House Bill 3424

Sponsored by COMMITTEE ON HEALTH CARE (at the request of Oregon State Pharmacy Association)

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.**

Requires dispensing drug outlet in which drugs are stored and dispensed by health care practitioner to register with State Board of Pharmacy.

Declares emergency, effective on passage.

A BILL FOR AN ACT

Relating to drug outlets; creating new provisions; amending ORS 689.005 and 689.305; 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; 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) "Dispensing drug outlet" means a facility in which drugs are stored and may be dispensed by a practitioner to a patient or other individual entitled to receive the drug.

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.

[*(9)*] **(10)** "Distribute" means the delivery of a drug other than by administering or dispensing.

[*(10)*] **(11)** "Drug" means:

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

(b) Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in a human or other animal;

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

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

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

[*(12)*] **(13)** "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)*] **(14)** "Drug room" means a secure and lockable location within an inpatient care facility that does not have a licensed pharmacy.

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

[*(15)*] **(16)** "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)*] **(17)** "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)*] **(18)** "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)*] **(19)** "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)*] **(20)** "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)*] **(21)** "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)*] **(22)** "Manufacturer" means a person engaged in the manufacture of drugs.

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

[*(23)*] **(24)** "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)*] **(25)** "Person" means an individual, corporation, partnership, association or any other legal entity.

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

[*(26)*] **(27)** "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)*] **(28)** "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)*] **(29)** "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.

[*(29)*] **(30)** "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)*] **(31)** "Preceptor" means a pharmacist or a person licensed by the board to supervise the

internship training of a licensed intern.

[*(31)*] **(32)** "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)*] **(33)** "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)*] **(34)** "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)*] **(35)** "Shopkeeper" means a business or other establishment, open to the general public, for the sale or nonprofit distribution of drugs.

[*(35)*] **(36)** "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)*] **(37)** "Wholesale drug outlet" means any person who imports, stores, distributes or sells for resale any drugs including legend drugs and nonprescription drugs.

SECTION 2. ORS 689.305 is amended to read:

689.305. (1) All drug outlets shall annually register with the State Board of Pharmacy.

(2)(a) Each drug outlet shall apply for a certificate of registration in one or more of the following classifications:

(A) Retail drug outlet.

(B) Institutional drug outlet.

(C) Manufacturing drug outlet.

(D) Wholesale drug outlet.

(E) Nonprescription drug outlet.

(F) Dispensing drug outlet.

(b) [*No*] **An** individual who is employed by a corporation [*which*] **that** is registered under any classification listed in paragraph (a) of this subsection [*need*] **is not required to** register under the provisions of this section.

(3) The board shall establish by rule under the powers granted to it under ORS 689.155 and 689.205 the criteria [*which*] **that** each drug outlet must meet to qualify for registration in each classification designated in subsection (2)(a) of this section. The board may issue various types of certificates of registration with varying restrictions to the designated outlets where the board deems it necessary by reason of the type of drug outlet requesting a certificate.

(4) [*It shall be lawful for*] A drug outlet registered under this section [*to*] **may** sell and distribute

nonprescription drugs. Drug outlets engaging in the sale and distribution of such items [*shall not be deemed to be*] **are not** improperly engaged in the practice of pharmacy.

SECTION 3. (1) The amendments to ORS 689.005 and 689.305 by sections 1 and 2 of this 2011 Act become operative on January 1, 2012.

(2) The State Board of Pharmacy may take any action before the operative date specified in subsection (1) of this section to enable the board to exercise, on and after the operative date specified in subsection (1) of this section, all the duties, functions and powers conferred on the board by the amendments to ORS 689.005 and 689.305 by sections 1 and 2 of this 2011 Act.

SECTION 4. This 2011 Act being necessary for the immediate preservation of the public peace, health and safety, an emergency is declared to exist, and this 2011 Act takes effect on its passage.