	in the Oklahoma Statutes as Section 353.31 of Title 59, unless there
23	is created a duplication in numbering, reads as follows:
24	

A. A pharmacist may test or screen for and initiate drug
 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:

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

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

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

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

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

- 23
- 24

 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:

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 <u>State</u> Board <u>of Pharmacy</u> for purposes of continuing professional
education;

9 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 this state 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;

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

24

Req. No. 10930

law. For the purposes of this paragraph, "licensed practitioner"
 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;

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;

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

a. for human use subject to 21 U.S.C. <u>Section</u> 353(b)(1),
or

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

24

1 11. "Director" means the Executive Director of the State Board
 2 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;

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

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. <u>Section</u> 353(b)(1) 23 or the dispensing of a product approved under 21 U.S.C. Section

24

Req. No. 10930

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;

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

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;

Req. No. 10930

1 19. "Durable medical equipment" has the same meaning as provided by Section 2 375.2 of this act title; 2 "Filled prescription" means a packaged prescription 3 20. medication to which a label has been affixed which contains such 4 5 information as is required by the Oklahoma Pharmacy Act; "Hospital" means any institution licensed as a hospital by 6 21. this state for the care and treatment of patients, or a pharmacy 7 operated by the Oklahoma Department of Veterans Affairs; 8 9 22. "Licensed practitioner" means an allopathic physician, osteopathic physician, podiatric physician, dentist, veterinarian or 10 optometrist licensed to practice and authorized to prescribe 11 dangerous drugs within the scope of practice of such practitioner; 12 "Manufacturer" or "virtual manufacturer" means with respect 23. 13 to a product: 14 a person that holds an application approved under 21 15 a. U.S.C. Section 355 or a license issued under 42 U.S.C. 16 Section 262 for such product, or if such product is 17 not the subject of an approved application or license, 18 the person who manufactured the product, 19 b. a co-licensed partner of the person described in 20 subparagraph a of this paragraph that obtains the 21 product directly from a person described in this 22 subparagraph or subparagraph a of this paragraph, 23

24

c. an affiliate of a person described in subparagraph a or b <u>of this paragraph</u> who receives the product directly from a person described in this subparagraph or in subparagraph a or b of this paragraph, or d. a person who contracts with another to manufacture a product;

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

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 to24 distribute, transfer, wholesale, deliver or sell medical gases on

Req. No. 10930

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;

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 <u>a.</u> influenzas,
- 14 b. streptococcus,
- 15 <u>c.</u> <u>SARS-CoV-2</u>,
- 16 <u>d.</u> 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;

20 <u>31.</u> "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 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.;

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

a. is engaged in the compounding of sterile drugs,
b. has elected to register as an outsourcing facility,
and

11 c. complies with all requirements of 21 U.S.C. <u>Section</u> 12 353b;

32. 33. "Package" means the smallest individual saleable unit 13 of product for distribution by a manufacturer or repackager that is 14 intended by the manufacturer for ultimate sale to the dispenser of 15 such product. For the purposes of this paragraph, "individual 16 saleable unit" means the smallest container of a product introduced 17 into commerce by the manufacturer or repackager that is intended by 18 the manufacturer or repackager for individual sale to a dispenser; 19 33. 34. "Person" means an individual, partnership, limited 20 liability company, corporation or association, unless the context 21 otherwise requires; 22

23 <u>34.</u> <u>35.</u> "Pharmacist-in-charge" or "PIC" means the pharmacist 24 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;

3 35. 36. "Pharmacy" means a place regularly licensed by the
4 <u>State</u> 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 <u>37.</u> <u>38.</u> "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:

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

24

- nonprescription drugs and commercially packaged legend
   drugs and devices,
  - c. the participation in drug selection and drug utilization reviews,
  - 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
- 14g.the ordering, performing, and interpreting of tests15for minor, nonchronic health conditions that meet the16requirements of Section 1 of this act and the17initiation 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 <u>i.</u> the provision of those acts or services that are
   23 necessary to provide pharmaceutical care;
- 24

3

4

5

6

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 <u>40. 41.</u> "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;

41. 42. "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:

10

a. by a licensed prescriber,

b. under the supervision of an Oklahoma licensed
 practitioner, an Oklahoma licensed advanced practice
 registered nurse Advanced Practice Registered Nurse or
 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. <u>43.</u> "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. <u>Product" Product</u> does not include 21 blood components intended for transfusion, radioactive drugs or 22 biologics and medical gas;

43. 44. "Repackager", including "virtual repackager", means a
 person who owns or operates an establishment that repacks and

Req. No. 10930

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

3 <u>44.</u> <u>45.</u> "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;

45. 46. "Supervising physician" means an individual holding a 7 current license to practice as a physician from the State Board of 8 9 Medical Licensure and Supervision, pursuant to the provisions of the Oklahoma Allopathic Medical and Surgical Licensure and Supervision 10 Act, or the State Board of Osteopathic Examiners, pursuant to the 11 provisions of the Oklahoma Osteopathic Medicine Act, who supervises 12 an advanced practice registered nurse Advanced Practice Registered 13 Nurse as defined in Section 567.3a of this title, and who is not in 14 training as an intern, resident, or fellow. To be eligible to 15 supervise an advanced practice registered nurse Advanced Practice 16 Registered Nurse, such physician shall remain in compliance with the 17 rules promulgated by the State Board of Medical Licensure and 18 Supervision or the State Board of Osteopathic Examiners; 19

20 <u>46. 47.</u> "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;

24

Req. No. 10930

1 47. 48. "Third-party logistics provider" including "virtual third-party logistics provider" means an entity that provides or 2 coordinates warehousing, or other logistics services of a product in 3 interstate commerce on behalf of a manufacturer, wholesale 4 5 distributor, or dispenser of a product but does not take ownership of the product, nor have responsibility to direct the sale or 6 disposition of the product. For the purposes of this paragraph, 7 "third-party logistics provider" third-party logistics provider does 8 9 not include shippers and the United States Postal Service; 48. 49. "Wholesale distributor" including "virtual wholesale 10 distributor" means a person other than a manufacturer, a 11 12 manufacturer's co-licensed partner, a third-party logistics provider, or repackager engaged in wholesale distribution as defined 13 by 21 U.S.C. Section 353(e)(4) as amended by the Drug Supply Chain 14 Security Act; 15

16 <u>49. 50.</u> "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 <u>50. 51.</u> "State correctional facility" means a facility or 21 institution that houses a prisoner population under the jurisdiction 22 of the Department of Corrections;

- 23
- 24

1 <u>51. 52.</u> "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

52. <u>53.</u> "Unit of issue package" means a package that provides
multiple doses of the same drug, but each drug is individually
separated and includes the name, lot number, and expiration date.
SECTION 3. AMENDATORY 59 O.S. 2021, Section 353.18A, is
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.

B. 1. No person shall serve as a pharmacy technician withoutfirst 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.

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

24

Req. No. 10930

1 4. Every permitted pharmacy technician who fails to complete a renewal form and remit the required renewal fee to the Board by the 2 fifteenth day after the expiration of the permit shall pay a late 3 fee to be fixed by the Board. 4 5 5. A pharmacy technician permit shall be <del>cancelled</del> canceled thirty (30) days after expiration. 6 6. A person may obtain reinstatement of a cancelled canceled 7 pharmacy technician permit by making application, paying a 8 9 reinstatement fee, and satisfactorily completing other requirements 10 set by the Board. C. A licensed pharmacy shall maintain a pharmacy technician-to-11 12 pharmacist ratio of not more than three pharmacy technicians for 13 every one licensed pharmacist. SECTION 4. This act shall become effective July 1, 2024. 14 SECTION 5. It being immediately necessary for the preservation 15 of the public peace, health or safety, an emergency is hereby 16 declared to exist, by reason whereof this act shall take effect and 17 be in full force from and after its passage and approval. 18 19 59-2-10930 SW 04/10/24 20 21 22 23 24