House Bill 4122

Sponsored by Representatives BAILEY, FREEMAN, Senator BATES, Representative GREENLICK; Representatives COWAN, KOTEK, THOMPSON (Presession filed.)

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 pharmacy benefit managers conducting business in Oregon to obtain license from and annually renew license with State Board of Pharmacy. Requires board to examine and make financial reports of licensed pharmacy benefit managers. Requires disclosure of certain information to pharmacists, pharmacies or providers of certain health insurance plans. Subjects pharmacy benefit managers to general licensure and civil enforcement powers of board.

Becomes operative July 1, 2012.

Declares emergency, effective on passage.

A BILL FOR AN ACT

Relating to pharmacy benefit managers; creating new provisions; amending ORS 689.005, 689.832 and 689.995; and declaring an emergency.

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

REGULATION OF PHARMACY BENEFIT MANAGERS

(Subjection to General Powers of State Board of Pharmacy)

SECTION 1. Sections 2 to 4 of this 2012 Act are added to and made a part of ORS chapter 689.

(Licensure)

SECTION 2. (1) To conduct business in this state, a pharmacy benefit manager must obtain a license from and annually renew a license with the State Board of Pharmacy.

(2) To obtain a license under this section, a pharmacy benefit manager must:

(a) Submit an application on a form prescribed by the board by rule;

(b) Pay a licensure fee adopted by the board by rule;

(c) Submit the pharmacy benefit manager's balance sheet and income statement from the preceding calendar year or from the pharmacy benefit manager's preceding fiscal year, unless the pharmacy benefit manager is in its first year of conducting business; and

(d) Submit any other information relating to the operations of the pharmacy benefit manager required by the board by rule.

(3) To renew a license under this section, a pharmacy benefit manager must:

(a) Pay a renewal fee adopted by the board by rule;

(b) Submit the pharmacy benefit manager's balance sheet and income statement from the preceding calendar year or from the pharmacy benefit manager's preceding fiscal year; and

(c) Submit any other information relating to the operations of the pharmacy benefit

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.

manager required by the board by rule.

(4)(a) A pharmacy benefit manager must annually renew a license under this section:

(A) If the pharmacy benefit manager submits a balance sheet and income statement from the preceding calendar year, by March 1; or

(B) If the pharmacy benefit manager submits a balance sheet and income statement from the pharmacy benefit manager's preceding fiscal year, within two months of the date on which the pharmacy benefit manager's fiscal year ends.

(b) The board may extend the date by which a pharmacy benefit manager must renew a license for good cause shown. An extension made under this paragraph may not exceed 60 days.

(5) In adopting fees under subsections (2)(b) and (3)(a) of this section, the board shall adopt fees that are reasonably calculated to cover the costs incurred by the board in administering sections 2 to 4 of this 2012 Act.

(6) In adopting rules under subsections (2)(d) and (3)(c) of this section, the board shall adopt rules that permit a pharmacy benefit manager to submit copies of substantially similar information that the pharmacy benefit manager is required by the laws of this state to submit to the Department of Consumer and Business Services.

(7) The board may refuse to issue or renew, or may suspend, revoke or restrict, the license of any pharmacy benefit manager for violation of this section.

(8) The board shall deposit all moneys collected under this section into the State Board of Pharmacy Account established in ORS 689.139.

(Financial Examinations)

SECTION 3. (1) Using the information submitted by a pharmacy benefit manager under section 2 of this 2012 Act, the State Board of Pharmacy shall:

(a) Examine and make a report on the finances of each pharmacy benefit manager that conducts business in this state; or

(b) If the pharmacy benefit manager is required to submit substantially similar information under the laws of another state, keep on file a notarized report prepared by a public body of that state that is responsible for keeping and maintaining that information.

(2) The board shall annually update reports made and kept under this section.

(3) The board may contract with an independent financial consultant to make an examination and a report under this section.

(Disclosure Requirements)

SECTION 4. (1) As used in this section, "trade secret" has the meaning given that term in ORS 192.501.

(2) The State Board of Pharmacy, upon request, shall provide a copy of any information submitted by a pharmacy benefit manager under section 2 of this 2012 Act or prepared by the board or an independent financial consultant under section 3 of this 2012 Act to a pharmacist, pharmacy or provider of a health insurance plan for which the pharmacy benefit manager processes or pays prescription drug claims.

(3) The board may disclose any information submitted by a pharmacy benefit manager

under section 2 of this 2012 Act or prepared by the board or an independent financial consultant under section 3 of this 2012 Act that does not constitute a trade secret to any person who requests the information, but the board may disclose information that constitutes a trade secret only to a pharmacist, pharmacy or the provider of a health insurance plan for which the pharmacy benefit manager processes or pays prescription drug claims.

(Definition of "Pharmacy Benefit Manager")

SECTION 5. 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) "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 benefit manager" means an entity that negotiates and executes contracts with pharmacies, manages preferred drug lists or negotiates rebates with prescription drug manufacturers.

[*(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 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 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.

(Penalties)

SECTION 6. ORS 689.832 is amended to read:

689.832. (1) In addition to any other liability or penalty provided by law, the State Board of Pharmacy may impose a civil penalty for any violation of the provisions of this chapter or ORS chapter 475 or any rule of the board. A civil penalty imposed under this subsection may not exceed $1,000 for each violation by an individual and $10,000 for each violation by a drug outlet **or pharmacy benefit manager**.

(2) All penalties recovered under this section shall be deposited into the State Board of Pharmacy Account established in ORS 689.139.

(3) Any civil penalty under this section shall be imposed in the manner provided in ORS 183.745.

(4) Notwithstanding ORS 183.745, the person to whom the notice is addressed shall have 10 days from the date of service of the notice in which to make written application for a hearing before the board.

SECTION 7. ORS 689.995 is amended to read:

689.995. (1)**(a)** Violation of any provision of this chapter or of any rule of the State Board of Pharmacy is a misdemeanor.

(b) This subsection does not apply to sections 2 to 4 of this 2012 Act or any rule adopted by the board under sections 2 to 4 of this 2012 Act.

(2) Failure to comply with any notice, citation or subpoena issued by the board under ORS 689.135 (12) is a misdemeanor. Each day during which the violation continues is a separate offense.

(3)**(a)** Refusal to furnish information required under this chapter or willfully furnishing false information, is a misdemeanor.

(b) This subsection does not apply to sections 2 to 4 of this 2012 Act.

(4) Any attempt to secure or the securing of registration or licensure for any person under any certificate, license or permit authorized by this chapter by making or causing to be made any false representations is a misdemeanor.

OPERATIVE DATE

SECTION 8. (1) Sections 1 to 4 of this 2012 Act and the amendments to ORS 689.005, 689.832 and 689.995 by sections 5 to 7 of this 2012 Act become operative on July 1, 2012.

(2) Notwithstanding the operative date specified in subsection (1) of this section, the State Board of Pharmacy may take any action before the operative date that is necessary 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 sections 1 to 4 of this 2012 Act and the amendments to ORS 689.005, 689.832 and 689.995 by sections 5 to 7 of this 2012 Act.

UNIT CAPTIONS

SECTION 9. The unit captions used in this 2012 Act are provided only for the convenience of the reader and do not become part of the statutory law of this state or express any legislative intent in the enactment of this 2012 Act.

EMERGENCY CLAUSE

SECTION 10. This 2012 Act being necessary for the immediate preservation of the public peace, health and safety, an emergency is declared to exist, and this 2012 Act takes effect on its passage.