House Bill 3046

Introduced and printed pursuant to House Rule 12.00. Presession filed (at the request of Governor Tina Kotek for State Board of Pharmacy)

SUMMARY

The following summary is not prepared by the sponsors of the measure and is not a part of the body thereof subject to consideration by the Legislative Assembly. It is an editor's brief statement of the essential features of the measure **as introduced.** The statement includes a measure digest written in compliance with applicable readability standards.

Digest: The Act lets pharmacists prescribe, dispense and administer some medicines. The Act also says some machines have to be registered with the State Board of Pharmacy. (Flesch Readability Score: 60.2).

Clarifies that a pharmacist may prescribe, dispense and administer medications for treatment of opioid use disorder. Allows pharmacists to register with the Drug Enforcement Administration of the United States Department of Justice for purposes of prescribing, dispensing and administering medications for treatment of opioid use disorder. Requires certain pharmacy prescription lockers to be registered with the State Board of Pharmacy. Defines "pharmacy prescription locker."

Takes effect on the 91st day following adjournment sine die.

A BILL FOR AN ACT

Relating to pharmacy; creating new provisions; amending ORS 414.766, 475.005 and 689.005 and sections 2, 7 and 8, chapter 70, Oregon Laws 2024; and prescribing an effective date.

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

SECTION 1. ORS 414.766, as amended by section 4, chapter 70, Oregon Laws 2024, is amended to read:

414.766. (1) Notwithstanding ORS 414.065 and 414.690, a coordinated care organization must provide behavioral health services to its members that include but are not limited to all of the following:

(a) For a member who is experiencing a behavioral health crisis:

(A) A behavioral health assessment; and

(B) Services that are medically necessary to transition the member to a lower level of care;

(b) At least the minimum level of services that are medically necessary to treat a member's underlying behavioral health condition rather than a mere amelioration of current symptoms, such as suicidal ideation or psychosis, as determined in a behavioral health assessment of the member or specified in the member's care plan;

(c) Treatment of co-occurring behavioral health disorders or medical conditions in a coordinated manner;

(d) Treatment at the least intensive and least restrictive level of care that is safe and effective and meets the needs of the individual's condition;

(e) For all level of care placement decisions, placement at the level of care consistent with a member's score or assessment using the relevant level of care placement criteria and guidelines;

(f) If the level of placement described in paragraph (e) of this subsection is not available, placement at the next higher level of care;

(g) Treatment to maintain functioning or prevent deterioration;

(h) Treatment for an appropriate duration based on the individual's particular needs;

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.

(i) Treatment appropriate to the unique needs of children and adolescents;

(j) Treatment appropriate to the unique needs of older adults;

(k) Treatment that is culturally and linguistically appropriate;

(L) Treatment that is appropriate to the unique needs of gay, lesbian, bisexual and transgender individuals and individuals of any other minority gender identity or sexual orientation;

(m) Coordinated care and case management as defined by the Department of Consumer and Business Services by rule;

(n) Mental health wellness appointments as prescribed by the Oregon Health Authority by rule; and

(o) Medications and refills of medications prescribed for the treatment of opioid use disorder and any co-occurring substance use disorder or mental health condition[*, including early refills as described in section 7, chapter 70, Oregon Laws 2024*].

(2) If there is a disagreement about the level of care required by subsection (1)(e) or (f) of this section, a coordinated care organization shall provide to the behavioral health treatment provider full details of the coordinated care organization's scoring or assessment, to the extent permitted by the federal Health Insurance Portability and Accountability Act privacy regulations, 45 C.F.R. parts 160 and 164, ORS 192.553 to 192.581 or other state or federal laws limiting the disclosure of health information.

(3) The Oregon Health Authority shall adopt by rule a list of behavioral health services that may not be subject to prior authorization.

SECTION 2. ORS 475.005, as amended by section 24, chapter 70, Oregon Laws 2024, and section 98, chapter 73, Oregon Laws 2024, is amended to read:

475.005. As used in ORS 475.005 to 475.285 and 475.752 to 475.980, unless the context requires otherwise:

(1) "Abuse" means the repetitive excessive use of a drug short of dependence, without legal or medical supervision, which may have a detrimental effect on the individual or society.

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

(a) A practitioner or an authorized agent thereof; or

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

(3) "Administration" means the Drug Enforcement Administration of the United States Department of Justice, or its successor agency.

(4) "Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor or dispenser. It does not include a common or contract carrier, public warehouseman or employee of the carrier or warehouseman.

(5) "Board" means the State Board of Pharmacy.

(6) "Controlled substance":

(a) Means a drug or its immediate precursor classified in Schedules I through V under the federal Controlled Substances Act, 21 U.S.C. 811 to 812, as modified under ORS 475.035. The use of the term "precursor" in this paragraph does not control and is not controlled by the use of the term "precursor" in ORS 475.752 to 475.980.

(b) Does not include:

(A) The plant Cannabis family Cannabaceae;

(B) Any part of the plant Cannabis family Cannabaceae, whether growing or not;

(C) Resin extracted from any part of the plant Cannabis family Cannabaceae;

(D) The seeds of the plant Cannabis family Cannabaceae;

(E) Any compound, manufacture, salt, derivative, mixture or preparation of a plant, part of a plant, resin or seed described in this paragraph; or

(F) Psilocybin or psilocin, but only if and to the extent that a person manufactures, delivers[,] or possesses psilocybin, psilocin[,] or psilocybin products in accordance with the provisions of ORS 475A.210 to 475A.722 and rules adopted under ORS 475A.210 to 475A.722.

(7) "Counterfeit substance" means a controlled substance or its container or labeling, which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, number or device, or any likeness thereof, of a manufacturer, distributor or dispenser other than the person who in fact manufactured, delivered or dispensed the substance.

(8) "Deliver" or "delivery" means the actual, constructive or attempted transfer of, or possession with the intent to transfer, other than by administering or dispensing, from one person to another, a controlled substance, whether or not there is an agency relationship.

(9) "Device" means instruments, apparatus or contrivances, including their components, parts or accessories, intended:

(a) For use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or animals; or

(b) To affect the structure of any function of the body of humans or animals.

(10) "Dispense" means to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, and includes the prescribing, administering, packaging, labeling or compounding necessary to prepare the substance for that delivery.

(11) "Dispenser" means a practitioner who dispenses.

(12) "Distributor" means a person who delivers.

(13) "Drug" means:

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

(b) Substances intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or animals;

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

(d) Substances intended for use as a component of any article specified in paragraph (a), (b) or (c) of this subsection; however, the term does not include devices or their components, parts or accessories.

(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 any similar apparatus having electrical, digital, magnetic, wireless, optical, electromagnetic or similar capabilities.

(15) "Manufacture" means the production, preparation, propagation, compounding, conversion or processing of a controlled substance, 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 substance or labeling or relabeling of its container, except that this term does not include the preparation or compounding of a controlled substance:

(a) By a practitioner as an incident to administering or dispensing of a controlled substance in

the course of professional practice; or

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

(16) "Person" includes a government subdivision or agency, business trust, estate, trust or any other legal entity.

(17) "Practitioner" means physician, dentist, veterinarian, scientific investigator, licensed nurse practitioner, physician associate or other person licensed, registered or otherwise permitted by law to dispense, conduct research with respect to or to administer a controlled substance in the course of professional practice or research in this state [*but does not include a pharmacist or a pharmacy*].

(18) "Prescription" means a written, oral or electronically transmitted direction, given by a practitioner 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. Any label affixed to a drug prepared under written, oral or electronically transmitted direction shall prominently display a warning that the removal thereof is prohibited by law.

(19) "Production" includes the manufacture, planting, cultivation, growing or harvesting of a controlled substance.

(20) "Research" means an activity conducted by the person registered with the federal Drug Enforcement Administration pursuant to a protocol approved by the United States Food and Drug Administration.

(21) "Ultimate user" means a person who lawfully possesses a controlled substance for the use of the person or for the use of a member of the household of the person or for administering to an animal owned by the person or by a member of the household of the person.

(22) "Usable quantity" means:

(a) An amount of a controlled substance that is sufficient to physically weigh independent of its packaging and that does not fall below the uncertainty of the measuring scale; or

(b) An amount of a controlled substance that has not been deemed unweighable, as determined by a Department of State Police forensic laboratory, due to the circumstances of the controlled substance.

(23) "Within 30 feet," "within 500 feet" and "within 1,000 feet" mean a straight line measurement in a radius extending for the specified number of feet or less in every direction from a specified location or from any point on the boundary line of a specified unit of property.

SECTION 3. ORS 689.005, as amended by section 5, chapter 17, Oregon Laws 2024, and section 9, chapter 70, Oregon Laws 2024, 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) "Clinical pharmacy agreement" means an agreement between a 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.

(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.

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

(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.

(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.

(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.

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

(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.

(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.

(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.

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

(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.

(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.

(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.

(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.

(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.

(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.

(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.

(21) "Manufacturer" means a person engaged in the manufacture of drugs.

(22) "Nonprescription drug outlet" means 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.

(23) "Nonprescription drugs" means drugs that may be sold without a prescription and 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.

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

(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.

(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.

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

(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.

(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;

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

(p) The prescribing [*and*]**,** dispensing **and administering** of [*early refills of*] medication for the treatment of opioid use disorder pursuant to section 7, chapter 70, Oregon Laws 2024 **and rules adopted under section 7, chapter 70, Oregon Laws 2024**; and

(q) The testing for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and the prescribing, dispensing and administering of treatment for SARS-CoV-2 pursuant to section 4, chapter 17, Oregon Laws 2024, and rules adopted by the board pursuant to section 4, chapter 17, Oregon Laws 2024.

(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.

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

(32) "Prescription drug" or "legend drug" means a drug 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.

(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.

(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.

(35) "Self-administered 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 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.

(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.

(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.

(38) "Wholesale distributor drug outlet" means a person, 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 4. ORS 689.005, as amended by sections 5 and 6, chapter 17, Oregon Laws 2024, and section 9, chapter 70, Oregon Laws 2024, 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) "Clinical pharmacy agreement" means an agreement between a 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.

(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.

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

(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.

(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.

(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.

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

(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.

(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.

(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.

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

(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.

(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.

(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.

(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.

(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.

(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.

(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.

(21) "Manufacturer" means a person engaged in the manufacture of drugs.

(22) "Nonprescription drug outlet" means 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.

(23) "Nonprescription drugs" means drugs that may be sold without a prescription and 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.

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

(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.

(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.

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

(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.

(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;

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

(p) The prescribing [*and*]**,** dispensing **and administering** of [*early refills of*] medication for the treatment of opioid use disorder pursuant to section 7, chapter 70, Oregon Laws 2024 **and rules adopted pursuant to section 7, chapter 70, Oregon Laws 2024**.

(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.

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

(32) "Prescription drug" or "legend drug" means a drug 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.

(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.

(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.

(35) "Self-administered 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 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.

(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.

(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.

(38) "Wholesale distributor drug outlet" means a person, 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 5. Section 2, chapter 70, Oregon Laws 2024, is amended to read:

Sec. 2. (1) As used in this section:

(a) "Group health insurance" has the meaning given that term in ORS 731.098.

(b) "Health benefit plan" has the meaning given that term in ORS 743B.005.

(c) "Substance use disorder" has the meaning given that term in the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders published by the American Psychiatric Association.

(d) "Utilization review" has the meaning given that term in ORS 743B.001.

(2) Notwithstanding any provision of ORS 743A.168, an issuer of group health insurance or an individual health benefit plan, other than a health plan that is subject to 42 U.S.C. 18011:

(a) May not impose a requirement for prior authorization or any other form of utilization review for the reimbursement of a covered medication approved by the United States Food and Drug Administration that is prescribed for the purpose of treating a substance use disorder, including but not limited to opioid addiction and opioid withdrawal.

(b) Shall reimburse the cost of refills of medications described in paragraph (a) of this subsection if dispensed by a licensed health care professional who is legally authorized to dispense such medications[*, including early refills described in section 7 of this 2024 Act*].

(3) Subsection (2) of this section applies to any form of buprenorphine, including but not limited to sublingual, tablet or injectable forms.

(4) This section does not prohibit prior authorization or other utilization review for opioids or opiates prescribed for a purpose other than medication-assisted treatment or the treatment of opiate abuse or addiction.

(5) This section does not prohibit utilization review for the purpose of:

(a) Auditing claims for improper payments, fraud or abuse; or

(b) Reasonable periodic redeterminations about the need for continuing care.

(6) Coverage under this section may be subject to the same terms and conditions that apply to other benefits under the plan except for utilization review as provided in subsection (2) of this section.

(7) This section is exempt from ORS 743A.001.

SECTION 6. Section 7, chapter 70, Oregon Laws 2024, is amended to read:

Sec. 7. [*(1) As used in this section:*]

[*(a) "Early refill" means:*]

[*(A) Up to three refills of a current prescription for a medication that a patient has lost or that has been stolen or destroyed; or*]

[*(B) One refill in a 12-month period of a medication for which the previous prescription expired in the prior 12-month period.*]

[*(b) "Refill" means a supply of a medication consistent with the amount specified in the most recent prescription for the medication.*]

[*(2) A pharmacist may prescribe and dispense to a patient, to the extent permitted by federal law, an early refill of a medication for the treatment of opioid use disorder in accordance with subsection (3) of this section.*]

[*(3) A pharmacist who prescribes and dispenses early refills under this section shall:*]

[*(a) Complete a patient assessment to determine whether the prescription 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 treatment and other relevant information; and*]

[*(c) Notify the patient's primary care provider, and the licensed health care provider who made the previous prescription, of the pharmacist's dispensing of early refills, to the extent permitted by state and federal law.*]

[*(4) Notations in a record documenting evidence of a patient's previous prescription under subsection (3)(b) of this section constitute verification of a valid prescription.*]

[*(5) The State Board of Pharmacy shall adopt rules to carry out this section, including but not limited to rules to allow a:*]

[*(a) Pharmacist to apply for and obtain a registration number from the Drug Enforcement Administration of the United States Department of Justice as a mid-level practitioner; and*]

[*(b) Pharmacy to store on the premises medications for the treatment of opioid use disorder.*]

[*(6) In adopting rules to carry out this section, the board shall consult with the Public Health and Pharmacy Formulary Advisory Committee described in ORS 689.649.*]

(1) A pharmacist may prescribe, dispense and administer to a patient, to the extent allowed by federal law, medications for the treatment of opioid use disorder in accordance with rules adopted by the State Board of Pharmacy pursuant to ORS 689.645 relating to prescriptions issued by pharmacists and rules adopted under subsection (3) of this section.

(2) A pharmacist may register with the Drug Enforcement Administration of the United States Department of Justice as a mid-level practitioner for the purpose of prescribing, dispensing and administering medications for the treatment of opioid use disorder under this section.

(3) The board may adopt rules to carry out this section.

SECTION 7. Section 8, chapter 70, Oregon Laws 2024, is amended to read:

Sec. 8. (1) As used in this section, "**pharmacy** prescription [*drug*] locker" means a mechanical device that serves as an extension of a retail drug outlet's will call or point of sale area in which completed patient-specific prescription drugs[*, devices and related supplies*] and nonprescription drugs, devices and related supplies are stored for pickup.

(2) A **pharmacy** prescription [*drug*] locker located within this state and at the same physical address as the retail drug outlet with which the prescription drug locker is associated[*:*]

[*(a)*] is considered part of the retail drug outlet and is not required to [*obtain a license or registration from*] **be registered with** the State Board of Pharmacy[*; and*]

[*(b) Is not required to obtain a registration from the Drug Enforcement Administration of the United States Department of Justice*].

(3) A **pharmacy** prescription [*drug*] locker located within this state but at a physical address other than the physical address of the retail drug outlet with which the **pharmacy** prescription [*drug*] locker is associated [*is considered a remote dispensing site pharmacy and must obtain a registration from the Drug Enforcement Administration in order to dispense controlled substances*] **must be registered with the board**.

(4) The board may adopt rules to carry out this section.

SECTION 8. (1) The amendments to ORS 414.766, 475.005 and 689.005 and sections 2, 7 and 8, chapter 70, Oregon Laws 2024, by sections 1 to 7 of this 2025 Act become operative on January 1, 2026.

(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 414.766, 475.005 and 689.005 and sections 2, 7 and 8, chapter 70, Oregon Laws 2024, by sections 1 to 7 of this 2025 Act.

SECTION 9. This 2025 Act takes effect on the 91st day after the date on which the 2025 regular session of the Eighty-third Legislative Assembly adjourns sine die.