A-Engrossed House Bill 2958

Ordered by the House April 19 Including House Amendments dated April 19

Sponsored by Representatives NOSSE, GRAYBER; Representatives CAMPOS, NERON, POWER, REYNOLDS, SCHOUTEN, WILLIAMS

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

Allows pharmacist to prescribe [and], dispense and administer preexposure prophylactic

Anows pnarmacist to prescribe [ana], dispense and administer preexposure prophylactic antiretroviral [drug to patient after completion of patient assessment] therapies and post-exposure prophylactic antiretroviral therapies. Directs State Board of Pharmacy to adopt rules. Requires health [insurance policies that have prescription drug benefit] insurers to cover cost of drugs and therapies prescribed [and], dispensed and administered by pharmacists within their scope of practice[, including cost of pharmacists' consultation fees associated with prescribing and dispensing drugs] and cover costs of services provided by pharmacist. Takes effect on 91st day following adjournment sine die.

1	A BILL FOR AN ACT
2	Relating to prescription drugs; creating new provisions; amending ORS 689.005, 743A.051, 743B.425
3	and 743B.602; and prescribing an effective date.
4	Be It Enacted by the People of the State of Oregon:
5	SECTION 1. Section 2 of this 2021 Act is added to and made a part of ORS chapter 689.
6	SECTION 2. (1) As used in this section:
7	(a) "HIV test" has the meaning given that term in ORS 433.045.
8	(b) "Post-exposure prophylactic antiretroviral therapy" means a drug or other therapy
9	intended to reduce the likelihood of the acquisition of human immunodeficiency virus fol-
10	lowing a possible exposure to human immunodeficiency virus.
11	(c) "Preexposure prophylactic antiretroviral therapy" means a drug or other therapy in-
12	tended to prevent the acquisition of human immunodeficiency virus.
13	(2) A pharmacist may prescribe, dispense and administer:
14	(a) Preexposure prophylactic antiretroviral therapies; and
15	(b) In accordance with any rules adopted by the State Board of Pharmacy under ORS
16	689.645, post-exposure prophylactic antiretroviral therapies.
17	(3)(a) A pharmacist may perform an HIV test or may order an HIV test performed by a
18	laboratory. A laboratory that performs an HIV test ordered under this subsection shall
19	submit the results of the HIV test to the pharmacist who ordered the test.
20	(b) A pharmacist who orders or performs an HIV test under this subsection shall comply
21	with the requirements of ORS 433.045.
22	(4) The State Board of Pharmacy shall adopt rules to carry out this section. The rules
23	adopted under this subsection must allow a pharmacist to prescribe, dispense and administer
24	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 1 2 this section indicate the patient is HIV-negative. 3 SECTION 3. ORS 689.005 is amended to read: 689.005. As used in this chapter: 4 5 (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: 6 (a) A practitioner or the practitioner's authorized agent; or 7 8 (b) The patient or research subject at the direction of the practitioner. 9 (2) "Approved continuing pharmacy education program" means those seminars, classes, meetings, workshops and other educational programs on the subject of pharmacy approved by the 10 board. 11 12(3) "Board of pharmacy" or "board" means the State Board of Pharmacy. 13 (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 14 15 defined in ORS 685.010 that permits the pharmacist to engage in the practice of clinical pharmacy 16 for the benefit of the patients of the health care organization, physician or naturopathic physician. 17 (5) "Continuing pharmacy education" means: 18 (a) Professional, pharmaceutical post-graduate education in the general areas of socio-economic and legal aspects of health care; 19 20(b) The properties and actions of drugs and dosage forms; and (c) The etiology, characteristics and therapeutics of the disease state. 2122(6) "Continuing pharmacy education unit" means the unit of measurement of credits for approved continuing education courses and programs. 23(7) "Deliver" or "delivery" means the actual, constructive or attempted transfer of a drug or 24 25device 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 2627reagent 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. 28(9) "Dispense" or "dispensing" means the preparation and delivery of a prescription drug pur-2930 suant to a lawful order of a practitioner in a suitable container appropriately labeled for subsequent 31 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. 32(11) "Drug" means: 33 34 (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 dis ease in a human or other animal;

(c) Articles, other than food, intended to affect the structure or any function of the body of hu-mans 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

[2]

A-Eng. HB 2958

1 pharmacist, licensed nurse or other practitioner.

2 (13) "Drug outlet" means a pharmacy, nursing home, shelter home, convalescent home, extended 3 care facility, drug abuse treatment center, penal institution, hospital, family planning clinic, student 4 health center, retail store, wholesaler, manufacturer, mail-order vendor or other establishment with 5 facilities located within or out of this state that is engaged in dispensing, delivery or distribution 6 of drugs within this state.

7 (14) "Drug room" means a secure and lockable location within an inpatient care facility that 8 does not have a licensed pharmacy.

9 (15) "Electronically transmitted" or "electronic transmission" means a communication sent or 10 received through technological apparatuses, including computer terminals or other equipment or 11 mechanisms linked by telephone or microwave relays, or similar apparatus having electrical, digital, 12 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.

30 (22) "Manufacture" means the production, preparation, propagation, compounding, conversion 31 or processing of a device or a drug, either directly or indirectly by extraction from substances of 32 natural origin or independently by means of chemical synthesis or by a combination of extraction 33 and chemical synthesis and includes any packaging or repackaging of the substances or labeling or 34 relabeling of its container, except that this term does not include the preparation or compounding 35 of a drug by an individual for their own use or the preparation, compounding, packaging or labeling 36 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.

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

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

44 (25) "Nonprescription drugs" means drugs which may be sold without a prescription and which 45 are prepackaged for use by the consumer and labeled in accordance with the requirements of the

A-Eng. HB 2958

1 statutes and regulations of this state and the federal government.

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

3 (27) "Pharmacist" means an individual licensed by this state to engage in the practice of phar4 macy or to engage in the practice of clinical pharmacy.

5 (28) "Pharmacy" means a place that meets the requirements of rules of the board, is licensed 6 and approved by the board where the practice of pharmacy may lawfully occur and includes 7 apothecaries, drug stores, dispensaries, hospital outpatient pharmacies, pharmacy departments and 8 prescription laboratories but does not include a place used by a manufacturer or wholesaler.

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

11 (30) "Practice of clinical pharmacy" means:

12 (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 pre vention and the patient's health and wellness;

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

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

18 (31) "Practice of pharmacy" means:

19 (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 pa tient care services pursuant to ORS 689.645;

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

26 (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 re-garding 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;

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

32 (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

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prescribe, dispense, conduct research with respect to or administer drugs in the course of profes-1

(a) In this state; or 3

sional practice or research:

(b) In another state or territory of the United States if the person does not reside in Oregon and 4 is registered under the federal Controlled Substances Act. $\mathbf{5}$

(33) "Preceptor" means a pharmacist or a person licensed by the board to supervise the 6 internship training of a licensed intern. 7

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(34) "Prescription drug" or "legend drug" means a drug which is:

9 (a) Required by federal law, prior to being dispensed or delivered, to be labeled with either of 10 the following statements:

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

12(B) "Caution: Federal law restricts this drug to use by or on the order of a licensed 13 veterinarian"; or

(b) Required by any applicable federal or state law or regulation to be dispensed on prescription 14 15 only or is restricted to use by practitioners only.

16(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 17 18 of a drug. When the context requires, "prescription" also means the drug prepared under such written, oral or electronically transmitted direction. 19

(36) "Retail drug outlet" means a place used for the conduct of the retail sale, administering or 20dispensing or compounding of drugs or chemicals or for the administering or dispensing of pre-2122scriptions and licensed by the board as a place where the practice of pharmacy may lawfully occur. 23(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 24

prevent pregnancy and that the patient to whom the drug is prescribed may administer to oneself. 25"Self-administered hormonal contraceptive" includes, but is not limited to, hormonal contraceptive 2627patches and hormonal contraceptive pills.

(38) "Shopkeeper" means a business or other establishment, open to the general public, for the 28sale or nonprofit distribution of drugs. 29

30 (39) "Unit dose" means a sealed single-unit container so designed that the contents are admin-31 istered to the patient as a single dose, direct from the container. Each unit dose container must bear 32a 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 33 34 medication.

35 (40) "Wholesale drug outlet" means a person who imports, stores, distributes or sells for resale drugs, including legend drugs and nonprescription drugs. 36

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

38 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 39 scope of practice of a pharmacist, the insurer: 40

(1) May provide payment or reimbursement for the service when the service is provided by a 41 pharmacist; and 42

(2) Shall provide, in the same manner as would be provided for any other health care 43 provider, payment or reimbursement for: 44

(a)(A) The prescription of emergency refills of insulin and associated insulin-related devices and 45

1 supplies as described in ORS 689.696; and

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

3 (b)(A) The prescription, dispensation and administration of preexposure and post-4 exposure prophylactic antiretroviral therapies pursuant to section 2 of this 2021 Act and any 5 rules adopted by the State Board of Pharmacy under section 2 of this 2021 Act and ORS 6 689.645; and

7 **(B)**

(B) The service provided by the pharmacist; and

8 (c)(A) The prescription and dispensation of other prescription drugs by a licensed 9 pharmacist if the State Board of Pharmacy or any state law authorizes the drug to be pre-10 scribed and dispensed by pharmacists licensed under ORS chapter 689; and

11 (B) The service provided by the pharmacist.

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

13 **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:

17 (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

20 (B) For post-exposure prophylactic antiretroviral drugs or at least one preexposure 21 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.

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(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:

33 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:

36 (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];

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

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

41 (E) A contract or agreement with a health care service contractor, as defined in ORS 750.005,

42 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

45 (G) An accident insurance policy or any other insurance contract [providing reimbursement for

A-Eng. HB 2958

1 the cost of prescription drugs, hospital expenses, health care services and medical expenses, equipment 2 and supplies].

3 (b) "Step therapy" means a drug protocol in which [a] **an entity that provides** health care 4 coverage [*plan*] will reimburse the cost of a prescribed drug only if the patient has first tried a 5 specified drug or series of drugs.

6 (2) [A] **An entity that provides** health care coverage [*plan*] that requires step therapy shall 7 make easily accessible to prescribing practitioners, clear explanations of:

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

9 (b) The procedure by which a practitioner may submit to the [*plan*] **entity** the practitioner's 10 medical rationale for determining that a particular step therapy protocol is not appropriate for a 11 particular patient based on the patient's medical condition and history; and

12 (c) The documentation, if any, that a practitioner must submit to the [plan] entity for the 13 [plan] entity to determine the appropriateness of step therapy for a specific patient.

14 <u>SECTION 7.</u> The amendments to ORS 743A.051, 743B.425 and 743B.602 by sections 4 to 6 15 of this 2021 Act apply to health insurance policies, health benefit plans and health care cov-16 erage 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.

24 <u>SECTION 9.</u> This 2021 Act takes effect on the 91st day after the date on which the 2021 25 regular session of the Eighty-first Legislative Assembly adjourns sine die.

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