

1 ENGROSSED SENATE AMENDMENT
TO

2 ENGROSSED HOUSE
BILL NO. 2649

By: Echols of the House

3
4 and

Dugger of the Senate

5
6
7 An Act relating to durable medical equipment;
8 creating the Oklahoma Durable Medical Equipment
9 Licensing Act; defining terms; requiring a license;
10 providing for effective date of license; authorizing
11 certain inspections; requiring promulgation of rules;
12 construing provision; providing for licensing
13 qualifications; providing for license revocation or
14 suspension; listing exceptions; providing for
15 codification; and providing an effective date.

13 AUTHOR: Remove as principal Senate author Dugger and substitute as
14 principal Senate author Garvin. Retain Dugger as Senate
15 coauthor

15 AUTHOR: Add the following Senate Coauthor: Stephens

16 AMENDMENT NO. 1. Page 1, strike the title, enacting clause and
17 entire bill and insert

18 "An Act relating to durable medical equipment;
19 creating the Oklahoma Durable Medical Equipment
20 Licensing Act; defining terms; requiring a license;
21 stipulating duration of license; authorizing certain
22 inspections; requiring promulgation of rules;
23 construing provision; stating licensing
24 qualifications; requiring license for each individual
location; allowing licensing of out-of-state supplier
under certain condition and assessment of additional
fee; requiring licensed supplier to meet established
safety standards; providing for license revocation or
suspension; listing exceptions; amending 59 O.S.
2021, Section 353.1, which relates to definitions
used in the Oklahoma Pharmacy Act; adding definition;

1 amending 59 O.S. 2021, Section 353.7, which relates
2 to powers and duties of the State Board of Pharmacy;
3 broadening power to issue licenses; establishing
4 licensure fees for stated entities; providing for
5 codification; and providing an effective date.

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

7 SECTION 1. NEW LAW A new section of law to be codified
8 in the Oklahoma Statutes as Section 375.1 of Title 59, unless there
9 is created a duplication in numbering, reads as follows:

10 Sections 2 through 5 of this act shall be known and may be cited
11 as the "Oklahoma Durable Medical Equipment Licensing Act".

12 SECTION 2. NEW LAW A new section of law to be codified
13 in the Oklahoma Statutes as Section 375.2 of Title 59, unless there
14 is created a duplication in numbering, reads as follows:

15 As used in the Oklahoma Durable Medical Equipment Licensing Act:

- 16 1. "Board" means the State Board of Pharmacy;
- 17 2. a. "Durable medical equipment" means equipment for which
18 a prescription is required including for repair and
19 replacement parts, and that:
 - 20 (1) can stand repeated use,
 - 21 (2) has an expected useful life of at least three (3)
22 years,
 - 23 (3) is primarily and customarily used to serve a
24 medical purpose,

- 1 (4) is not generally useful to a person in the
2 absence of illness or injury,
3 (5) is appropriate for use in the home, and
4 (6) is intended for use by the consumer.

5 b. Durable medical equipment includes, but is not limited
6 to:

- 7 (1) ambulating assistance equipment,
8 (2) mobility equipment,
9 (3) rehabilitation seating,
10 (4) oxygen care and oxygen delivery systems,
11 (5) respiratory equipment and respiratory disease
12 management devices,
13 (6) rehabilitation environmental control equipment,
14 (7) ventilators,
15 (8) apnea monitors,
16 (9) diagnostic equipment,
17 (10) feeding pumps,
18 (11) beds prescribed by physicians to alleviate
19 medical conditions,
20 (12) transcutaneous electrical nerve stimulators, and
21 (13) sequential compression devices; and

22 3. "Supplier" means any person or entity that provides durable
23 medical equipment services or products and that currently bills or
24

1 plans to bill a claim for reimbursement of services or products to a
2 third party.

3 SECTION 3. NEW LAW A new section of law to be codified
4 in the Oklahoma Statutes as Section 375.3 of Title 59, unless there
5 is created a duplication in numbering, reads as follows:

6 A. Any supplier of durable medical equipment to a consumer in
7 this state shall possess a durable medical equipment supplier
8 license issued by the State Board of Pharmacy pursuant to the
9 Oklahoma Durable Medical Equipment Licensing Act.

10 B. Licenses issued by the Board pursuant to the Oklahoma
11 Durable Medical Equipment Licensing Act shall be effective for
12 twelve (12) months from the date of issuance and shall not be
13 transferable or assignable.

14 C. The Board may initially and periodically inspect the
15 applicant's office or place of business.

16 D. The Board shall promulgate rules necessary to implement the
17 provisions of the Oklahoma Durable Medical Equipment Licensing Act.
18 Such rules shall prioritize patient safety and quality of durable
19 medical equipment. The Board may provide by rule that any person or
20 entity accredited by organizations recognized by the Centers for
21 Medicare and Medicaid Services is deemed to meet all or some of the
22 requirements of the Oklahoma Durable Medical Equipment Licensing
23 Act.

24

1 E. Nothing in this section shall be construed to restrict or
2 prohibit private transactions between two parties.

3 SECTION 4. NEW LAW A new section of law to be codified
4 in the Oklahoma Statutes as Section 375.4 of Title 59, unless there
5 is created a duplication in numbering, reads as follows:

6 A. The State Board of Pharmacy may issue a license to an
7 applicant for licensure as a supplier of durable medical equipment
8 if the applicant pays the appropriate license fee established under
9 Section 8 of this act and submits in a form prescribed by the Board
10 an application and proof that the applicant:

11 1. a. Maintains a physical office or place of business
12 within this state, or

13 b. For a Medicare or Medicaid enrolled out-of-state
14 supplier, maintains a physical office or place of
15 business is within one hundred (100) miles of a
16 resident of this state being served by the supplier;

17 2. Has obtained a state sales tax permit and any other
18 necessary license or permit as determined by the Board including but
19 not limited to any permit from the State Department of Health; and

20 3. Meets all state and federal accreditation requirements.

21 Each individual physical office or place of business owned or
22 operated by the supplier must be licensed separately.

23 B. 1. The Board may issue a license to a Medicare or Medicaid
24 enrolled out-of-state supplier who has at least one accredited

1 facility within one hundred (100) miles of any resident of this
2 state being served by the supplier.

3 2. The Board may assess a fee on out-of-state suppliers
4 necessary to cover the cost of inspection of those suppliers. The
5 inspection fee shall be in addition to the licensure fee.

6 C. A supplier licensed by the Board shall meet all safety
7 standards established by the Board, which shall include, but not be
8 limited to:

9 1. Ensuring that all personnel engaged in delivery, maintenance
10 and repair of durable medical equipment receive annual continuing
11 education;

12 2. Instructing the patient or patient's caregiver about how to
13 use the durable medical equipment provided;

14 3. Receiving and responding to complaints from patients;

15 4. Maintaining records of all patients receiving durable
16 medical equipment; and

17 5. Managing, maintaining, and servicing durable medical
18 equipment.

19 D. The Board may revoke or suspend a license for:

20 1. Violation of state or federal law;

21 2. Violation of rules promulgated pursuant to the Oklahoma
22 Durable Medical Equipment Licensing Act;

23 3. Permitting, aiding, or abetting any illegal act;

24

1 4. Failing to meet the safety standards established by the
2 Board pursuant to the Oklahoma Durable Medical Equipment Licensing
3 Act;

4 5. Engaging in conduct or practices found by the Board to be
5 detrimental to the health, safety, or welfare of patients; or

6 6. Failing to renew a license.

7 SECTION 5. NEW LAW A new section of law to be codified
8 in the Oklahoma Statutes as Section 375.5 of Title 59, unless there
9 is created a duplication in numbering, reads as follows:

10 The Oklahoma Durable Medical Equipment Licensing Act shall not
11 apply to:

12 1. Pharmacies and pharmacists;

13 2. Hospitals;

14 3. Ambulatory surgical centers;

15 4. Health care facilities owned or operated by the state or
16 federal government;

17 5. Skilled nursing facilities;

18 6. Assisted living facilities;

19 7. Prosthetic or orthotic practitioners;

20 8. Health care practitioners who are licensed to practice
21 health care in this state and who provide durable medical equipment
22 within the scope of their health care practice;

23 9. Manufacturers or wholesale distributors that do not sell or
24 rent durable medical equipment directly to consumers;

1 10. Suppliers of insulin infusion pumps and related supplies or
2 services; or

3 11. Suppliers of medical devices approved by the Food and Drug
4 Administration that are used in the treatment of cancerous tumors.

5 SECTION 6. AMENDATORY 59 O.S. 2021, Section 353.1, is
6 amended to read as follows:

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

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

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

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

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

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

21 6. "Certify" or "certification of a prescription" means the
22 review of a filled prescription by a licensed pharmacist or a
23 licensed practitioner with dispensing authority to confirm that the
24 medication, labeling and packaging of the filled prescription are

1 accurate and meet all requirements prescribed by state and federal
2 law. For the purposes of this paragraph, "licensed practitioner"
3 shall not include optometrists with dispensing authority;

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

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

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

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

- 19 a. for human use subject to 21 U.S.C. 353(b)(1), or
- 20 b. is labeled "Prescription Only", or labeled with the
21 following statement: "Caution: Federal law restricts
22 this drug except for use by or on the order of a
23 licensed veterinarian";

24

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" does not mean a
17 person who dispenses only products to be used in animals in
18 accordance with 21 U.S.C. 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. 353(b) (1) or the
23 dispensing of a product approved under 21 U.S.C. 360b(b); provided,
24

1 taking actual physical possession of a product or title shall not be
2 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 and National
15 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 of this act;

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

9 ~~21.~~ 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 ~~22.~~ 23. "Manufacturer" or "virtual manufacturer" means with
14 respect to a product:

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

20 b. a co-licensed partner of the person described in
21 subparagraph a that obtains the product directly from
22 a person described in this subparagraph or
23 subparagraph a,
24

1 c. an affiliate of a person described in subparagraph a
2 or b who receives the product directly from a person
3 described in this subparagraph or in subparagraph a or
4 ~~b+~~l or

5 d. a person who contracts with another to manufacture a
6 product;

7 ~~23.~~ 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" also includes the preparation and promotion of
15 commercially available products from bulk compounds for resale by
16 licensed pharmacies, licensed practitioners or other persons;

17 ~~24.~~ 25. "Medical gas" means those gases including those in
18 liquid state upon which the manufacturer or distributor has placed
19 one of several cautions, such as "Rx Only", in compliance with
20 federal law;

21 ~~25.~~ 26. "Medical gas order" means an order for medical gas
22 issued by a licensed prescriber;

23 ~~26.~~ 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 ~~27.~~ 28. "Medical gas supplier" means a person who dispenses
5 medical gases on drug orders only to a patient or ultimate user;

6 ~~28.~~ 29. "Medicine" means any drug or combination of drugs which
7 has the property of curing, preventing, treating, diagnosing or
8 mitigating diseases, or which is used for that purpose;

9 ~~29.~~ 30. "Nonprescription drugs" means medicines or drugs which
10 are sold without a prescription and which are prepackaged for use by
11 the consumer and labeled in accordance with the requirements of the
12 statutes and regulations of this state and the federal government.
13 Such items shall also include medical and dental supplies and
14 bottled or nonbulk chemicals which are sold or offered for sale to
15 the general public if such articles or preparations meet the
16 requirements of the Federal Food, Drug and Cosmetic Act, 21
17 U.S.C.A., Section 321 et seq.;

18 ~~30.~~ 31. "Outsourcing facility"~~7~~ including "virtual outsourcing
19 facility" means a facility at one geographic location or address
20 that:

- 21 a. is engaged in the compounding of sterile drugs,
- 22 b. has elected to register as an outsourcing facility,
- 23 and
- 24 c. complies with all requirements of 21 U.S.C. 353b;

1 ~~31.~~ 32. "Package" means the smallest individual saleable unit
2 of product for distribution by a manufacturer or repackager that is
3 intended by the manufacturer for ultimate sale to the dispenser of
4 such product. For the purposes of this paragraph, "individual
5 saleable unit" means the smallest container of a product introduced
6 into commerce by the manufacturer or repackager that is intended by
7 the manufacturer or repackager for individual sale to a dispenser;

8 ~~32.~~ 33. "Person" means an individual, partnership, limited
9 liability company, corporation or association, unless the context
10 otherwise requires;

11 ~~33.~~ 34. "Pharmacist-in-charge" or "PIC" means the pharmacist
12 licensed in this state responsible for the management control of a
13 pharmacy and all other aspects of the practice of pharmacy in a
14 licensed pharmacy as defined by Section 353.18 of this title;

15 ~~34.~~ 35. "Pharmacy" means a place regularly licensed by the
16 Board of Pharmacy in which prescriptions, drugs, medicines,
17 chemicals and poisons are compounded or dispensed or such place
18 where pharmacists practice the profession of pharmacy, or a pharmacy
19 operated by the Oklahoma Department of Veterans Affairs;

20 ~~35.~~ 36. "Pharmacy technician", "technician", "Rx tech", or
21 "tech" means a person issued a Technician permit by the State Board
22 of Pharmacy to assist the pharmacist and perform nonjudgmental,
23 technical, manipulative, non-discretionary functions in the
24

1 prescription department under the immediate and direct supervision
2 of a pharmacist;

3 ~~36.~~ 37. "Poison" means any substance which when introduced into
4 the body, either directly or by absorption, produces violent, morbid
5 or fatal changes, or which destroys living tissue with which such
6 substance comes into contact;

7 ~~37.~~ 38. "Practice of pharmacy" means:

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

23

24

- 1 f. the offering or performing of those acts, services,
2 operations or transactions necessary in the conduct,
3 operation, management and control of a pharmacy, or
4 g. the provision of those acts or services that are
5 necessary to provide pharmaceutical care;

6 ~~38.~~ 39. "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 ~~39.~~ 40. "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 ~~40.~~ 41. "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 or an Oklahoma licensed physician
19 assistant, or
20 c. by an Oklahoma licensed wholesaler or distributor as
21 authorized in Section 353.29.1 of this title;

22 ~~41.~~ 42. "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

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

4 ~~42.~~ 43. "Repackager"~~7~~ 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 ~~43.~~ 44. "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 ~~44.~~ 45. "Supervising physician" means an individual holding a
13 current license to practice as a physician from the State Board of
14 Medical Licensure and Supervision, pursuant to the provisions of the
15 Oklahoma Allopathic Medical and Surgical Licensure and Supervision
16 Act, or the State Board of Osteopathic Examiners, pursuant to the
17 provisions of the Oklahoma Osteopathic Medicine Act, who supervises
18 an advanced practice registered nurse as defined in Section 567.3a
19 of this title, and who is not in training as an intern, resident, or
20 fellow. To be eligible to supervise an advanced practice registered
21 nurse, such physician shall remain in compliance with the rules
22 promulgated by the State Board of Medical Licensure and Supervision
23 or the State Board of Osteopathic Examiners;

24

1 ~~45.~~ 46. "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 ~~46.~~ 47. "Third-party logistics provider"~~7~~ including "virtual
6 third-party logistics provider" means an entity that provides or
7 coordinates warehousing, or other logistics services of a product in
8 interstate commerce on behalf of a manufacturer, wholesale
9 distributor, or dispenser of a product but does not take ownership
10 of the product, nor have responsibility to direct the sale or
11 disposition of the product. For the purposes of this paragraph,
12 "third-party logistics provider" does not include shippers and the
13 United States Postal Service;

14 ~~47.~~ 48. "Wholesale distributor"~~7~~ 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. 353(e) (4) as amended by the Drug Supply Chain Security
19 Act;

20 ~~48.~~ 49. "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;

24

1 ~~49.~~ 50. "State correctional facility" means a facility or
2 institution that houses a prisoner population under the jurisdiction
3 of the Department of Corrections;

4 ~~50.~~ 51. "Unit dose package" means a package that contains a
5 single dose drug with the name, strength, control number, and
6 expiration date of that drug on the label; and

7 ~~51.~~ 52. "Unit of issue package" means a package that provides
8 multiple doses of the same drug, but each drug is individually
9 separated and includes the name, lot number, and expiration date.

10 SECTION 7. AMENDATORY 59 O.S. 2021, Section 353.7, is
11 amended to read as follows:

12 Section 353.7. The State Board of Pharmacy shall have the power
13 and duty to:

14 1. Regulate the practice of pharmacy;

15 2. Regulate the sale and distribution of drugs, medicines,
16 chemicals and poisons;

17 3. Regulate the dispensing of drugs and medicines in all places
18 where drugs and medicines are compounded and/or dispensed;

19 4. Examine and issue appropriate certificates of licensure as
20 Doctor of Pharmacy to all applicants whom the Board deems qualified
21 under the provisions of the Oklahoma Pharmacy Act;

22 5. Issue licenses to manufacturers, repackagers, outsourcing
23 facilities, wholesale distributors, third-party logistics providers,
24

1 pharmacies and other dispensers, medical gas suppliers ~~and~~, medical
2 gas distributors, and suppliers of durable medical equipment;

3 6. Issue sterile compounding and drug supplier permits for
4 pharmacies at the fee set by the Board, with the expiration date of
5 such permits to coincide with the pharmacy license annual expiration
6 date;

7 7. Prescribe minimum standards with respect to floor space and
8 other physical characteristics of pharmacies and hospital drug rooms
9 as may be reasonably necessary for the maintenance of professional
10 surroundings and for the protection of the safety and welfare of the
11 public, and to refuse the issuance of new or renewal licenses for
12 failure to comply with such standards. Minimum standards for
13 hospital drug rooms shall be consistent with the State Department of
14 Health, Hospital Standards, as defined in OAC 310:667;

15 8. Authorize its inspectors, compliance officers and duly
16 authorized representatives to enter and inspect any and all places
17 including premises, vehicles, equipment, contents and records, where
18 drugs, medicines, chemicals or poisons are stored, sold, vended,
19 given away, compounded, dispensed, manufactured, repackaged or
20 transported;

21 9. Employ the number of inspectors and pharmacist compliance
22 officers necessary in the investigation of criminal activity or
23 preparation of administrative actions at an annual salary to be
24 fixed by the Board, and to authorize necessary expenses. Any

1 inspector certified as a peace officer by the Council of Enforcement
2 Education and Training shall have statewide jurisdiction to perform
3 the duties authorized by this section. In addition, the inspectors
4 shall be considered peace officers and shall have the same powers
5 and authority as that granted to peace officers. In addition, such
6 inspectors or pharmacist compliance officers shall have the
7 authority to take and copy records and the duty to confiscate all
8 drugs, medicines, chemicals or poisons found to be stored, sold,
9 vended, given away, compounded, dispensed or manufactured contrary
10 to the provisions of the Oklahoma Pharmacy Act;

11 10. Investigate complaints, subpoena witnesses and records,
12 initiate prosecution and hold hearings;

13 11. Administer oaths in all manners pertaining to the affairs
14 of the Board and to take evidence and compel the attendance of
15 witnesses on questions pertaining to the enforcement of the Oklahoma
16 Pharmacy Act;

17 12. Reprimand, place on probation, suspend, revoke permanently
18 and levy fines not to exceed Three Thousand Dollars (\$3,000.00) for
19 each count for which any person charged with violating the Oklahoma
20 Pharmacy Act or Oklahoma Board of Pharmacy administrative rules has
21 been convicted in Board hearings. The Board also may take other
22 disciplinary action. The Board may impose as part of any
23 disciplinary action the payment of costs expended by the Board for
24 any legal fees and costs including, but not limited to, staff time,

1 salary and travel expense, witness fees and attorney fees. The
2 Board may also require additional continuing education including
3 attendance at a live continuing education program, and may require
4 participation in a rehabilitation program for the impaired. The
5 Board may take such actions singly or in combination, as the nature
6 of the violation requires;

7 13. Adopt and establish rules of professional conduct
8 appropriate to the establishment and maintenance of a high standard
9 of integrity and dignity in the profession of pharmacy. Such rules
10 shall be subject to amendment or repeal by the Board as the need may
11 arise;

12 14. Make and publish rules such as may be necessary for
13 carrying out and enforcing the provisions of the Oklahoma Pharmacy
14 Act, Oklahoma drug laws and rules, federal drug laws and
15 regulations, and make such other rules as in its discretion may be
16 necessary to protect the health, safety and welfare of the public;

17 15. Establish and collect appropriate fees for licenses,
18 permits, inspections and services provided; and such fees shall be
19 nonrefundable. Such fees shall be promulgated to implement the
20 provisions of the Oklahoma Pharmacy Act and the Oklahoma Abortion-
21 Inducing Drug Certification Program Act under the provisions of the
22 Administrative Procedures Act;

23 16. Regulate:
24

- 1 a. personnel working in a pharmacy, such as interns and
2 supportive personnel including technicians, and issue
3 pharmacy technician permits and intern licenses,
4 b. interns, preceptors and training areas through which
5 the training of applicants occurs for licensure as a
6 pharmacist, and
7 c. such persons regarding all aspects relating to the
8 handling of drugs, medicines, chemicals and poisons;

9 17. Acquire by purchase, lease, gift, solicitation of gift or
10 by any other manner, and to maintain, use and operate or to contract
11 for the maintenance, use and operation of or lease of any and all
12 property of any kind, real, personal or mixed or any interest
13 therein unless otherwise provided by the Oklahoma Pharmacy Act;
14 provided, all contracts for real property shall be subject to the
15 provisions of Section 63 of Title 74 of the Oklahoma Statutes;

16 18. Perform other such duties, exercise other such powers and
17 employ such personnel as the provisions and enforcement of the
18 Oklahoma Pharmacy Act may require; and

19 19. Approve pilot projects designed to utilize new or expanded
20 technology or processes and provide patients with better pharmacy
21 products or provide pharmacy services in a more safe and efficient
22 manner. Such approvals may include provisions granting exemptions
23 to any rule adopted by the Board.

1 SECTION 8. NEW LAW A new section of law to be codified
2 in the Oklahoma Statutes as Section 353.7a of Title 59, unless there
3 is created a duplication in numbering, reads as follows:

4 The State Board of Pharmacy shall assess the following licensure
5 fees for the stated entities:

6 1. For a medical gas distributor, Four Hundred Dollars
7 (\$400.00) for an initial license and Two Hundred Dollars (\$200.00)
8 for a license renewal;

9 2. For a supplier of durable medical equipment, Four Hundred
10 Dollars (\$400.00) for an initial license and Two Hundred Dollars
11 (\$200.00) for a license renewal;

12 3. For a combined license for a medical gas distributor and
13 supplier of durable medical equipment, Six Hundred Dollars (\$600.00)
14 for an initial license and Three Hundred Dollars (\$300.00) for a
15 license renewal; and

16 4. For a medical gas supplier, an amount determined by the
17 Board in rule.

18 SECTION 9. This act shall become effective November 1, 2022.”
19
20
21
22
23
24

1 Passed the Senate the 28th day of April, 2022.

2
3 _____
4 Presiding Officer of the Senate

5 Passed the House of Representatives the ____ day of _____,
6 2022.

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

1 ENGROSSED HOUSE
2 BILL NO. 2649

By: Echols of the House

and

Dugger of the Senate

3
4
5
6
7 An Act relating to durable medical equipment;
8 creating the Oklahoma Durable Medical Equipment
9 Licensing Act; defining terms; requiring a license;
10 providing for effective date of license; authorizing
11 certain inspections; requiring promulgation of rules;
12 construing provision; providing for licensing
13 qualifications; providing for license revocation or
14 suspension; listing exceptions; providing for
15 codification; and providing an effective date.

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

17 SECTION 10. NEW LAW A new section of law to be codified
18 in the Oklahoma Statutes as Section 375 of Title 59, unless there is
19 created a duplication in numbering, reads as follows:

20 This act shall be known and may be cited as the "Oklahoma
21 Durable Medical Equipment Licensing Act".

22 SECTION 11. NEW LAW A new section of law to be codified
23 in the Oklahoma Statutes as Section 376 of Title 59, unless there is
24 created a duplication in numbering, reads as follows:

As used in the Oklahoma Durable Medical Equipment Licensing Act:

1. "Board" means the State Board of Pharmacy;

1 2. a. "Durable medical equipment" means equipment for which
2 a prescription is required, including for repair and
3 replacement parts, and that:

4 (1) can stand repeated use,

5 (2) has an expected useful life of at least three (3)
6 years,

7 (3) is primarily and customarily used to serve a
8 medical purpose,

9 (4) is not generally useful to a person in the
10 absence of illness or injury,

11 (5) is appropriate for use in the home, and

12 (6) is intended for use by the consumer.

13 b. Durable medical equipment includes, but is not limited
14 to:

15 (1) ambulating assistance equipment,

16 (2) mobility equipment,

17 (3) rehabilitation seating,

18 (4) oxygen care and oxygen delivery systems,

19 (5) respiratory equipment and respiratory disease
20 management devices,

21 (6) rehabilitation environmental control equipment,

22 (7) ventilators,

23 (8) apnea monitors,

24 (9) diagnostic equipment,

- 1 (10) feeding pumps,
- 2 (11) beds prescribed by physicians to alleviate
- 3 medical conditions,
- 4 (12) transcutaneous electrical nerve stimulators, and
- 5 (13) sequential compression devices; and

6 3. "Supplier" means any person or entity that provides durable
7 medical equipment services or products and that currently bills or
8 plans to bill a claim for reimbursement of services or products to a
9 third party.

10 SECTION 12. NEW LAW A new section of law to be codified
11 in the Oklahoma Statutes as Section 377 of Title 59, unless there is
12 created a duplication in numbering, reads as follows:

13 A. Any supplier of durable medical equipment to a consumer in
14 Oklahoma shall possess a durable medical equipment supplier license
15 issued by the Board pursuant to this act.

16 B. Licenses issued by the Board pursuant to this act shall be
17 effective for twelve (12) months from the date of issuance and shall
18 not be transferable or assignable.

19 C. The Board shall have the authority to initially and
20 periodically inspect the applicant's office or place of business.

21 D. The Board shall promulgate rules necessary to implement the
22 provisions of this act. Such rules shall prioritize patient safety
23 and quality of durable medical equipment. The Board may provide by
24 rule that any person or entity accredited by organizations

1 recognized by the Centers for Medicare and Medicaid Services is
2 deemed to meet all or some of the requirements of this act.

3 E. Nothing in this section shall be construed to restrict or
4 prohibit private transactions between two parties.

5 SECTION 13. NEW LAW A new section of law to be codified
6 in the Oklahoma Statutes as Section 378 of Title 59, unless there is
7 created a duplication in numbering, reads as follows:

8 A. The Board shall be authorized to issue a license to an
9 applicant for licensure as a supplier of durable medical equipment
10 if the applicant:

- 11 1. Submits an application in a form prescribed by the Board;
- 12 2. Maintains a physical office or place of business within this
13 state;
- 14 3. Pays a license fee established by the Board;
- 15 4. Meets all state and federal accreditation requirements; and
- 16 5. Meets all safety standards established by the Board, which
17 shall include, but not be limited to:

- 18 a. ensuring that all personnel engaged in delivery,
19 maintenance and repair of durable medical equipment
20 receive annual continuing education,
- 21 b. instructing the patient or patient's caregiver about
22 how to use the durable medical equipment provided,
- 23 c. receiving and responding to complaints from patients,

24

- 1 d. maintaining records of all patients receiving durable
2 medical equipment, and
3 e. managing, maintaining and servicing durable medical
4 equipment.

5 B. The Board may issue a license to a Medicare or Medicaid
6 enrolled out-of-state supplier who has at least one accredited
7 facility within one hundred (100) miles of any Oklahoma resident
8 being served by the supplier.

9 C. The Board may revoke or suspend a license for:

- 10 1. Violation of state or federal law;
11 2. Violation of rules promulgated pursuant to this act;
12 3. Permitting, aiding or abetting any illegal act;
13 4. Failing to meet the safety standards established by the

14 Board pursuant to this act;

15 5. Engaging in conduct or practices found by the Board to be
16 detrimental to the health, safety or welfare of patients; or

- 17 6. Failing to renew a license.

18 SECTION 14. NEW LAW A new section of law to be codified
19 in the Oklahoma Statutes as Section 379 of Title 59, unless there is
20 created a duplication in numbering, reads as follows:

21 The Oklahoma Durable Medical Equipment Licensing Act shall not
22 apply to:

- 23 1. Pharmacies and pharmacists;
24 2. Hospitals;

