Enrolled
House Bill 3103

Sponsored by Representative THOMPSON; Representative MAURER

CHAPTER .....

AN ACT

Relating to the practice of pharmacy; creating new provisions; amending ORS 442.580, 689.005, 689.225, 689.515, 689.655 and 689.765; repealing ORS 689.015; and declaring an emergency.

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 [*thereof*]; 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 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 [*any person who has completed the junior or third academic year of a course of study at an approved college of pharmacy and*] **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 and practical experience program approved by the board under the supervision of a licensed pharmacist registered with the board as a preceptor.

(18) "Itinerant vendor" means [*all persons who sell or otherwise distribute*] **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 [*use*] **uses** the customary devices for attracting crowds [*and therewith*]**,** 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. [*Any such label shall include all information required by federal and state law or regulation.*]

(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 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 offering or performing of those acts, services, operations or transactions necessary in the conduct, operation, management and control of pharmacy.

[*(28)*] **(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 [*not residing*] **if the person does not reside** in Oregon and **is** registered under the federal Controlled Substances Act.

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

[*(30)*] **(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.

[*(31)*] **(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.

[*(32)*] **(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.

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

[*(34)*] **(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.

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

[*(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.*]

[*(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.*]

SECTION 2. ORS 689.015 is repealed.

SECTION 3. ORS 689.225 is amended to read:

689.225. (1) [*It shall be unlawful for any person to*] **A person may not** engage in the practice of pharmacy unless **the person is** licensed [*to so practice under the provisions of*] **under** this chapter. Nothing in this section prevents physicians, dentists, veterinarians, osteopaths or other practitioners of the healing arts who are licensed under the laws of this state from dispensing and administering prescription drugs to their patients in the practice of their respective professions where specifically authorized to do so by law of this state.

(2) [*It shall be unlawful for any person, not legally licensed as a pharmacist, to*] **A person may not** take, use or exhibit the title of pharmacist or the title of druggist or apothecary, or any other title or description of like import **unless the person is licensed to practice pharmacy under this chapter**.

(3) [*In the practice of pharmacy, a pharmacist is licensed to practice as defined in ORS 689.015, but is not authorized to*] **A pharmacist may not** possess personally or [*to*] store drugs other than in a licensed pharmacy except for those drugs legally prescribed for the personal use of the pharmacist **or when the pharmacist possesses or stores the drugs in the usual course of business and within the pharmacist's scope of practice**. An employee, agent or owner of any registered manufacturer, wholesaler or pharmacy may lawfully possess legend drugs if the person is acting in the usual course of the business or employment of the person.

(4) The State Board of Pharmacy shall adopt rules relating to the use of pharmacy technicians working under the supervision, direction and control of a [*licensed*] pharmacist. For retail and institutional drug outlets, the board shall adopt rules which include requirements for training, including provisions for appropriate on-the-job training, guidelines for adequate supervision, standards and appropriate ratios for the use of pharmacy technicians. Improper use of pharmacy technicians [*shall be*] **is** subject to the reporting requirements of ORS 689.455.

(5) The mixing of intravenous admixtures by pharmacy technicians working under the supervision, direction and control of a [*licensed*] pharmacist is authorized and does not constitute the practice of pharmacy by the pharmacy technicians.

(6) Any person who is found to have unlawfully engaged in the practice of pharmacy is guilty of a Class A misdemeanor.

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 sol-

utions, 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, [*the*] **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.

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

(4) [*Every*] **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 [*shall*] **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 [*shall*] **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 [*must*] **shall** label the prescription container with the name of the dispensed drug. If the dispensed drug does not have a brand name, [*the prescription label shall indicate*] **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 [*shall*] **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 [*licensed*] pharmacist or the pharmacist's employer pursuant to this section does not constitute the practice of medicine.

(10) [*No*] **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 [*shall*] **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 689.655 is amended to read:

689.655. [*(1) Only as provided in this section and in accordance with rules adopted by the State Board of Pharmacy under ORS 689.205, a pharmacist may:*]

[*(a) In collaboration with and under an order from a physician, nurse practitioner or physician assistant practicing within the scope of practice allowed by law, flush heparin or saline through existing intravenous lines that are connected to a person;*]

[*(b) In collaboration with and under an order from a physician, nurse practitioner or physician assistant practicing within the scope of practice allowed by law, attach an infusion pump or enteric feeding pump to existing intravenous lines or enteric feeding lines that are connected to a person, and activate the pump;*]

[*(c) Administer drugs and devices in a medical emergency within a health care facility in the presence of and under the direction of a physician or nurse practitioner; and*]

[*(d) Administer a drug or device to a person in the course of teaching the person to self-administer the drug or device that the person will be required routinely to self-administer as part of a course of therapy ordered by a physician, nurse practitioner or physician assistant practicing within the scope of practice allowed by law.*]

[*(2) Nothing in this section shall be construed to allow a pharmacist to establish an intravenous or enteric line or to attach or activate a pump for any intrathecal medication.*] **A pharmacist may administer a drug or device if the pharmacist is acting:**

(1) Under the direction of or pursuant to a lawful prescription or order issued by a licensed practitioner acting within the scope of the practitioner's practice; and

(2) In accordance with the rules adopted by the State Board of Pharmacy regarding the administration of drugs and devices.

SECTION 6. ORS 689.765, as amended by section 4, chapter 4, Oregon Laws 2008, is amended to read:

689.765. (1) [*No drugs shall be dispensed*] **Except as approved by rule by the State Board of Pharmacy, a person may not dispense drugs** to the public by means of automatic vending machines.

(2) As used in this section, "automatic vending machine" means any mechanical device or contrivance whereby the purchaser is able to secure drugs.

(3) [*No person shall*] **A person may not** adulterate for the purpose of sale any drug in such manner as to render it injurious to health, or knowingly sell or offer for sale any adulterated drug.

(4) [*No person shall*] **A person may not** manufacture, compound or sell or offer for sale or cause to be manufactured, compounded, sold or offered for sale any drug, compound or preparation for internal or external use under or by a name recognized in the United States Pharmacopoeia, Homeopathic Pharmacopoeia or National Formulary which differs from the standard of strength and purity specified therein as official at the time of manufacture, compounding, sale or offering for sale.

(5) [*No person shall*] **A person may not** manufacture, compound, sell or offer for sale, or cause to be manufactured, sold or offered for sale, any drug, the strength and purity of which falls below the professed standard of strength and purity under which it is sold.

(6) [*No person shall*] **A person may not** sell, give away, barter, dispense, distribute, buy, receive or possess any prescription drug except as authorized by law.

(7) [*No manufacturer or wholesaler shall*] **A manufacturer or wholesaler may not** sell or otherwise distribute, or offer to sell or otherwise distribute, any drug or device except to a person legally authorized to resell, dispense or otherwise redistribute such drug or device. The board may

grant an exemption from the requirement of this subsection in the form of a special permit if the board finds that an exemption is in the best interest of the public health and safety.

[*(8) Any practitioner who receives any complimentary samples of any controlled substance, as defined in ORS 475.005, shall keep the samples in a securely locked, substantially constructed cabinet and shall maintain a record of receipts and withdrawals from each inventory of samples. The record requirements shall be specified by rule of the licensing board that has jurisdiction over the practitioner's license. The licensing board may inspect the records and the inventory of samples.*]

[*(9)(a)*] **(8)(a)** [*No person may*] **A person may not** sell, purchase or trade or offer to sell, purchase or trade any drug sample.

(b) As used in paragraph (a) of this subsection, "drug sample" means a unit of a drug, subject to this chapter, that is not intended to be sold and is intended to promote the sale of the drug, and includes a coupon or other form which may be redeemed for a drug.

[*(10)*] **(9)** For purposes of this section and ORS 678.375, distribution of prepackaged complimentary samples of medications by a nurse practitioner or clinical nurse specialist with prescription writing authority shall not constitute dispensing when the sample medication is within the prescriptive authority granted to that nurse practitioner or clinical nurse specialist.

SECTION 7. Section 8 of this 2009 Act is added to and made a part of ORS chapter 689.

SECTION 8. A practitioner who receives a complimentary sample of a controlled substance as defined in ORS 475.005 shall keep the sample in a securely locked, substantially constructed cabinet and shall maintain a record of receipts and withdrawals from each inventory of samples. Each licensing board that has jurisdiction over a practitioner's license shall specify the recording requirements for complimentary samples by rule. The licensing board may inspect the records and the inventory of samples.

SECTION 9. ORS 442.580 is amended to read:

442.580. (1) There is created the Health Resources Commission, consisting of eleven members appointed by the Governor.

(2) The commission shall include:

(a) Four physicians, one of whom engages in family practice, and each of whom shall be licensed to practice in this state and experienced in health research and the evaluation of medical technologies and clinical outcomes;

(b) One representative of hospitals;

(c) One insurance industry representative;

(d) One business representative;

(e) One representative of labor organizations;

(f) One consumer representative; and

(g) Two pharmacists engaged in the practice of pharmacy, one of whom engages in the practice of pharmacy at a retail drug outlet. For the purposes of this paragraph:

(A) "Pharmacist" has the meaning given that term in ORS 689.005;

(B) "Practice of pharmacy" has the meaning given that term in ORS [*689.015*] **689.005**; and

(C) "Retail drug outlet" has the meaning given that term in ORS 689.005.

(3) The term of office of each member of the commission is three years. Each member serves at the pleasure of the Governor. Before the expiration of the term of a member, the Governor shall appoint a successor whose term begins on July 1 next following. A member is eligible for reappointment. If there is a vacancy for any cause, the Governor shall make an appointment to become immediately effective for the unexpired term.

(4) The consumer representative on the commission shall be entitled to compensation and expenses as provided in ORS 292.495. The other members shall not be entitled to compensation or expenses.

SECTION 10. This 2009 Act being necessary for the immediate preservation of the public peace, health and safety, an emergency is declared to exist, and this 2009 Act takes effect on its passage.

Passed by House April 30, 2009

Repassed by House June 1, 2009

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Chief Clerk of House

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Speaker of House

Passed by Senate May 28, 2009

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President of Senate

Received by Governor:

.....M.,....., 2009

Approved:

.....M.,....., 2009

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Governor

Filed in Office of Secretary of State:

.....M.,....., 2009

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Secretary of State