

SENATE CHAMBER
STATE OF OKLAHOMA

DISPOSITION

FLOOR AMENDMENT

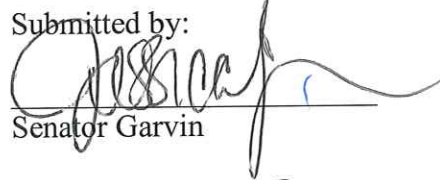
No. 1

COMMITTEE AMENDMENT

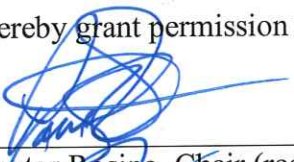
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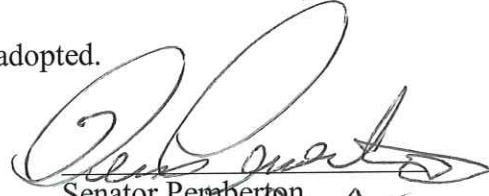
I move to amend Senate Bill No. 931 by substituting the attached floor substitute (Request #1944) for the title, enacting clause and entire body of the measure.

Submitted by:

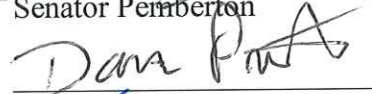

Senator Garvin

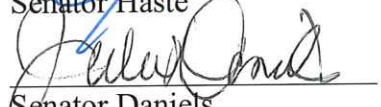
I hereby grant permission for the floor substitute to be adopted.

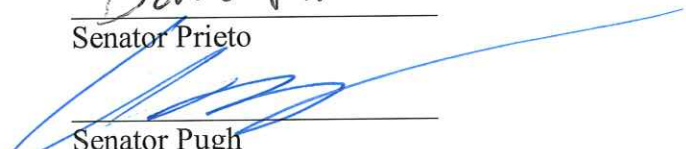

Senator Rosino, Chair (required)

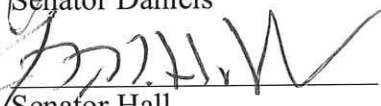

Senator Pemberton


Senator Haste


Senator Prieto


Senator Daniels

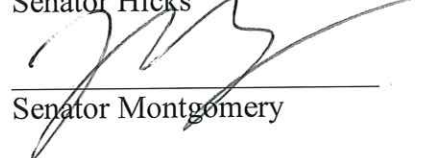

Senator Pugh


Senator Hall

Senator Standridge

Senator Hicks

Senator Stanley


Senator Montgomery

Senator Young

Senator Treat, President Pro Tempore

Senator McCortney, Majority Floor Leader

Note: Health and Human Services committee majority requires seven (7) members' signatures.

Garvin-DC-FS-SB931
3/13/2023 8:32 AM

(Floor Amendments Only) Date and Time Filed: 3-13-23 2:20 pm jfd

Untimely Amendment Cycle Extended Secondary Amendment

STATE OF OKLAHOMA

1st Session of the 59th Legislature (2023)

FLOOR SUBSTITUTE
FOR

SENATE BILL NO. 931

By: Garvin of the Senate

and

Marti of the House

FLOOR SUBSTITUTE

An Act relating to the practice of pharmacy; allowing pharmacist to test or screen for and initiate drug therapy for minor, nonchronic health conditions; specifying allowed tests; allowing pharmacist to dispense certain products under certain protocol; directing promulgation of rules; amending 59 O.S. 2021, Section 353.1, as amended by Section 6, Chapter 288, O.S.L. 2022 (59 O.S. Supp. 2022, Section 353.1), which relates to definitions used in the Oklahoma Pharmacy Act; modifying and adding definitions; updating statutory language and 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. The State Board of Pharmacy shall adopt rules establishing a
18 protocol for dispensing self-administered hormonal contraceptives by
19 January 1, 2024.

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

23 Section 353.1. For the purposes of the Oklahoma Pharmacy Act:
24

- 1 1. "Accredited program" means those seminars, classes,
2 meetings, work projects, and other educational courses approved by
3 the ~~Board~~ State Board of Pharmacy for purposes of continuing
4 professional education;
- 5 2. "Act" means the Oklahoma Pharmacy Act;
- 6 3. "Administer" means the direct application of a drug, whether
7 by injection, inhalation, ingestion or any other means, to the body
8 of a patient;
- 9 4. "Assistant pharmacist" means any person presently licensed
10 as an assistant pharmacist in ~~the State of Oklahoma~~ this state by
11 the Board pursuant to Section 353.10 of this title and for the
12 purposes of the Oklahoma Pharmacy Act shall be considered the same
13 as a pharmacist, except where otherwise specified;
- 14 5. "Board" or "State Board" means the State Board of Pharmacy;
- 15 6. "Certify" or "certification of a prescription" means the
16 review of a filled prescription by a licensed pharmacist or a
17 licensed practitioner with dispensing authority to confirm that the
18 medication, labeling and packaging of the filled prescription are
19 accurate and meet all requirements prescribed by state and federal
20 law. For the purposes of this paragraph, "licensed practitioner"
21 shall not include optometrists with dispensing authority;
- 22 7. "Chemical" means any medicinal substance, whether simple or
23 compound or obtained through the process of the science and art of
24 chemistry, whether of organic or inorganic origin;

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

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

11 10. "Dangerous drug", "legend drug", "prescription drug" or "Rx
12 Only" means a drug:

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

14 b. is labeled "Prescription Only", or labeled with the

15 following statement: "Caution: Federal law restricts

16 this drug ~~except for~~ to use by or on the order of a

17 licensed veterinarian.";

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

20 12. "Dispense" or "dispensing" means the interpretation,
21 evaluation, and implementation of a prescription drug order
22 including the preparation and delivery of a drug or device to a
23 patient or a patient's agent in a suitable container appropriately
24 labeled for subsequent administration to, or use by, a patient.

1 Dispense includes sell, distribute, leave with, give away, dispose
2 of, deliver or supply;

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

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

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

24

1 16. "Drug outlet" means all manufacturers, repackagers,
2 outsourcing facilities, wholesale distributors, third-party
3 logistics providers, pharmacies, and all other facilities which are
4 engaged in dispensing, delivery, distribution or storage of
5 dangerous drugs;

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

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

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

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

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24

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

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

8 23. "Manufacturer" or "virtual manufacturer" means with respect
9 to a product:

- 10 a. a person that holds an application approved under 21
11 U.S.C. 355 or a license issued under 42 U.S.C. 262 for
12 such product, or if such product is not the subject of
13 an approved application or license, the person who
14 manufactured the product,
- 15 b. a co-licensed partner of the person described in
16 subparagraph a of this paragraph that obtains the
17 product directly from a person described in this
18 subparagraph or subparagraph a of this paragraph,
- 19 c. an affiliate of a person described in subparagraph a
20 or b of this paragraph who receives the product
21 directly from a person described in this subparagraph
22 or in subparagraph a or b of this paragraph, or
- 23 d. a person who contracts with another to manufacture a
24 product;

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

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

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

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

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

24

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

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

8 a. influenzas,

9 b. streptococcus,

10 c. SARS-CoV-2,

11 d. lice, and

12 e. other emerging and existing public health threats
13 identified by the State Department of Health if
14 permitted by an order, rule, or regulation;

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

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 for minor, nonchronic health conditions that meet the
10 requirements of Section 1 of this act and the
11 initiation of drug therapy for minor, nonchronic
12 health conditions,
- 13 h. the dispensing of self-administered hormonal
14 contraceptives as provided by Section 1 of this act,
15 or
- 16 i. the provision of those acts or services that are
17 necessary to provide pharmaceutical care;

18 ~~39.~~ 40. "Preparation" means an article which may or may not
19 contain sterile products compounded in a licensed pharmacy pursuant
20 to the order of a licensed prescriber;

21 ~~40.~~ 41. "Prescriber" means a person licensed in this state who
22 is authorized to prescribe dangerous drugs within the scope of
23 practice of the person's profession;

1 ~~41.~~ 42. "Prescription" means and includes any order for drug or
2 medical supplies written or signed, or transmitted by word of mouth,
3 telephone or other means of communication:

4 a. by a licensed prescriber,

5 b. under the supervision of an Oklahoma licensed
6 practitioner, an Oklahoma licensed ~~advanced practice~~
7 ~~registered nurse~~ Advanced Practice Registered Nurse or
8 an Oklahoma licensed physician assistant, or

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

11 ~~42.~~ 43. "Product" means a prescription drug in a finished
12 dosage form for administration to a patient without substantial
13 further manufacturing, such as capsules, tablets, and lyophilized
14 products before reconstitution. ~~"Product"~~ Product does not include
15 blood components intended for transfusion, radioactive drugs or
16 biologics and medical gas;

17 ~~43.~~ 44. "Repackager", including "virtual repackager", means a
18 person who owns or operates an establishment that repacks and
19 relabels a product or package for further sale or distribution
20 without further transaction;

21 ~~44.~~ 45. "Sterile drug" means a drug that is intended for
22 parenteral administration, an ophthalmic or oral inhalation drug in
23 aqueous format, or a drug that is required to be sterile under state
24 and federal law;

1 ~~45.~~ 46. "Supervising physician" means an individual holding a
2 current license to practice as a physician from the State Board of
3 Medical Licensure and Supervision, pursuant to the provisions of the
4 Oklahoma Allopathic Medical and Surgical Licensure and Supervision
5 Act, or the State Board of Osteopathic Examiners, pursuant to the
6 provisions of the Oklahoma Osteopathic Medicine Act, who supervises
7 an ~~advanced practice registered nurse~~ Advanced Practice Registered
8 Nurse as defined in Section 567.3a of this title, and who is not in
9 training as an intern, resident, or fellow. To be eligible to
10 supervise an ~~advanced practice registered nurse~~ Advanced Practice
11 Registered Nurse, such physician shall remain in compliance with the
12 rules promulgated by the State Board of Medical Licensure and
13 Supervision or the State Board of Osteopathic Examiners;

14 ~~46.~~ 47. "Supportive personnel" means technicians and auxiliary
15 supportive persons who are regularly paid employees of a pharmacy
16 who work and perform tasks in the pharmacy as authorized by Section
17 353.18A of this title;

18 ~~47.~~ 48. "Third-party logistics provider" including "virtual
19 third-party logistics provider" means an entity that provides or
20 coordinates warehousing, or other logistics services of a product in
21 interstate commerce on behalf of a manufacturer, wholesale
22 distributor, or dispenser of a product but does not take ownership
23 of the product, nor have responsibility to direct the sale or
24 disposition of the product. For the purposes of this paragraph,

1 ~~"third-party logistics provider"~~ third-party logistics provider does
2 not include shippers and the United States Postal Service;

3 ~~48.~~ 49. "Wholesale distributor" including "virtual wholesale
4 distributor" means a person other than a manufacturer, a
5 manufacturer's co-licensed partner, a third-party logistics
6 provider, or repackager engaged in wholesale distribution as defined
7 by 21 U.S.C. 353(e)(4) as amended by the Drug Supply Chain Security
8 Act;

9 ~~49.~~ 50. "County jail" means a facility operated by a county for
10 the physical detention and correction of persons charged with, or
11 convicted of, criminal offenses or ordinance violations or persons
12 found guilty of civil or criminal contempt;

13 ~~50.~~ 51. "State correctional facility" means a facility or
14 institution that houses a prisoner population under the jurisdiction
15 of the Department of Corrections;

16 ~~51.~~ 52. "Unit dose package" means a package that contains a
17 single dose drug with the name, strength, control number, and
18 expiration date of that drug on the label; and

19 ~~52.~~ 53. "Unit of issue package" means a package that provides
20 multiple doses of the same drug, but each drug is individually
21 separated and includes the name, lot number, and expiration date.

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

23 SECTION 4. It being immediately necessary for the preservation
24 of the public peace, health or safety, an emergency is hereby

1 | declared to exist, by reason whereof this act shall take effect and
2 | be in full force from and after its passage and approval.

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4 | 59-1-1944 DC 3/13/2023 8:31:53 AM

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