OKLAHOMA STATE SENATE CONFERENCE COMMITTEE REPORT

May 28, 2024

Mr. President:

Mr. Speaker:

The Conference Committee, to which was referred

<u>SB232</u>

By: Garvin of the Senate and McEntire of the House

Title: Practice of pharmacy; allowing pharmacist to test or screen for and initiate therapy for certain conditions; dispensing; pharmacy technicians; ratio.

together with Engrossed House Amendments thereto, beg leave to report that we have had the same under consideration and herewith return the same with the following recommendations:

- 1. That the House recede from all Amendments.
- 2. That the attached Conference Committee Substitute (Request #3850) be adopted.

Rosi

Respectfully submitted,

SENATE CONFEREES:

Deevers

Hicks

HOUSE CONFEREES:

Conference Committee on Business and Conference

Senate Action_

_Date__

House Action_

Date_

1	STATE OF OKLAHOMA		
2	2nd Session of the 59th Legislature (2024)		
3	CONFERENCE COMMITTEE SUBSTITUTE FOR ENGROSSED		
4	SENATE BILL NO. 232 By: Garvin of the Senate		
5	and		
6	McEntire of the House		
7			
8			
9	CONFERENCE 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; and providing for codification.		
17	references, and providing for coarriedefon.		
18			
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, except that a
 pharmacist may not test or screen for or initiate drug therapy for
 streptococcus to individuals under six (6) years of age.

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 non-abortifacient selfadministered hormonal contraceptives under the protocol established pursuant to subsection D of this section, regardless of whether the patient has obtained a prescription, subject to the following conditions:

The pharmacist must have a standing order or similar
 arrangement with a physician as approved by the State Board of
 Pharmacy in accordance with the protocol established under
 subsection D of this section;

The pharmacist may only dispense non-abortifacient self administered hormonal contraceptives to biological women; and

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3. The pharmacist shall not dispense abortifacient self administered hormonal contraceptives.

D. The State Board of Pharmacy shall adopt rules establishing a
protocol for dispensing non-abortifacient self-administered hormonal
contraceptives as described in subsection C of this section by
January 1, 2025.

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

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

 "Accredited program" means those seminars, classes,
 meetings, work projects, and other educational courses approved by

13 the <u>State</u> Board <u>of Pharmacy</u> for purposes of continuing professional 14 education;

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

16 3. "Administer" means the direct application of a drug, whether 17 by injection, inhalation, ingestion, or any other means, to the body 18 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;

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

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

8 7. "Chemical" means any medicinal substance, whether simple or 9 compound or obtained through the process of the science and art of 10 chemistry, whether of organic or inorganic origin;

11 8. "Compounding" means the combining, admixing, mixing, 12 diluting, pooling, reconstituting, or otherwise altering of a drug 13 or bulk drug substance to create a drug. Compounding includes the 14 preparation of drugs or devices in anticipation of prescription drug 15 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;

21 10. "Dangerous drug", "legend drug", "prescription drug", or
22 "Rx Only" means a drug:

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

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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.";

5 11. "Director" means the Executive Director of the State Board6 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 13. 14 group of chain pharmacies under common ownership and control that do 15 not act as a wholesale distributor, or any other person authorized 16 by law to dispense or administer prescription drugs, and the 17 affiliated warehouses or distributions of such entities under common 18 ownership and control that do not act as a wholesale distributor. 19 For the purposes of this paragraph, "dispenser" dispenser does not 20 mean a person who dispenses only products to be used in animals in 21 accordance with 21 U.S.C., Section 360b(a)(5); 22

14. "Distribute" or "distribution" means the sale, purchase,trade, delivery, handling, storage, or receipt of a product, and

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does not include the dispensing of a product pursuant to a prescription executed in accordance with 21 U.S.C., Section 353(b)(1) or the dispensing of a product approved under 21 U.S.C., <u>Section</u> 360b(b); provided, taking actual physical possession of a product or title shall not be required;

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

11 16. "Drug outlet" means all manufacturers, repackagers, 12 outsourcing facilities, wholesale distributors, third-party 13 logistics providers, pharmacies, and all other facilities which are 14 engaged in dispensing, delivery, distribution, or storage of 15 dangerous drugs;

17. "Drugs" means all medicinal substances and preparations 16 recognized by the United States Pharmacopoeia Pharmacopeia and 17 National Formulary, or any revision thereof, and all substances and 18 preparations intended for external and/or internal use in the cure, 19 diagnosis, mitigation, treatment, or prevention of disease in humans 20 or animals and all substances and preparations, other than food, 21 intended to affect the structure or any function of the body of a 22 human or animals; 23

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1 18. "Drug sample" means a unit of a prescription drug packaged 2 under the authority and responsibility of the manufacturer that is 3 not intended to be sold and is intended to promote the sale of the 4 drug;

5 19. "Durable medical equipment" has the same meaning as
6 provided by Section 2 <u>375.2</u> of this act title;

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

10 21. "Hospital" means any institution licensed as a hospital by 11 this state for the care and treatment of patients, or a pharmacy 12 operated by the Oklahoma Department of Veterans Affairs;

13 22. "Licensed practitioner" means an allopathic physician,
14 osteopathic physician, podiatric physician, dentist, veterinarian,
15 or optometrist licensed to practice and authorized to prescribe
16 dangerous drugs within the scope of practice of such practitioner;
17 23. "Manufacturer" or "virtual manufacturer" means with respect

19a. a person that holds an application approved under 2120U.S.C., Section 355 or a license issued under 4221U.S.C., Section 262 for such product, or if such22product is not the subject of an approved application23or license, the person who manufactured the product,

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to a product:

1 b. a co-licensed partner of the person described in 2 subparagraph a of this paragraph that obtains the product directly from a person described in this 3 subparagraph or subparagraph a of this paragraph, 4 5 с. an affiliate of a person described in subparagraph a or b of this paragraph who receives the product 6 directly from a person described in this subparagraph 7 or in subparagraph a or b of this paragraph, or 8 9 d. a person who contracts with another to manufacture a product; 10

"Manufacturing" means the production, preparation, 11 24. propagation, compounding, conversion, or processing of a device or a 12 drug, either directly or indirectly by extraction from substances of 13 natural origin or independently by means of chemical or biological 14 synthesis and includes any packaging or repackaging of the 15 substances or labeling or relabeling of its container, and the 16 promotion and marketing of such drugs or devices. The term 17 "manufacturing" manufacturing also includes the preparation and 18 promotion of commercially available products from bulk compounds for 19 resale by licensed pharmacies, licensed practitioners, or other 20 persons; 21

22 25. "Medical gas" means those gases including those in liquid 23 state upon which the manufacturer or distributor has placed one of 24 several cautions, such as "Rx Only", in compliance with federal law; 26. "Medical gas order" means an order for medical gas issued
 by a licensed prescriber;

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

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

10 29. "Medicine" means any drug or combination of drugs which has 11 the property of curing, preventing, treating, diagnosing, or 12 mitigating diseases, or which is used for that purpose;

13 30. <u>"Minor, nonchronic health condition" means a typically</u>

14 short-term health condition that is generally managed with

15 noncontrolled drug therapies, minimal treatment, or self-care, and

16 is limited to the following:

- 17 <u>a.</u> influenzas,
- 18 <u>b.</u> streptococcus,
- 19 <u>c.</u> <u>SARS-CoV-2</u>,
- 20 <u>d.</u> <u>lice</u>, and
- e. other emerging and existing public health threats
 identified by the State Department of Health if
 permitted by an order, rule, or regulation;
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1 31. "Nonprescription drugs" means medicines or drugs which are sold without a prescription and which are prepackaged for use by the 2 consumer and labeled in accordance with the requirements of the 3 statutes and regulations of this state and the federal government. 4 5 Such items shall also include medical and dental supplies and bottled or nonbulk chemicals which are sold or offered for sale to 6 the general public if such articles or preparations meet the 7 requirements of the Federal Food, Drug, and Cosmetic Act, 21 8 9 U.S.C.A., Section 321 et seq.;

10 <u>31. 32.</u> "Outsourcing facility" including "virtual outsourcing 11 facility" means a facility at one geographic location or address 12 that:

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

16 c. complies with all requirements of 21 U.S.C., Section
17 353b;

18 32. 33. "Package" means the smallest individual saleable unit 19 of product for distribution by a manufacturer or repackager that is 20 intended by the manufacturer for ultimate sale to the dispenser of 21 such product. For the purposes of this paragraph, "individual 22 saleable unit" means the smallest container of a product introduced 23 into commerce by the manufacturer or repackager that is intended by 24 the manufacturer or repackager for individual sale to a dispenser;

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1 33. 34. "Person" means an individual, partnership, limited
2 liability company, corporation, or association, unless the context
3 otherwise requires;

34. 35. "Pharmacist-in-charge" or "PIC" means the pharmacist
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;

8 <u>35.</u> <u>36.</u> "Pharmacy" means a place regularly licensed by the 9 <u>State</u> Board of Pharmacy in which prescriptions, drugs, medicines, 10 chemicals, and poisons are compounded or dispensed or such place 11 where pharmacists practice the profession of pharmacy, or a pharmacy 12 operated by the Oklahoma Department of Veterans Affairs;

13 36. <u>37.</u> "Pharmacy technician", "technician", "Rx tech", or 14 "tech" means a person issued a <u>Technician technician</u> permit by the 15 State Board of Pharmacy to assist the pharmacist and perform 16 nonjudgmental, technical, manipulative, non-discretionary functions 17 in the prescription department under the immediate and direct 18 supervision of a pharmacist;

19 37. 38. "Poison" means any substance which when introduced into 20 the body, either directly or by absorption, produces violent, 21 morbid, or fatal changes, or which destroys living tissue with which 22 such substance comes into contact;

23 38. 39. "Practice of pharmacy" means:

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- 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
 nonprescription drugs and commercially packaged legend
 drugs and devices,
- 8 c. the participation in drug selection and drug9 utilization reviews,
- d. 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,
- 16 f. the offering or performing of those acts, services,
 17 operations, or transactions necessary in the conduct,
 18 operation, management, and control of a pharmacy, or
- 19g.the ordering, performing, and interpreting of tests20for minor, nonchronic health conditions that meet the21requirements of Section 1 of this act and the22initiation of drug therapy for minor, nonchronic23health conditions,
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1	h. the dispensing of non-abortifacient self-administered
2	hormonal contraceptives as provided by Section 1 of
3	this act, or
4	<u>i.</u> the provision of those acts or services that are
5	necessary to provide pharmaceutical care;
6	39. <u>40.</u> "Preparation" means an article which may or may not
7	contain sterile products compounded in a licensed pharmacy pursuant
8	to the order of a licensed prescriber;
9	40. <u>41.</u> "Prescriber" means a person licensed in this state who
10	is authorized to prescribe dangerous drugs within the scope of
11	practice of the person's profession;
12	41. 42. "Prescription" means and includes any order for drug or
13	medical supplies written or signed, or transmitted by word of mouth,
14	telephone, or other means of communication:
15	a. by a licensed prescriber,
16	b. under the supervision of an Oklahoma licensed
17	practitioner, an Oklahoma licensed advanced practice
18	registered nurse Advanced Practice Registered Nurse,
19	or an Oklahoma licensed physician assistant, or
20	c. by an Oklahoma licensed wholesaler or distributor as
21	authorized in Section 353.29.1 of this title;
22	42. 43. "Product" means a prescription drug in a finished
23	dosage form for administration to a patient without substantial
24	further manufacturing, such as capsules, tablets, and lyophilized

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1 products before reconstitution. <u>"Product" Product</u> does not include 2 blood components intended for transfusion, radioactive drugs or 3 biologics and medical gas;

4 43. 44. "Repackager", including "virtual repackager", means a
5 person who owns or operates an establishment that repacks and
6 relabels a product or package for further sale or distribution
7 without further transaction;

8 <u>44. 45.</u> "Sterile drug" means a drug that is intended for 9 parenteral administration, an ophthalmic or oral inhalation drug in 10 aqueous format, or a drug that is required to be sterile under state 11 and federal law;

12 45. 46. "Supervising physician" means an individual holding a current license to practice as a physician from the State Board of 13 Medical Licensure and Supervision, pursuant to the provisions of the 14 Oklahoma Allopathic Medical and Surgical Licensure and Supervision 15 Act, or the State Board of Osteopathic Examiners, pursuant to the 16 provisions of the Oklahoma Osteopathic Medicine Act, who supervises 17 an advanced practice registered nurse Advanced Practice Registered 18 Nurse as defined in Section 567.3a of this title, and who is not in 19 training as an intern, resident, or fellow. To be eligible to 20 supervise an advanced practice registered nurse Advanced Practice 21 Registered Nurse, such physician shall remain in compliance with the 22 rules promulgated by the State Board of Medical Licensure and 23 Supervision or the State Board of Osteopathic Examiners; 24

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1 46. <u>47.</u> "Supportive personnel" means technicians and auxiliary 2 supportive persons who are regularly paid employees of a pharmacy 3 who work and perform tasks in the pharmacy as authorized by Section 4 353.18A of this title;

5 47. 48. "Third-party logistics provider" including "virtual third-party logistics provider" means an entity that provides or 6 coordinates warehousing, or other logistics services of a product in 7 interstate commerce on behalf of a manufacturer, wholesale 8 9 distributor, or dispenser of a product but does not take ownership 10 of the product, nor have responsibility to direct the sale or disposition of the product. For the purposes of this paragraph, 11 12 "third-party logistics provider" third-party logistics provider does not include shippers and the United States Postal Service; 13

14 48. <u>49.</u> "Wholesale distributor" including "virtual wholesale 15 distributor" means a person other than a manufacturer, a 16 manufacturer's co-licensed partner, a third-party logistics 17 provider, or repackager engaged in wholesale distribution as defined 18 by 21 U.S.C., Section 353(e)(4) as amended by the Drug Supply Chain 19 Security Act;

20 49. <u>50.</u> "County jail" means a facility operated by a county for 21 the physical detention and correction of persons charged with, or 22 convicted of, criminal offenses or ordinance violations or persons 23 found guilty of civil or criminal contempt;

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1 50. 51. "State correctional facility" means a facility or 2 institution that houses a prisoner population under the jurisdiction 3 of the Department of Corrections;

51. 52. "Unit dose package" means a package that contains a
single dose drug with the name, strength, control number, and
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:

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

B. 1. No person shall serve as a pharmacy technician withoutfirst procuring a permit from the Board.

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

3. 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

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pursuant to this subsection shall be valid for a period to be
 determined by the Board.

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

7 5. A pharmacy technician permit shall be cancelled <u>cancelled</u>
8 thirty (30) days after expiration.

9 6. A person may obtain reinstatement of a cancelled <u>cancelled</u>
10 pharmacy technician permit by making application, paying a
11 reinstatement fee, and satisfactorily completing other requirements
12 set by the Board.

13 <u>C. A licensed pharmacy shall maintain a pharmacy technician-to-</u> 14 <u>pharmacist ratio of not more than three pharmacy technicians for</u> 15 every one licensed pharmacist.

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