

(To Resolve Conflicts)

B-Engrossed

House Bill 2627

Ordered by the Senate June 4
Including House Amendments dated April 26 and Senate Amendments
dated June 4 to resolve conflicts

Sponsored by Representative MORRISETTE; Representatives BATES, GARDNER, HANSEN, HILL, HOPSON, JENSON, KRUSE, LOWE, MONNES ANDERSON, WITT

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.

Permits practitioners authorized to prescribe drugs to electronically transmit prescription drug order to pharmacist. Requires Department of Human Services to seek waiver from federal Health Care Financing Administration permitting Office of Medical Assistance Programs to communicate prescription drug orders by electronic means from prescribing practitioner to pharmacist.

1 A BILL FOR AN ACT

2 Relating to electronically transmitted prescriptions; creating new provisions; and amending ORS
3 475.005, 475.185, 678.375, 689.005 and 689.515.

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

5 **SECTION 1. Section 2 of this 2001 Act is added to and made a part of ORS 475.005 to**
6 **475.285.**

7 **SECTION 2. (1) Prescription drug orders may be transmitted by electronic means from**
8 **a practitioner authorized to prescribe drugs directly to the dispensing pharmacist.**

9 **(2) All prescription drug orders communicated by way of electronic transmission shall:**

10 **(a) Be transmitted only by an authorized practitioner;**

11 **(b) Be transmitted directly to a pharmacist in a pharmacy of the patient's choice with**
12 **no intervening person having access to the prescription drug order;**

13 **(c) Specify the prescribing practitioner's telephone number for verbal confirmation, the**
14 **time and date of transmission, the identity of the pharmacy intended to receive the trans-**
15 **mission and all other information required for a prescription by federal or state law; and**

16 **(d) Be traceable to the prescribing practitioner by an electronic signature or other secure**
17 **method of validation.**

18 **(3) An electronic transmission of a prescription drug order shall be stored by electronic**
19 **means or reduced promptly to writing, filed by the pharmacy and retained in conformity with**
20 **the requirements of ORS 475.165.**

21 **(4) The dispensing pharmacist shall exercise professional judgment regarding the accu-**
22 **racy, validity and authenticity of an electronically transmitted prescription drug order.**

23 **(5) All equipment for transmission, storage or receipt of electronically transmitted pre-**
24 **scription drug orders shall be maintained to protect against unauthorized access.**

25 **(6) A pharmacist, pharmacy or pharmacy department shall not enter into an agreement**

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.

1 **with a practitioner or health care facility concerning the provision of any electronic trans-**
2 **mission equipment or apparatus that would adversely affect a patient's freedom to select the**
3 **pharmacy or pharmacy department of the patient's choice.**

4 **(7) A pharmacist, pharmacy or pharmacy department shall not provide any electronic**
5 **equipment or apparatus to a practitioner or health care facility for the purpose of providing**
6 **an incentive to the practitioner or health care facility to refer patients to a particular**
7 **pharmacy or pharmacy department.**

8 **(8) There shall be no additional charge to the patient because the prescription drug order**
9 **was electronically transmitted.**

10 **(9) Nothing in this section shall be construed as authorizing the electronic transmission**
11 **of a prescription drug order when a written prescription is required under ORS 127.815,**
12 **137.473, 169.750, 453.025, 475.185 (1) or 689.535 or section 7, chapter 388, Oregon Laws 1981.**

13 **SECTION 3.** ORS 475.005 is amended to read:

14 475.005. As used in ORS 475.005 to 475.285 and 475.940 to 475.995, unless the context requires
15 otherwise:

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

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

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

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

22 (3) "Administration" means the Drug Enforcement Administration of the United States Depart-
23 ment of Justice, or its successor agency.

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

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

28 (6) "Controlled substance" means a drug or its immediate precursor classified in Schedules I
29 through V under the federal Controlled Substances Act, 21 U.S.C. 811 to 812, as modified under ORS
30 475.035. The use of the term "precursor" in this subsection does not control and is not controlled
31 by the use of the term "precursor" in ORS 475.940, 475.950 and 475.955.

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

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

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

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

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

44 (10) "Dispense" means to deliver a controlled substance to an ultimate user or research subject
45 by or pursuant to the lawful order of a practitioner, and includes the prescribing, administering,

1 packaging, labeling or compounding necessary to prepare the substance for that delivery.

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

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

4 (13) "Drug" means:

5 (a) Substances recognized as drugs in the official United States Pharmacopoeia, official

6 Homeopathic Pharmacopoeia of the United States or official National Formulary, or any supplement

7 to any of them;

8 (b) Substances intended for use in the diagnosis, cure, mitigation, treatment or prevention of

9 disease in humans or animals;

10 (c) Substances (other than food) intended to affect the structure or any function of the body of

11 humans or animals; and

12 (d) Substances intended for use as a component of any article specified in paragraph (a), (b) or

13 (c) of this subsection; however, the term does not include devices or their components, parts or ac-

14 cessories.

15 (14) **"Electronically transmitted" or "electronic transmission" means a communication**

16 **sent or received through technological apparatuses, including computer terminals or other**

17 **equipment or mechanisms linked by telephone or microwave relays, or any similar apparatus**

18 **having electrical, digital, magnetic, wireless, optical, electromagnetic or similar capabilities.**

19 [(14)] (15) "Manufacture" means the production, preparation, propagation, compounding, con-

20 version or processing of a controlled substance, either directly or indirectly by extraction from

21 substances of natural origin, or independently by means of chemical synthesis, or by a combination

22 of extraction and chemical synthesis, and includes any packaging or repackaging of the substance

23 or labeling or relabeling of its container, except that this term does not include the preparation or

24 compounding of a controlled substance:

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

26 the course of professional practice; or

27 (b) By a practitioner, or by an authorized agent under the practitioner's supervision, for the

28 purpose of, or as an incident to, research, teaching or chemical analysis and not for sale.

29 [(15)] (16) "Marijuana" means all parts of the plant Cannabis family Moraceae, whether growing

30 or not; the resin extracted from any part of the plant; and every compound, manufacture, salt, de-

31 rivative, mixture, or preparation of the plant or its resin. It does not include the mature stalks of

32 the plant, fiber produced from the stalks, oil or cake made from the seeds of the plant, any other

33 compound, manufacture, salt, derivative, mixture, or preparation of the mature stalks (except the

34 resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of the plant which is incapable

35 of germination.

36 [(16)] (17) "Person" includes a government subdivision or agency, business trust, estate, trust

37 or any other legal entity.

38 [(17)] (18) "Practitioner" means physician, dentist, veterinarian, scientific investigator, certified

39 nurse practitioner, physician assistant or other person licensed, registered or otherwise permitted

40 by law to dispense, conduct research with respect to or to administer a controlled substance in the

41 course of professional practice or research in this state but does not include a pharmacist or a

42 pharmacy.

43 [(18)] (19) "Prescription" means a written, [or] oral **or electronically transmitted** direction,

44 given by a practitioner for the preparation and use of a drug. When the context requires, "pre-

45 script" also means the drug prepared under such written, [or] oral **or electronically transmit-**

1 **ted** direction. Any label affixed to a drug prepared under written, *[or]* oral **or electronically transmitted** direction shall prominently display a warning that the removal thereof is prohibited by law.

4 [(19)] **(20)** "Production" includes the manufacture, planting, cultivation, growing or harvesting
5 of a controlled substance.

6 [(20)] **(21)** "Research" means an activity conducted by the person registered with the federal
7 Drug Enforcement Administration pursuant to a protocol approved by the United States Food and
8 Drug Administration.

9 [(21)] **(22)** "Ultimate user" means a person who lawfully possesses a controlled substance for the
10 use of the person or for the use of a member of the household of the person or for administering to
11 an animal owned by the person or by a member of the household of the person.

12 SECTION 4. ORS 475.185 is amended to read:

13 475.185. (1) Except when dispensed directly by a practitioner to an ultimate user, no controlled
14 substance in Schedule II may be dispensed without the written prescription of a practitioner.

15 (2) In emergency situations, as defined by rule of the State Board of Pharmacy, Schedule II
16 drugs may be dispensed upon oral **or electronically transmitted** prescription of a practitioner, re-
17 duced promptly to writing and filed by the pharmacy. Prescriptions shall be retained in conformity
18 with the requirements of ORS 475.165. No prescription for a Schedule II substance may be refilled.

19 (3) Except when dispensed directly by a practitioner to an ultimate user, a controlled substance
20 included in Schedule III, IV or V, which is a prescription drug, shall not be dispensed without a
21 written, *[or]* oral **or electronically transmitted** prescription of a practitioner. The prescription
22 shall not be filled or refilled more than six months after the date on which it was issued and no
23 prescription authorized to be refilled may be refilled more than five times. Additional quantities of
24 the controlled substances listed in Schedule III, IV or V may only be authorized by a practitioner
25 through issuance of a new prescription.

26 (4) A controlled substance shall not be delivered or dispensed other than for a medical purpose.

27 (5) Except in good faith and in the course of professional practice only, a practitioner or a
28 pharmacist may not dispense controlled substances.

29 (6) Any oral **or electronically transmitted** prescription authorized by statute or rule shall be
30 **stored by electronic means** **or** reduced promptly to writing and filed by the pharmacy.

31 (7) Issuance, preparation, labeling, dispensing, recordkeeping and filing of prescriptions or
32 medication orders shall be in conformance with the requirements of the federal law and rules of the
33 board.

34 SECTION 5. ORS 678.375 is amended to read:

35 678.375. (1) The Oregon State Board of Nursing is authorized to issue certificates of special
36 competency to licensed registered nurses to practice as nurse practitioners if they meet the re-
37 quirements of the board pursuant to ORS 678.380.

38 (2) No person shall practice as a nurse practitioner or hold oneself out to the public or to an
39 employer, or use the initials, name, title, designation or abbreviation as a nurse practitioner until
40 and unless such person is certified by the board.

41 (3) A registered nurse, certified as a nurse practitioner, is authorized to prescribe drugs for the
42 use of and administration to other persons if approval has been given under ORS 678.390. The drugs
43 which the nurse practitioner is authorized to prescribe shall be included within the certified nurse
44 practitioner's scope of practice as defined by rules of the board subject to ORS 678.385.

45 (4) The dispensing of certain limited medications prescribed by a nurse practitioner in accord-

1 ance with the formulary established under ORS 678.385 and dispensed by a licensed pharmacist or
2 an employee thereof may be filled by a pharmacist according to the terms of the prescription. The
3 filling of such a prescription shall not constitute evidence of negligence on the part of the
4 pharmacist if the prescription was dispensed within the reasonable and prudent practice of phar-
5 macy.

6 (5) As used in this section:

7 (a) "Drug" means medicines and preparations for internal or external use of human beings which
8 are recognized in the formulary adopted pursuant to ORS 678.385.

9 (b) "Prescribe" means to direct, order or designate the preparation, use of or manner of using
10 by spoken or written words **or other means**.

11 SECTION 6. ORS 689.005 is amended to read:

12 689.005. As used in this chapter:

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

15 (a) A practitioner or the authorized agent thereof; or

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

17 (2) "Approved continuing pharmacy education program" means those seminars, classes,
18 meetings, workshops and other educational programs on the subject of pharmacy approved by the
19 board.

20 (3) "Board of pharmacy" or "board" means the State Board of Pharmacy.

21 (4) "Continuing pharmacy education" means professional, pharmaceutical post-graduate educa-
22 tion in the general areas of socio-economic and legal aspects of health care; the properties and
23 actions of drugs and dosage forms; and the etiology, characteristics and therapeutics of the disease
24 state.

25 (5) "Continuing pharmacy education unit" means the unit of measurement of credits for ap-
26 proved continuing education courses and programs.

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

29 (7) "Device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro
30 reagent or other similar or related article, including any component part or accessory, which is re-
31 quired under federal or state law to be prescribed by a practitioner and dispensed by a pharmacist.

32 (8) "Dispense" or "dispensing" means the preparation and delivery of a prescription drug pur-
33 suant to a lawful order of a practitioner in a suitable container appropriately labeled for subsequent
34 administration to or use by a patient or other individual entitled to receive the prescription drug.

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

36 (10) "Drug" means:

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

40 (b) Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of dis-
41 ease in a human or other animal;

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

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

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

5 (12) "Drug outlet" means any pharmacy, nursing home, shelter home, convalescent home, ex-
6 tended care facility, drug abuse treatment center, penal institution, hospital, family planning clinic,
7 student health center, retail store, wholesaler, manufacturer or mail order vendor with facilities lo-
8 cated within or out of this state that is engaged in dispensing, delivery or distribution of drugs
9 within this state.

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

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

16 [**(14)**] **(15)** "Institutional drug outlet" means hospitals and inpatient care facilities where
17 medications are dispensed to another health care professional for administration to patients served
18 by the hospitals or facilities.

19 [**(15)**] **(16)** "Intern" means any person who has completed the junior or third academic year of
20 a course of study at an approved college of pharmacy and is licensed with the board as an intern.

21 [**(16)**] **(17)** "Internship" means a professional and practical experience program approved by the
22 board under the supervision of a licensed pharmacist registered with the board as a preceptor.

23 [**(17)**] **(18)** "Itinerant vendor" means all persons who sell or otherwise distribute nonprescription
24 drugs by passing from house to house, or by haranguing the people on the public streets or in public
25 places, or who use the customary devices for attracting crowds and therewith recommending their
26 wares and offering them for sale.

27 [**(18)**] **(19)** "Labeling" means the process of preparing and affixing of a label to any drug con-
28 tainer exclusive, however, of the labeling by a manufacturer, packer or distributor of a
29 nonprescription drug or commercially packaged legend drug or device. Any such label shall include
30 all information required by federal and state law or regulation.

31 [**(19)**] **(20)** "Manufacture" means the production, preparation, propagation, compounding, con-
32 version or processing of a device or a drug, either directly or indirectly by extraction from sub-
33 stances of natural origin or independently by means of chemical synthesis or by a combination of
34 extraction and chemical synthesis and includes any packaging or repackaging of the substances or
35 labeling or relabeling of its container, except that this term does not include the preparation or
36 compounding of a drug by an individual for their own use or the preparation, compounding, pack-
37 aging or labeling of a drug:

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

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

42 [**(20)**] **(21)** "Manufacturer" means a person engaged in the manufacture of drugs.

43 [**(21)**] **(22)** "Nonprescription drug outlet" means shopkeepers and itinerant vendors registered
44 under ORS 689.305.

45 [**(22)**] **(23)** "Nonprescription drugs" means drugs which may be sold without a prescription and

1 which are prepackaged for use by the consumer and labeled in accordance with the requirements
2 of the statutes and regulations of this state and the federal government.

3 **[23] (24)** "Person" means an individual, corporation, partnership, association or any other legal
4 entity.

5 **[24] (25)** "Pharmacist" means an individual licensed by this state to engage in the practice of
6 pharmacy.

7 **[25] (26)** "Pharmacy" means a place that meets the requirements of rules of the board, is li-
8 censed and approved by the board where the practice of pharmacy may lawfully occur and includes
9 apothecaries, drug stores, dispensaries, hospital outpatient pharmacies, pharmacy departments and
10 prescription laboratories but does not include a place used by a manufacturer or wholesaler.

11 **[26] (27)** "Pharmacy technician" means a person registered by the State Board of Pharmacy
12 who assists the pharmacist in the practice of pharmacy pursuant to rules of the board.

13 **[27] (28)** "Practitioner" means a person licensed and operating within the scope of such license
14 to prescribe, dispense, conduct research with respect to or administer drugs in the course of pro-
15 fessional practice or research:

16 (a) In this state; or

17 (b) In another state or territory of the United States not residing in Oregon and registered un-
18 der the federal Controlled Substances Act.

19 **[28] (29)** "Preceptor" means a pharmacist licensed and in good standing, registered by the
20 board to supervise the internship training of a licensed intern.

21 **[29] (30)** "Prescription drug" or "legend drug" means a drug which is:

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

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

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

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

29 **[30] (31)** "Prescription" or "prescription drug order" means a written, *[or]* oral **or electronically transmitted**
30 direction, given by a practitioner authorized to prescribe drugs, for the prepa-
31 ration and use of a drug. When the context requires, "prescription" also means the drug prepared
32 under such written, *[or]* oral **or electronically transmitted** direction.

33 **[31] (32)** "Retail drug outlet" means a place used for the conduct of the retail sale, adminis-
34 tering or dispensing or compounding of drugs or chemicals or for the administering or dispensing
35 of prescriptions and licensed by the board as a place wherein the practice of pharmacy may lawfully
36 occur.

37 **[32] (33)** "Shopkeeper" means a business establishment, open to the general public, for the sale
38 of nonlegend drugs, in the original and unbroken package, properly labeled according to state and
39 federal laws, in conformity with the rules of the board.

40 **[33] (34)** "Unit dose" means a sealed single-unit container so designed that the contents are
41 administered to the patient as a single dose, direct from the container. Each unit dose container
42 must bear a separate label, be labeled with the name and strength of the medication, the name of
43 the manufacturer or distributor, an identifying lot number and, if applicable, the expiration date of
44 the medication.

45 **[34] (35)** "Wholesale drug outlet" means any person who imports, stores, distributes or sells for

1 resale any drugs including legend drugs and nonprescription drugs.

2 **[(35)] (36)** "Class I wholesaler" means any person operating or maintaining a wholesale distribution center, wholesale business or any other business in which drugs, medicinal chemicals, or poisons are sold, dispensed, stocked, exposed or offered for sale at wholesale to a pharmacy or other legally licensed drug outlets or persons.

3 **[(36)] (37)** "Class II wholesaler" means any person operating or maintaining a wholesale distribution center, wholesale business or any other business in which nonprescription drugs are offered for sale at wholesale to a drug outlet legally authorized to resell.

4 **SECTION 7. ORS 689.515** is amended to read:

5 689.515. (1) As used in this section unless the context requires otherwise:

6 (a) "Brand name" means the proprietary or trade name selected by the manufacturer and placed upon a drug, its container, label or wrapping at the time of packaging.

7 (b) "Dosage form" means the physical formulation or medium in which the product is intended, manufactured and made available for use, including but not limited to tablets, capsules, oral solutions, aerosols, ointments, inhalers and suppositories, and the particular form of which utilizes a specific technology or mechanism to control, enhance or direct the release, targeting, systemic absorption or other delivery of a dosage regimen in the body.

8 (c) "Generic name" means the official title of a drug or drug ingredients published in the latest edition of the official Pharmacopoeia, Homeopathic Pharmacopoeia or Formulary.

9 (d) "Substitute" means to dispense without the prescriber's express authorization a different drug product in place of the drug ordered or prescribed.

10 (e) "Therapeutically equivalent" means drugs that are approved by the United States Food and Drug Administration for interstate distribution and the Food and Drug Administration has determined that the drugs will provide essentially the same efficacy and toxicity when administered to an individual in the same dosage regimen.

11 (2) Except as limited by subsections (3) and (5) of this section, unless the purchaser instructs otherwise, the pharmacist may substitute as follows:

12 (a) A drug product with the same generic name in the same strength, quantity, dose and dosage form as the prescribed drug which is, in the pharmacist's professional opinion, therapeutically equivalent.

13 (b) When the prescriber is not reasonably available for consultation and the prescribed drug does not utilize a unique delivery system technology, an oral tablet, capsule or liquid form of the prescribed drug so long as the form dispensed or administered has the same strength, dose and dose schedule and is therapeutically equivalent to the drug prescribed.

14 (3) A practitioner may specify in writing, **[or]** by a telephonic communication **or by electronic transmission** that there shall be no substitution for the specified brand name drug in any prescription. The phrase "no substitution" or the notation "N.S." must be in the practitioner's handwriting or, if the prohibition was communicated by telephonic communication **or electronic transmission**, in the pharmacist's handwriting and shall not be preprinted or stamped or initialed on the prescription form.

15 (4) Every pharmacy shall post a sign in a location easily seen by patrons at the counter where prescriptions are dispensed or administered stating that, "This pharmacy may be able to substitute a less expensive drug which is therapeutically equivalent to the one prescribed by your doctor unless you do not approve." The printing on the sign shall be in block letters not less than one inch in height. If the pharmacist has reasonable cause to believe that the purchaser cannot read the sign

1 or comprehend its content, the pharmacist shall endeavor to explain the meaning of the sign.

2 (5) A pharmacist shall substitute a drug product under this section only when there will be a
3 savings in or no increase in cost to the purchaser.

4 (6) If the practitioner prescribes a drug by its generic name, the pharmacist shall, consistent
5 with reasonable professional judgment, dispense or administer the lowest retail cost, effective brand
6 which is in stock.

7 (7) Except as provided in subsection (8) of this section, when a pharmacist dispenses a substi-
8 tuted drug as authorized by subsection (2) of this section, the pharmacist must label the prescription
9 container with the name of the dispensed drug. If the dispensed drug does not have a brand name,
10 the prescription label shall indicate the generic name of the drug dispensed along with the name
11 of the drug manufacturer.

12 (8) A prescription dispensed by a pharmacist shall bear upon the label the name of the
13 medication in the container except if the prescriber writes "do not label," or words of similar im-
14 port, on the prescription or so designates in an oral **or electronic** transmission of the prescription.

15 (9) The substitution of any drug by a licensed pharmacist or the pharmacist's employer pursuant
16 to this section does not constitute the practice of medicine.

17 (10) No substitution of drugs made by a pharmacist or the pharmacist's employer in accordance
18 with this section and any rules that the State Board of Pharmacy may adopt thereunder shall con-
19 stitute evidence of negligence if the substitution was made within reasonable and prudent practice
20 of pharmacy or if the substituted drug was accepted in a generally recognized formulary or gov-
21 ernment list.

22 (11) Failure of a practitioner to specify that no substitution is authorized does not constitute
23 evidence of negligence unless the practitioner knows that the health condition of the patient for
24 whom the practitioner is prescribing warrants the use of the brand name drug product and not the
25 substituted drug.

26 **SECTION 7a. If Senate Bill 568 becomes law, section 7 of this 2001 Act (amending ORS**
27 **689.515) is repealed and ORS 689.515, as amended by section 1, chapter _____, Oregon Laws**
28 **2001 (Enrolled Senate Bill 568), is amended to read:**

29 689.515. (1) As used in this section unless the context requires otherwise:

30 (a) "Brand name" means the proprietary or trade name selected by the manufacturer and placed
31 upon a drug, its container, label or wrapping at the time of packaging.

32 (b) "Dosage form" means the physical formulation or medium in which the product is intended,
33 manufactured and made available for use, including but not limited to tablets, capsules, oral sol-
34 utions, aerosols, ointments, inhalers and suppositories, and the particular form of which utilizes a
35 specific technology or mechanism to control, enhance or direct the release, targeting, systemic ab-
36 sorption or other delivery of a dosage regimen in the body.

37 (c) "Generic name" means the official title of a drug or drug ingredients published in the latest
38 edition of the official Pharmacopoeia, Homeopathic Pharmacopoeia or Formulary.

39 (d) "Substitute" means to dispense without the prescriber's express authorization a different
40 drug product in place of the drug ordered or prescribed.

41 (e) "Therapeutically equivalent" means drugs that are approved by the United States Food and
42 Drug Administration for interstate distribution and the Food and Drug Administration has deter-
43 mined that the drugs will provide essentially the same efficacy and toxicity when administered to
44 an individual in the same dosage regimen.

45 (2) Except as limited by subsections (3) and (5) of this section, unless the purchaser instructs

1 otherwise, the pharmacist may substitute as follows:

2 (a) A drug product with the same generic name in the same strength, quantity, dose and dosage
3 form as the prescribed drug which is, in the pharmacist's professional opinion, therapeutically
4 equivalent.

5 (b) When the prescriber is not reasonably available for consultation and the prescribed drug
6 does not utilize a unique delivery system technology, an oral tablet, capsule or liquid form of the
7 prescribed drug so long as the form dispensed or administered has the same strength, dose and dose
8 schedule and is therapeutically equivalent to the drug prescribed.

9 (3) A practitioner may specify in writing, *[or]* by a telephonic communication **or by electronic**
10 **transmission** that there shall be no substitution for the specified brand name drug in any pre-
11 script. The phrase "no substitution" or the notation "N.S." must be in the practitioner's hand-
12 writing or, if the prohibition was communicated by telephonic communication **or electronic**
13 **transmission**, in the pharmacist's handwriting and shall not be preprinted or stamped or initialed
14 on the prescription form.

15 (4) Every pharmacy shall post a sign in a location easily seen by patrons at the counter where
16 prescriptions are dispensed or administered stating that, "This pharmacy may be able to substitute
17 a less expensive drug which is therapeutically equivalent to the one prescribed by your doctor un-
18 less you do not approve." The printing on the sign shall be in block letters not less than one inch
19 in height. If the pharmacist has reasonable cause to believe that the purchaser cannot read the sign
20 or comprehend its content, the pharmacist shall endeavor to explain the meaning of the sign.

21 (5) A pharmacist shall substitute a drug product under this section only when there will be a
22 savings in or no increase in cost to the purchaser.

23 (6) If the practitioner prescribes a drug by its generic name, the pharmacist shall, consistent
24 with reasonable professional judgment, dispense or administer the lowest retail cost, effective brand
25 which is in stock.

26 (7) Except as provided in subsection (8) of this section, when a pharmacist dispenses a substi-
27 tuted drug as authorized by subsection (2) of this section, the pharmacist must label the prescription
28 container with the name of the dispensed drug. If the dispensed drug does not have a brand name,
29 the prescription label shall indicate the generic name of the drug dispensed along with the name
30 of the drug manufacturer.

31 (8) A prescription dispensed by a pharmacist shall bear upon the label the name of the
32 medication in the container or shall be labeled as intended by the prescriber.

33 (9) The substitution of any drug by a licensed pharmacist or the pharmacist's employer pursuant
34 to this section does not constitute the practice of medicine.

35 (10) No substitution of drugs made by a pharmacist or the pharmacist's employer in accordance
36 with this section and any rules that the State Board of Pharmacy may adopt thereunder shall con-
37 stitute evidence of negligence if the substitution was made within reasonable and prudent practice
38 of pharmacy or if the substituted drug was accepted in a generally recognized formulary or gov-
39 ernment list.

40 (11) Failure of a practitioner to specify that no substitution is authorized does not constitute
41 evidence of negligence unless the practitioner knows that the health condition of the patient for
42 whom the practitioner is prescribing warrants the use of the brand name drug product and not the
43 substituted drug.

44 **SECTION 8. (1) The Department of Human Services shall seek a waiver from the federal**
45 **Health Care Financing Administration to allow the Office of Medical Assistance Programs**

- 1 **to communicate prescription drug orders by electronic means from a practitioner authorized**
- 2 **to prescribe drugs directly to the dispensing pharmacist.**
- 3 **(2) The Department of Human Services and the Office of Medical Assistance Programs**
- 4 **shall adopt rules permitting the Office of Medical Assistance Programs to communicate**
- 5 **prescription drug orders by electronic means from a practitioner authorized to prescribe**
- 6 **drugs directly to the dispensing pharmacist.**

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