LC 577
2023 Regular Session
85500-002
7/27/22 (SCT/ps)

D R A F T

SUMMARY

Revises definitions related to pharmacy for consistency with applicable federal law.

Becomes operative November 26, 2023.

Takes effect on 91st day following adjournment sine die.

A BILL FOR AN ACT

Relating to pharmacy; creating new provisions; amending ORS 137.473, 453.025, 689.005, 689.305, 689.605 and 689.696; and prescribing an effective date.

Be It Enacted by the People of the State of Oregon:

SECTION 1. ORS 689.005, as amended by section 25, chapter 45, Oregon Laws 2022, is amended to read:

689.005. As used in this chapter:

(1) "Administer" means the direct application of a drug or device whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject by:

(a) A practitioner or the practitioner's authorized agent; or

(b) The patient or research subject at the direction of the practitioner.

(2) "Approved continuing pharmacy education program" means those seminars, classes, meetings, workshops and other educational programs on the subject of pharmacy approved by the **State** Board **of Pharmacy**.

[*(3) "Board of pharmacy" or "board" means the State Board of Pharmacy.*]

[*(4)*] **(3)** "Clinical pharmacy agreement" means an agreement between a

NOTE: Matter in **boldfaced** type in an amended section is new; matter [*italic and bracketed*] is existing law to be omitted. New sections are in **boldfaced** type.

pharmacist or pharmacy and a health care organization or a physician as defined in ORS 677.010 or a naturopathic physician as defined in ORS 685.010 that permits the pharmacist to engage in the practice of clinical pharmacy for the benefit of the patients of the health care organization, physician or naturopathic physician.

[*(5)*] **(4)** "Continuing pharmacy education" means:

(a) Professional, pharmaceutical post-graduate education in the general areas of socio-economic and legal aspects of health care;

(b) The properties and actions of drugs and dosage forms; and

(c) The etiology, characteristics and therapeutics of the disease state.

[*(6)*] **(5)** "Continuing pharmacy education unit" means the unit of measurement of credits for approved continuing education courses and programs.

[*(7)*] **(6)** "Deliver" or "delivery" means the actual, constructive or attempted transfer of a drug or device other than by administration from one person to another, whether or not for a consideration.

[*(8)*] **(7)** "Device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including any component part or accessory, which is required under federal or state law to be prescribed by a practitioner and dispensed by a pharmacist.

[*(9)*] **(8)** "Dispense" or "dispensing" means the preparation and delivery of a prescription drug pursuant to a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to or use by a patient or other individual entitled to receive the prescription drug.

[*(10)*] **(9)** "Distribute" means the delivery of a drug other than by administering or dispensing.

[*(11)*] **(10)** "Drug" means:

(a) Articles recognized as drugs in the official United States Pharmacopoeia, official National Formulary, official Homeopathic Pharmacopoeia, other drug compendium or any supplement to any of them;

(b) Articles intended for use in the diagnosis, cure, mitigation, treatment

or prevention of disease in a human or other animal;

(c) Articles, other than food, intended to affect the structure or any function of the body of humans or other animals; and

(d) Articles intended for use as a component of any articles specified in paragraph (a), (b) or (c) of this subsection.

[*(12)*] **(11)** "Drug order" means a written order, in a hospital or other inpatient care facility, for an ultimate user of any drug or device issued and signed by a practitioner, or an order transmitted by other means of communication from a practitioner, that is immediately reduced to writing by a pharmacist, licensed nurse or other practitioner.

[*(13)*] **(12)** "Drug outlet" means a pharmacy, nursing home, shelter home, convalescent home, extended care facility, drug abuse treatment center, penal institution, hospital, family planning clinic, student health center, retail store, wholesaler, manufacturer, mail-order vendor or other establishment with facilities located within or out of this state that is engaged in dispensing, delivery or distribution of drugs within this state.

[*(14)*] **(13)** "Drug room" means a secure and lockable location within an inpatient care facility that does not have a licensed pharmacy.

[*(15)*] **(14)** "Electronically transmitted" or "electronic transmission" means a communication sent or received through technological apparatuses, including computer terminals or other equipment or mechanisms linked by telephone or microwave relays, or similar apparatus having electrical, digital, magnetic, wireless, optical, electromagnetic or similar capabilities.

[*(16)*] **(15)** "Injectable hormonal contraceptive" means a drug composed of a hormone or a combination of hormones that is approved by the United States Food and Drug Administration to prevent pregnancy and that a health care practitioner administers to the patient by injection.

[*(17)*] **(16)** "Institutional drug outlet" means hospitals and inpatient care facilities where medications are dispensed to another health care professional for administration to patients served by the hospitals or facilities.

[*(18)*] **(17)** "Intern" means a person who is enrolled in or has completed

a course of study at a school or college of pharmacy approved by the board and who is licensed with the board as an intern.

[*(19)*] **(18)** "Internship" means a professional experiential program approved by the board under the supervision of a licensed pharmacist registered with the board as a preceptor.

[*(20) "Itinerant vendor" means a person who sells or distributes nonprescription drugs by passing from house to house, or by haranguing the people on the public streets or in public places, or who uses the customary devices for attracting crowds, recommending their wares and offering them for sale.*]

[*(21)*] **(19)** "Labeling" means the process of preparing and affixing of a label to any drug container exclusive, however, of the labeling by a manufacturer, packer or distributor of a nonprescription drug or commercially packaged legend drug or device.

[*(22)*] **(20)** "Manufacture" means the production, preparation, propagation, compounding, conversion or processing of a device or a drug, either directly or indirectly by extraction from substances of natural origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis and includes any packaging or repackaging of the substances or labeling or relabeling of its container, except that this term does not include the preparation or compounding of a drug by an individual for their own use or the preparation, compounding, packaging or labeling of a drug:

(a) By a practitioner as an incident to administering or dispensing of a drug in the course of professional practice; or

(b) By a practitioner or by the practitioner's authorization under supervision of the practitioner for the purpose of or as an incident to research, teaching or chemical analysis and not for sale.

[*(23)*] **(21)** "Manufacturer" means a person engaged in the manufacture of drugs.

[*(24)*] **(22)** "Nonprescription drug outlet" means [*shopkeepers and itinerant*

vendors] **a business or other establishment that is open to the general public for the sale or nonprofit distribution of nonprescription drugs and is** registered under ORS 689.305.

[*(25)*] **(23)** "Nonprescription drugs" means drugs [*which*] **that** may be sold without a prescription and [*which*] **that** are prepackaged for use by the consumer and labeled in accordance with the requirements of the statutes and regulations of this state and the federal government.

[*(26)*] **(24)** "Person" means an individual, corporation, partnership, association or other legal entity.

[*(27)*] **(25)** "Pharmacist" means an individual licensed by this state to engage in the practice of pharmacy or to engage in the practice of clinical pharmacy.

[*(28)*] **(26)** "Pharmacy" means a place that meets the requirements of rules of the board, is licensed and approved by the board where the practice of pharmacy may lawfully occur and includes apothecaries, drug stores, dispensaries, hospital outpatient pharmacies, pharmacy departments and prescription laboratories but does not include a place used by a manufacturer or wholesaler.

[*(29)*] **(27)** "Pharmacy technician" means a person licensed by the [*State*] board [*of Pharmacy*] who assists in the practice of pharmacy pursuant to rules of the board.

[*(30)*] **(28)** "Practice of clinical pharmacy" means:

(a) The health science discipline in which, in conjunction with the patient's other practitioners, a pharmacist provides patient care to optimize medication therapy and to promote disease prevention and the patient's health and wellness;

(b) The provision of patient care services, including but not limited to post-diagnostic disease state management services; and

(c) The practice of pharmacy by a pharmacist pursuant to a clinical pharmacy agreement.

[*(31)*] **(29)** "Practice of pharmacy" means:

(a) The interpretation and evaluation of prescription orders;

(b) The compounding, dispensing and labeling of drugs and devices, except labeling by a manufacturer, packer or distributor of nonprescription drugs and commercially packaged legend drugs and devices;

(c) The prescribing and administering of vaccines and immunizations and the providing of patient care services pursuant to ORS 689.645;

(d) The administering of drugs and devices to the extent permitted under ORS 689.655;

(e) The participation in drug selection and drug utilization reviews;

(f) The proper and safe storage of drugs and devices and the maintenance of proper records regarding the safe storage of drugs and devices;

(g) The responsibility for advising, where necessary or where regulated, of therapeutic values, content, hazards and use of drugs and devices;

(h) The monitoring of therapeutic response or adverse effect to drug therapy;

(i) The optimizing of drug therapy through the practice of clinical pharmacy;

(j) Patient care services, including medication therapy management and comprehensive medication review;

(k) The offering or performing of those acts, services, operations or transactions necessary in the conduct, operation, management and control of pharmacy;

(L) The prescribing and administering of injectable hormonal contraceptives and the prescribing and dispensing of self-administered hormonal contraceptives pursuant to ORS 689.689;

(m) The prescribing and dispensing of emergency refills of insulin and associated insulin-related devices and supplies pursuant to ORS 689.696;

(n) The prescribing, dispensing and administering of preexposure prophylactic antiretroviral therapies and post-exposure prophylactic antiretroviral therapies, pursuant to ORS 689.704 and rules adopted by the board under ORS 689.645 and 689.704; and

(o) The delegation of tasks to other health care providers who are appropriately trained and authorized to perform the delegated tasks.

[*(32)*] **(30)** "Practitioner" means a person licensed and operating within the scope of such license to prescribe, dispense, conduct research with respect to or administer drugs in the course of professional practice or research:

(a) In this state; or

(b) In another state or territory of the United States if the person does not reside in Oregon and is registered under the federal Controlled Substances Act.

[*(33)*] **(31)** "Preceptor" means a pharmacist or a person licensed by the board to supervise the internship training of a licensed intern.

[*(34)*] **(32)** "Prescription drug" or "legend drug" means a drug [*which*] **that** is:

(a) Required by federal law, prior to being dispensed or delivered, to be labeled with either of the following statements:

(A) "Caution: Federal law prohibits dispensing without prescription"; or

(B) "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian"; or

(b) Required by any applicable federal or state law or regulation to be dispensed on prescription only or is restricted to use by practitioners only.

[*(35)*] **(33)** "Prescription" or "prescription drug order" means a written, oral or electronically transmitted direction, given by a practitioner authorized to prescribe drugs, for the preparation and use of a drug. When the context requires, "prescription" also means the drug prepared under such written, oral or electronically transmitted direction.

[*(36)*] **(34)** "Retail drug outlet" means a place used for the conduct of the retail sale, administering or dispensing or compounding of drugs or chemicals or for the administering or dispensing of prescriptions and licensed by the board as a place where the practice of pharmacy may lawfully occur.

[*(37)*] **(35)** "Self-administered hormonal contraceptive" means a drug com-

posed of a hormone or a combination of hormones that is approved by the United States Food and Drug Administration to prevent pregnancy and that the patient to whom the drug is prescribed may administer to oneself. "Self-administered hormonal contraceptive" includes, but is not limited to, hormonal contraceptive patches and hormonal contraceptive pills.

[*(38) "Shopkeeper" means a business or other establishment, open to the general public, for the sale or nonprofit distribution of drugs.*]

(36) "Third-party logistics provider" means an entity that:

(a) Provides or coordinates warehousing of, or other logistics services for, a product in interstate commerce on behalf of a manufacturer, wholesale distributor or dispenser of the product; and

(b) Does not take ownership of, or have responsibility to direct the sale or disposition of, the product.

[*(39)*] **(37)** "Unit dose" means a sealed single-unit container so designed that the contents are administered to the patient as a single dose, direct from the container. Each unit dose container must bear a separate label, be labeled with the name and strength of the medication, the name of the manufacturer or distributor, an identifying lot number and, if applicable, the expiration date of the medication.

[*(40)*] **(38)** "Wholesale **distributor** drug outlet" means a person [*who imports, stores, distributes or sells for resale drugs, including legend drugs and nonprescription drugs*]**, other than a manufacturer, manufacturer's colicensed partner, third-party logistics provider or repackager, as defined in 21 U.S.C. 360eee(16), that is engaged in wholesale distribution, as defined in 21 U.S.C. 353(e)(4)**.

SECTION 2. ORS 689.305 is amended to read:

689.305. (1) All drug outlets shall annually register with the State Board of Pharmacy.

(2)(a) Each drug outlet shall apply for a certificate of registration in one or more of the following classifications:

(A) Retail drug outlet.

(B) Institutional drug outlet.

(C) [*Manufacturing*] **Manufacturer** drug outlet.

(D) Wholesale **distributor** drug outlet.

(E) Nonprescription drug outlet.

(F) Third-party logistics provider drug outlet.

(b) [*No*] **An** individual who is employed by a corporation [*which*] **that** is registered under any classification listed in paragraph (a) of this subsection [*need*] **is not required to** register under the provisions of this section.

(3) The board shall establish by rule [*under the powers granted to it under*] **pursuant to** ORS 689.155 and 689.205 the criteria [*which*] **that** each drug outlet must meet to qualify for registration in each classification designated in subsection (2)(a) of this section. The board may issue various types of certificates of registration with varying restrictions to the designated outlets where the board deems it necessary by reason of the type of drug outlet requesting a certificate.

(4) [*It shall be lawful for*] A drug outlet registered under this section [*to*] **may lawfully** sell and distribute nonprescription drugs. Drug outlets engaging in the sale and distribution of [*such items*] **nonprescription drugs** [*shall*] **may** not be deemed to be improperly engaged in the practice of pharmacy.

SECTION 3. ORS 137.473 is amended to read:

137.473. (1) The punishment of death shall be inflicted by the intravenous administration of a lethal quantity of an ultra-short-acting barbiturate in combination with a chemical paralytic agent and potassium chloride or other equally effective substances sufficient to cause death. The judgment shall be executed by the superintendent of the Department of Corrections institution in which the execution takes place, or by the designee of that superintendent. All executions shall take place within the enclosure of a Department of Corrections institution designated by the Director of the Department of Corrections. The superintendent of the institution shall be present at the execution and shall invite the presence of one or more physicians, physician

assistants or nurse practitioners, the Attorney General, the sheriff of the county in which the judgment was rendered and representatives from the media. At the request of the defendant, the superintendent shall allow no more than two members of the clergy designated by the defendant to be present at the execution. At the discretion of the superintendent, no more than five friends and relatives designated by the defendant may be present at the execution. The superintendent shall allow the presence of any peace officers as the superintendent thinks expedient.

(2) The person who administers the lethal injection under subsection (1) of this section shall not thereby be considered to be engaged in the practice of medicine.

(3)(a) Any wholesale **distributor** drug outlet, as defined in ORS 689.005, registered with the State Board of Pharmacy under ORS 689.305 may provide the lethal substance or substances described in subsection (1) of this section upon written order of the Director of the Department of Corrections, accompanied by a certified copy of the judgment of the court imposing the punishment.

(b) For purposes of ORS 689.527 (7) the director shall be considered authorized to purchase the lethal substance or substances described in subsection (1) of this section.

(c) The lethal substance or substances described in subsection (1) of this section are not controlled substances when purchased, possessed or used for purposes of this section.

(4) The superintendent may require that persons who are present at the execution under subsection (1) of this section view the initial execution procedures, prior to the point of the administration of the lethal injection, by means of a simultaneous closed-circuit television transmission under the direction and control of the superintendent.

SECTION 4. ORS 453.025 is amended to read:

453.025. (1) Nothing in ORS 453.005 to 453.135 and 453.990 (2) is intended to interfere with or prevent the legitimate sale of completely denatured al-

cohol or methyl alcohol (methanol) by garages and filling stations, when used for antifreeze purposes and poured directly into the radiator of any automobile or motor vehicle by the seller thereof.

(2) Stores and shops other than pharmacies may sell completely denatured alcohol or methyl alcohol (methanol) in quantities of not less than one gallon only in original containers and only when properly labeled by distiller or wholesale distributor and bearing also seller's label. The name and address of seller must be applied by label on the container. The record of such wholesale quantities must be kept by the seller and information including date, means of identification and purported use must also be kept.

(3) Sellers of denatured alcohol or methyl alcohol (methanol) only are not required to [*obtain a shopkeepers' license*] **be registered with the State Board of Pharmacy** under ORS 689.305.

(4)(a) Subject to the exemption under paragraph (b) of this subsection, retail sales of completely denatured alcohol, methyl alcohol (methanol), heating fuel mixtures and other forms of denatured alcohol except heating fuel mixtures and other forms of denatured alcohol containing less than five percent methanol by weight and containing additives that render them unpalatable for human consumption, in quantities of less than one gallon, shall be confined to pharmacists and registration of the sales must be made in their poison register.

(b) Hotel, restaurant or food catering wholesalers or suppliers of heating fuel mixtures and other forms of denatured alcohol are exempt from paragraph (a) of this subsection when the supplying of these products is restricted for use solely in the preparation of commercially prepared foods in businesses supplying food needs directly to the public for immediate consumption. Products so classified when purchased shall be used only for this specified purpose and shall not be resold, given away or in any way made available to the public.

(5) Distributors and transporters, stores and shops, other than pharmacies, may deliver, or sell carbolic acid (phenol), for commercial use only in

quantities of at least one pound but only when the container is properly labeled by the manufacturer or wholesaler and also bears a label containing the name and address of the seller or deliverer. Record of sales or deliveries of quantities of one pound or more of carbolic acid (phenol) shall be kept by the seller and deliverer. The record shall contain information, including the date, name of purchaser or person receiving the delivery and purported use.

(6) A distributor, transporter, store or shop shall not by reason of the delivery or sale of carbolic acid (phenol) in quantities of at least one pound be required to [*obtain a shopkeepers' license*] **be registered with the State Board of Pharmacy** under ORS 689.305. Retail sales of carbolic acid (phenol) in quantities of less than one pound shall be confined to pharmacies and registration of such sales shall be made on their poison register.

(7) Except as specifically provided by law, the provisions of laws governing the sale and distribution of poisons do not apply to the sale or distribution of compounds, preparations or remedies which do not contain more than two grains of opium, or more than one-fourth grain of morphine, or more than one-eighth grain of heroin, or more than one grain of codeine, or any salt or derivative of any of them in one fluid ounce, or, if solid or semisolid preparations, in one avoirdupois ounce; or to liniments, ointments or other preparations which are prepared for external use only, when sold or distributed for use as medicines.

(8)(a) Whenever poisons are dispensed in accordance with a written prescription by a practitioner, and such written prescription is filed and retained by the pharmacist as required by law, all of the requirements of ORS 453.005 to 453.135 and 453.990 (2) are satisfied.

(b) A pharmacist shall affix a poison label to a prescription when the prescribing practitioner so directs.

(9) Nothing in ORS 453.005 to 453.135 and 453.990 (2) applies to the manufacture or wholesale of any poisons. However, each box, vessel or package, other than prescriptions, in which any poison is contained must be labeled

as provided in ORS 453.035.

(10) Nothing in ORS 453.005 to 453.135 and 453.990 (2) applies to:

(a) The manufacture, sale, repair, distribution, maintenance, refurbishment or modification of any new raw material or component part used in a motor vehicle, as that term is defined in ORS 801.360, or an airplane with component parts, including but not limited to original spare parts, that contain decabrominated diphenyl ether.

(b) The use of commercial decabrominated diphenyl ether in the maintenance, refurbishment or modification of equipment used for purposes related to transportation.

SECTION 5. ORS 689.605 is amended to read:

689.605. (1) In a hospital or long term care facility having a pharmacy and employing a pharmacist, the pharmacy and pharmacist are subject to the requirements of this chapter, except that in a hospital when a pharmacist is not in attendance, pursuant to standing orders of the pharmacist, a registered nurse supervisor on the written order of a person authorized to prescribe a drug may withdraw such drug in such volume or amount as needed for administration to or treatment of an inpatient or outpatient until regular pharmacy services are available in accordance with the rules adopted by the **State** Board **of Pharmacy**. However, the [*State Board of Pharmacy*] **board** may grant an exception to the requirement for a written order by issuing a special permit authorizing the registered nurse supervisor in a hospital to dispense medication on the oral order of a person authorized to prescribe a drug. An inpatient care facility which does not have a pharmacy must have a drug room. In an inpatient care facility having a drug room as may be authorized by rule of the Department of Human Services or the Oregon Health Authority, the drug room is not subject to the requirements of this chapter relating to pharmacies. However, a drug room must be supervised by a pharmacist and is subject to the rules of the [*State Board of Pharmacy*] **board**. When a pharmacist is not in attendance, any person authorized by the prescriber or by the pharmacist on written order may with-

draw such drug in such volume or amount as needed for administration to or treatment of a patient, entering such withdrawal in the record of the responsible pharmacist.

(2) In a hospital having a drug room, any drug may be withdrawn from storage in the drug room by a registered nurse supervisor on the written order of a licensed practitioner in such volume or amount as needed for administration to and treatment of an inpatient or outpatient in the manner set forth in subsection (1) of this section and within the authorized scope of practice.

(3) A hospital having a drug room shall cause accurate and complete records to be kept of the receipt, withdrawal from stock and use or other disposal of all legend drugs stored in the drug room. Such record shall be open to inspection by agents of the board and other qualified authorities.

(4) In an inpatient care facility other than a hospital, the drug room shall contain only prescribed drugs already prepared for patients therein and such emergency drug supply as may be authorized by rule by the Department of Human Services.

(5) The requirements of this section shall not apply to facilities described in ORS 441.065.

(6) A registered nurse who is an employee of a local health department that is registered by the board under ORS 689.305 may, pursuant to the order of a person authorized to prescribe a drug or device, dispense a drug or device to a client of the local health department for purposes of caries prevention, birth control or prevention or treatment of a communicable disease. Such dispensing shall be subject to rules jointly adopted by the board and the Oregon Health Authority.

(7) The board shall adopt rules authorizing a pharmacist to delegate to a registered nurse the authority to withdraw prescription drugs from a manufacturer's labeled container for administration to persons confined in penal institutions including, but not limited to, adult and juvenile correctional facilities. A penal institution, in consultation with a pharmacist,

shall develop policies and procedures regarding medication management, procurement and distribution. A pharmacist shall monitor a penal institution for compliance with the policies and procedures and shall perform drug utilization reviews. The penal institution shall submit to the board for approval a written agreement between the pharmacist and the penal institution regarding medication policies and procedures.

SECTION 6. ORS 689.696, as amended by section 3, chapter 95, Oregon Laws 2019, is amended to read:

689.696. (1) As used in this section:

(a) "Insulin" includes various types of insulin analogs and insulin-like medications, regardless of activation period or whether the solution is mixed before or after dispensation.

(b) "Insulin-related devices and supplies":

(A) Includes needles, syringes, cartridge systems, prefilled pen systems, glucose meters and test strips.

(B) Does not include insulin pump devices.

(2)(a) A pharmacist may prescribe and dispense emergency refills of insulin and associated insulin-related devices and supplies to a person who has evidence of a previous prescription from a licensed health care provider.

(b) The insulin prescribed and dispensed under this section must be the lesser of a 30-day supply or the smallest available package.

(c) A person may be prescribed and receive not more than three emergency refills of insulin and associated insulin-related devices and supplies in a calendar year.

(3) A pharmacist who prescribes and dispenses emergency refills of insulin and associated insulin-related devices and supplies under this section shall:

(a) Complete a patient assessment to determine whether the prescription of emergency refills of insulin and associated insulin-related devices and supplies is appropriate;

(b) Document the patient visit and include notations regarding evidence of the patient's previous prescription from the patient's licensed health care

provider, information relating to the patient's diabetes management and other relevant information; and

(c) Make a reasonable attempt to inform the person's primary care provider, and the licensed health care provider who made the previous prescription, of the pharmacist's prescription for emergency refills of insulin and associated insulin-related devices and supplies.

(4) The **State** Board **of Pharmacy** shall adopt rules to carry out this section.

SECTION 7. (1) The amendments to ORS 137.473, 453.025, 689.005, 689.305, 689.605 and 689.696 by sections 1 to 6 of this 2023 Act become operative on November 26, 2023.

(2) The State Board of Pharmacy may take any action before the operative date specified in subsection (1) of this section that is necessary to enable the board to exercise, on and after the operative date specified in subsection (1) of this section, all of the duties, functions and powers conferred on the board by the amendments to ORS 137.473, 453.025, 689.005, 689.305, 689.605 and 689.696 by sections 1 to 6 of this 2023 Act.

SECTION 8. This 2023 Act takes effect on the 91st day after the date on which the 2023 regular session of the Eighty-second Legislative Assembly adjourns sine die.
