House Bill 3466

Sponsored by Representative THOMPSON; Representatives KENY-GUYER, KOMP

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.**

Authorizes pharmacist to initiate or modify drug therapy in accordance with guidelines and protocols established by physician licensed to practice medicine. Specifies guidelines and protocols that must be followed. Prohibits pharmacist from initiating or modifying drug therapy for drugs that are controlled substances classified in Schedules I through IV of federal Controlled Substances Act.

Authorizes pharmacist to substitute, under certain conditions, prescribed drug with therapeutically equivalent drug in accordance with rules adopted by State Board of Pharmacy.

Clarifies provision authorizing prescriptive authority with respect to Schedule II controlled substances.

A BILL FOR AN ACT

Relating to the practice of pharmacy; creating new provisions; and amending ORS 475.185, 475.188, 689.005 and 689.515.

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

SECTION 1. 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) "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

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.

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

(15) "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.

(16) "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.

(17) "Internship" means a professional experiential program approved by the board under the supervision of a licensed pharmacist registered with the board as a preceptor.

(18) "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.

(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 shopkeepers and itinerant vendors registered under ORS 689.305.

(23) "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.

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

(25) "Pharmacist" means an individual licensed by this state to engage in the practice of 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 State Board of Pharmacy who assists the pharmacist in the practice of pharmacy pursuant to rules of the board.

(28) "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 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 therefor;

(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; [*and*]

(i) The initiation or modification of drug therapy as described in section 3 of this 2013 Act; and

[*(i)*] **(j)** The offering or performing of those acts, services, operations or transactions necessary in the conduct, operation, management and control of pharmacy.

(29) "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.

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

(31) "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.

(32) "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.

(33) "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 wherein the practice of pharmacy may lawfully occur.

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

(35) "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.

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

SECTION 2. Section 3 of this 2013 Act is added to and made a part of ORS chapter 689.

SECTION 3. (1)(a) Except as provided in paragraph (b) of this subsection, a pharmacist may initiate or modify drug therapy in accordance with guidelines and protocols established by a physician licensed to practice medicine under ORS chapter 677 if the guidelines and protocols are in compliance with the provisions of this section.

(b) A pharmacist may not initiate or modify drug therapy for a drug that is a controlled substance classified in Schedules I through IV under the federal Controlled Substances Act, 21 U.S.C. 811 and 812, as modified under ORS 475.035.

(2) Guidelines and protocols established under this section must contain, at a minimum:

(a) The identities of the physician and the pharmacist;

(b) The time period, not to exceed two years, during which the pharmacist may initiate or modify drug therapy;

(c) The scope of the pharmacist's prescriptive authority, including:

(A) The types of injuries, illnesses or diseases for which the pharmacist may initiate or modify drug therapy; and

(B) The types of drugs that the pharmacist may prescribe for those injuries, illnesses or diseases;

(d) The procedures that the pharmacist must follow and the criteria that the pharmacist must consider when initiating or modifying drug therapy; and

(e) The procedures that the pharmacist must follow after initiating or modifying drug therapy, including:

(A) The procedures for documenting the initiation or modification;

(B) The means of documenting the initiation or modification; and

(C) The procedures for communicating the initiation or modification to the physician.

SECTION 4. ORS 689.515 is amended to read:

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

(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.

(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.

(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.

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

(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.

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

(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.

(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.

(c) A drug that is therapeutically equivalent to the drug prescribed as established by the State Board of Pharmacy by rule.

(3) A practitioner may specify in writing, by a telephonic communication or by electronic transmission that there may be no substitution for the specified brand name drug in a prescription.

(4) A 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 must 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 or comprehend its content, the pharmacist shall endeavor to explain the meaning of the sign.

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

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

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

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

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

(10) A substitution of drugs made by a pharmacist or the pharmacist's employer in accordance with this section and any rules that the [*State*] board [*of Pharmacy*] may adopt thereunder does not constitute evidence of negligence if the substitution was made within reasonable and prudent practice of pharmacy or if the substituted drug was accepted in a generally recognized formulary or government list.

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

SECTION 5. ORS 475.185 is amended to read:

475.185. [*(1) Except when dispensed directly by a practitioner to an ultimate user, a controlled substance in Schedule II may not be dispensed without the written prescription of a practitioner.*]

[*(2)*] **(1)** In emergency situations, as defined by rule of the State Board of Pharmacy, Schedule II drugs may be dispensed upon oral or electronically transmitted prescription of a practitioner, reduced promptly to writing and filed by the pharmacy. Prescriptions shall be retained in conformity with the requirements of ORS 475.165. A prescription for a Schedule II substance may not be refilled.

[*(3)*] **(2)** Except when dispensed directly by a practitioner to an ultimate user, a controlled substance included in Schedule **II,** III or IV may not be dispensed without a written, oral or electronically transmitted prescription of a practitioner. The prescription **for a controlled substance in Schedule II may not be refilled. Additional quantities of a controlled substance in Schedule II may be authorized by a practitioner only through issuance of a new prescription. The prescription for a controlled substance in Schedule III or IV** may not be filled or refilled more than six months after the date on which it was issued and a prescription authorized to be refilled may not be refilled more than five times. Additional quantities of the controlled substances listed in Schedule III or IV may [*only*] be authorized by a practitioner **only** through issuance of a new prescription.

[*(4)*] **(3)** Except when dispensed directly by a practitioner to an ultimate user, a controlled substance included in Schedule V that is a prescription drug may not be dispensed without a written, oral or electronically transmitted prescription of a practitioner. The prescription may not be filled or refilled more than six months after the date on which it was issued and a prescription authorized to be refilled may not be refilled more than five times. Additional quantities of the controlled substances listed in Schedule V may [*only*] be authorized by a practitioner **only** through issuance of a

new prescription.

[*(5)*] **(4)** A controlled substance may not be delivered or dispensed other than for a medical purpose.

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

[*(7)*] **(6)** Any oral or electronically transmitted prescription authorized by statute or rule must be stored by electronic means or reduced promptly to writing and filed by the pharmacy.

[*(8)*] **(7)** Issuance, preparation, labeling, dispensing, recordkeeping and filing of prescriptions or medication orders must be in conformance with the requirements of the federal law and rules of the board.

SECTION 6. ORS 475.188 is amended to read:

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

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

(a) Be transmitted only by an authorized practitioner;

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

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

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

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

(4) The dispensing pharmacist shall exercise professional judgment regarding the accuracy, validity and authenticity of an electronically transmitted prescription drug order.

(5) All equipment for transmission, storage or receipt of electronically transmitted prescription drug orders shall be maintained to protect against unauthorized access.

(6) A pharmacist, pharmacy or pharmacy department shall not enter into an agreement with a practitioner or health care facility concerning the provision of any electronic transmission equipment or apparatus that would adversely affect a patient's freedom to select the pharmacy or pharmacy department of the patient's choice.

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

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

(9) Nothing in this section shall be construed as authorizing the electronic transmission of a prescription drug order when a written prescription is required under ORS 127.815, 137.473, 169.750[,] **or** 453.025 [*or 475.185 (1)*].
