

Enrolled
House Bill 2958

Sponsored by Representatives NOSSE, GRAYBER, Senator LIEBER; Representatives ALONSO LEON, CAMPOS, DEXTER, FAHEY, HOLVEY, MARSH, NERON, POWER, REYNOLDS, SCHOUTEN, SOLLMAN, WILDE, WILLIAMS, Senator FREDERICK

CHAPTER

AN ACT

Relating to prescription drugs; creating new provisions; amending ORS 689.005, 743A.051, 743B.425 and 743B.602 and section 12, chapter 154, Oregon Laws 2021 (Enrolled House Bill 2517); repealing section 6, chapter 154, Oregon Laws 2021 (Enrolled House Bill 2517); and prescribing an effective date.

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

SECTION 1. Section 2 of this 2021 Act is added to and made a part of ORS chapter 689.

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

(a) "HIV test" has the meaning given that term in ORS 433.045.

(b) "Post-exposure prophylactic antiretroviral therapy" means a drug or other therapy intended to reduce the likelihood of the acquisition of human immunodeficiency virus following a possible exposure to human immunodeficiency virus.

(c) "Preexposure prophylactic antiretroviral therapy" means a drug or other therapy intended to prevent the acquisition of human immunodeficiency virus.

(2) A pharmacist may prescribe, dispense and administer:

(a) Preexposure prophylactic antiretroviral therapies; and

(b) In accordance with any rules adopted by the State Board of Pharmacy under ORS 689.645, post-exposure prophylactic antiretroviral therapies.

(3)(a) A pharmacist may perform an HIV test or may order an HIV test performed by a laboratory. A laboratory that performs an HIV test ordered under this subsection shall submit the results of the HIV test to the pharmacist who ordered the test.

(b) A pharmacist who orders or performs an HIV test under this subsection shall comply with the requirements of ORS 433.045.

(4) The State Board of Pharmacy shall adopt rules to carry out this section. The rules adopted under this subsection must allow a pharmacist to prescribe, dispense and administer up to a 30-day supply of a preexposure prophylactic antiretroviral therapy to a patient based solely on the pharmacist's interpretation that the results of an HIV test administered under this section indicate the patient is HIV-negative.

SECTION 3. ORS 689.005 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 board.
- (3) “Board of pharmacy” or “board” means the State Board of Pharmacy.
- (4) “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.
- (5) “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) “Continuing pharmacy education unit” means the unit of measurement of credits for approved continuing education courses and programs.
- (7) “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) “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) “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) “Distribute” means the delivery of a drug other than by administering or dispensing.
- (11) “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) “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) “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) “Drug room” means a secure and lockable location within an inpatient care facility that does not have a licensed pharmacy.
- (15) “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) "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) "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) "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) "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) "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) "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) "Manufacturer" means a person engaged in the manufacture of drugs.

(24) "Nonprescription drug outlet" means shopkeepers and itinerant vendors registered under ORS 689.305.

(25) "Nonprescription drugs" means drugs which may be sold without a prescription and which 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) "Person" means an individual, corporation, partnership, association or other legal entity.

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

(30) "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) "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; [and]

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

(n) The prescribing, dispensing and administering of preexposure prophylactic antiretroviral therapies and post-exposure prophylactic antiretroviral therapies, pursuant to section 2 of this 2021 Act and rules adopted by the board under section 2 of this 2021 Act and ORS 689.645.

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

(34) "Prescription drug" or "legend drug" means a drug which 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) "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) "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) "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.

(38) “Shopkeeper” means a business or other establishment, open to the general public, for the sale or nonprofit distribution of drugs.

(39) “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) “Wholesale drug outlet” means a person who imports, stores, distributes or sells for resale drugs, including legend drugs and nonprescription drugs.

SECTION 4. ORS 743A.051 is amended to read:

743A.051. Notwithstanding any provisions of a health benefit plan as defined in ORS 743B.005, whenever the plan provides for payment or reimbursement for a service that is within the lawful scope of practice of a pharmacist, the insurer:

(1) May provide payment or reimbursement for the service when the service is provided by a pharmacist; and

(2) Shall provide, **in the same manner as would be provided for any other health care provider**, payment or reimbursement for:

(a)(A) The prescription of emergency refills of insulin and associated insulin-related devices and supplies as described in ORS 689.696; and

[*(b)*] (B) The service provided by the pharmacist[.];

(b)(A) The prescription, dispensation and administration of preexposure and post-exposure prophylactic antiretroviral therapies pursuant to section 2 of this 2021 Act and any rules adopted by the State Board of Pharmacy under section 2 of this 2021 Act and ORS 689.645; and

(B) The service provided by the pharmacist; and

(c)(A) The prescription and dispensation of other prescription drugs by a licensed pharmacist if the State Board of Pharmacy or any state law authorizes the drug to be prescribed and dispensed by pharmacists licensed under ORS chapter 689; and

(B) The service provided by the pharmacist.

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

SECTION 5. ORS 743B.425 is amended to read:

743B.425. (1) [*In reimbursing the cost of medication prescribed for the purpose of treating opioid or opiate withdrawal,*] An insurer offering a health benefit plan as defined in ORS 743B.005 may not:

(a) Require prior authorization [*of payment*]:

(A) During the first [30] 60 days of treatment[.], including medication therapy, prescribed for opioid or opiate withdrawal; or

(B) For post-exposure prophylactic antiretroviral drugs or at least one preexposure prophylactic antiretroviral drug; or

(b) Restrict the reimbursement for medication therapies, preexposure prophylactic antiretroviral drugs or post-exposure prophylactic antiretroviral drugs to in-network pharmacists or pharmacies.

(2) This section is not subject to ORS 743A.001.

(3) [*Nothing in this section shall be interpreted to*] **This section does not** prohibit prior authorization for [*reimbursement for payment for prescribing*] opioids or opiates **prescribed** for purposes other than [*medical management*] **medication therapy** or treatment of opioid or opiate abuse or addiction.

(4) Subsection (1)(b) of this section does not apply to a health maintenance organization as defined in ORS 750.005.

SECTION 6. ORS 743B.602 is amended to read:

743B.602. (1) As used in this section:

(a) "Health care coverage [plan]" includes **any of the following that reimburse the cost of prescription drugs:**

(A) A health benefit plan, as defined in ORS 743B.005;

(B) An insurance policy or certificate [covering the cost of prescription drugs, hospital expenses, health care services and medical expenses, equipment and supplies];

(C) A medical services contract, as defined in ORS 743B.001;

(D) A multiple employer welfare arrangement, as defined in ORS 750.301;

(E) A contract or agreement with a health care service contractor, as defined in ORS 750.005, or a preferred provider organization;

(F) **Payment of claims by** a pharmacy benefit manager, as defined in ORS 735.530, or other third party administrator [that pays prescription drug claims]; and

(G) An accident insurance policy or any other insurance contract [providing reimbursement for the cost of prescription drugs, hospital expenses, health care services and medical expenses, equipment and supplies].

(b) "Step therapy" means a drug protocol in which [a] **an entity that provides** health care coverage [plan] will reimburse the cost of a prescribed drug only if the patient has first tried a specified drug or series of drugs.

(2) [A] **An entity that provides** health care coverage [plan] that requires step therapy shall make easily accessible to prescribing practitioners, clear explanations of:

(a) The clinical criteria for each step therapy protocol;

(b) The procedure by which a practitioner may submit to the [plan] **entity** the practitioner's medical rationale for determining that a particular step therapy protocol is not appropriate for a particular patient based on the patient's medical condition and history; and

(c) The documentation, if any, that a practitioner must submit to the [plan] **entity** for the [plan] **entity** to determine the appropriateness of step therapy for a specific patient.

SECTION 6a. If House Bill 2517 becomes law, section 6, chapter 154, Oregon Laws 2021 (Enrolled House Bill 2517) (amending ORS 743B.602), is repealed and ORS 743B.602, as amended by section 6 of this 2021 Act, is amended to read:

743B.602. (1) As used in this section:

(a) "**Beneficiary**" means **an individual receiving health care that is provided or reimbursed by an entity that provides health care coverage.**

[(a)] (b) "Health care coverage" includes any of the following that reimburse the cost of prescription drugs:

(A) A health benefit plan[, as defined in ORS 743B.005];

(B) An insurance policy or certificate;

(C) A medical services contract[, as defined in ORS 743B.001];

(D) A multiple employer welfare arrangement, as defined in ORS 750.301;

(E) A contract or agreement with a health care service contractor, as defined in ORS 750.005, or a preferred provider organization;

(F) [Payment of claims] **Claims payments** by a pharmacy benefit manager, as defined in ORS 735.530, or other third party administrator; and

(G) An accident insurance policy or any other insurance contract.

[(b)] "Step therapy" means a drug protocol in which an entity that provides health care coverage will reimburse the cost of a prescribed drug only if the patient has first tried a specified drug or series of drugs.]

[(2)] An entity that provides health care coverage that requires step therapy shall make easily accessible to prescribing practitioners, clear explanations of:]

(2) **An entity that provides health care coverage that requires step therapy shall:**

(a) **Post to the entity's website clear explanations that are easily accessible to prescribing practitioners and beneficiaries of the coverage, written in plain language and understandable to practitioners and beneficiaries, of:**

[(a)] (A) The clinical criteria for each step therapy protocol **and the criteria for approving an exception to step therapy;**

[(b)] (B) The procedure by which a practitioner may submit to the entity the practitioner's medical rationale for determining that a particular step therapy [*protocol*] is not appropriate for a particular [*patient*] **beneficiary** based on the [*patient's*] **beneficiary's** medical condition and history; and

[(c)] (C) The documentation, if any, that a practitioner must submit to the entity for the entity to determine the appropriateness of step therapy for a specific [*patient*] **beneficiary.**

(b) **Provide a clear, readily accessible and convenient process for a prescribing practitioner to request an exception to step therapy, which may be the same process used to request exceptions to other coverage restrictions or limitations.**

(c) **Approve a request for an exception to step therapy if the entity determines that the evidence submitted by the prescribing practitioner is sufficient to establish that:**

(A) **The prescription drug required by the step therapy is contraindicated or will cause the beneficiary to experience a clinically predictable adverse reaction;**

(B) **The prescription drug required by the step therapy is expected to be ineffective based on the known clinical characteristics of the beneficiary and the known characteristics of the prescription drug regimen;**

(C) **The beneficiary has tried the drug required by the step therapy, a drug in the same pharmacologic class as the drug required by the step therapy or a drug with the same mechanism of action as the drug required by the step therapy, and the beneficiary's use of the drug required by the step therapy was discontinued due to the lack of efficacy or effectiveness, a diminished effect or an adverse reaction;**

(D) **For a period of at least 90 days the beneficiary has experienced a positive therapeutic outcome from the drug for which the exception is requested while enrolled in the current or immediately preceding health care coverage and changing to the drug required by the step therapy may cause a clinically predictable adverse reaction or physical or mental harm to the beneficiary; or**

(E) **The prescription drug required by the step therapy is not in the best interest of the beneficiary based on medical necessity.**

(d) **Grant or deny a request for an exception to step therapy or an appeal of a denial of coverage no later than 72 hours or two business days, whichever is later, after receipt of the request unless exigent circumstances exist. If exigent circumstances exist the entity shall grant or deny the request for an exception no later than one business day after receipt of the request. A request for an exception to step therapy or an appeal of a denial of coverage shall be deemed granted if the entity fails to act within the time frames specified in this paragraph.**

(3) **A prescribing practitioner may not use a pharmaceutical sample for the sole purpose of qualifying for an exception to step therapy under subsection (2)(c)(C) or (D) of this section.**

(4) **This section does not prevent:**

(a) **An entity that provides health care coverage from requiring a beneficiary to try an AB-rated generic equivalent or a biological product that is a biosimilar agent approved by the United States Food and Drug Administration prior to covering the equivalent brand name prescription drug;**

(b) **An entity that provides health care coverage from denying a request for an exception to allow coverage of a drug that has been removed from the market due to the safety concerns of the United States Food and Drug Administration; or**

(c) **A practitioner from prescribing a prescription drug that is medically appropriate regardless of coverage.**

SECTION 6b. If House Bill 2517 becomes law, the amendments to ORS 743B.602 by section 6a of this 2021 Act become operative on January 1, 2022.

SECTION 6c. If House Bill 2517 becomes law, section 12, chapter 154, Oregon Laws 2021 (Enrolled House Bill 2517), is amended to read:

Sec. 12. (1) An entity subject to ORS 743B.423 must meet the website requirements in ORS 743B.423, as amended by section 5, [of this 2021 Act] **chapter 154, Oregon Laws 2021 (Enrolled House Bill 2517)**, no later than June 1, 2022.

(2) An entity described in ORS 743B.602 must meet the website requirements in ORS 743B.602, as amended by [section 6 of this 2021 Act] **section 6a of this 2021 Act**, no later than June 1, 2022.

SECTION 7. The amendments to ORS 743A.051, 743B.425 and 743B.602 by sections 4 to 6 of this 2021 Act apply to health insurance policies, health benefit plans and health care coverage issued, renewed or extended on or after the effective date of this 2021 Act.

SECTION 8. (1) Section 2 of this 2021 Act and the amendments to ORS 689.005, 743A.051, 743B.425 and 743B.602 by sections 3 to 6 of this 2021 Act become operative on January 1, 2022.

(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 section 2 of this 2021 Act and the amendments to ORS 689.005, 743A.051, 743B.425 and 743B.602 by sections 3 to 6 of this 2021 Act.

SECTION 9. This 2021 Act takes effect on the 91st day after the date on which the 2021 regular session of the Eighty-first Legislative Assembly adjourns sine die.

Passed by House April 27, 2021

Received by Governor:

Repassed by House June 14, 2021

.....M.,....., 2021

Approved:

.....
Timothy G. Sekerak, Chief Clerk of House

.....M.,....., 2021

.....
Tina Kotek, Speaker of House

.....
Kate Brown, Governor

Passed by Senate June 9, 2021

Filed in Office of Secretary of State:

.....M.,....., 2021

.....
Peter Courtney, President of Senate

.....
Shemia Fagan, Secretary of State