HB 4122-2
(LC 143)
2/2/12 (LHF/mbm/ps)

PROPOSED AMENDMENTS TO
HOUSE BILL 4122

On page 1 on the printed bill, delete lines 14 through 28.

On page 2, delete lines 1 through 21 and insert:

"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.

"(b) Pay a licensure fee, not to exceed $____, adopted by the board.

"(c) Submit the formulas and an explanation of the processes used by the pharmacy benefit manager to:

"(A) Determine which drugs to place on a payment schedule that specifies maximum allowable costs;

"(B) Adjust the maximum allowable costs specified on a payment schedule; and

"(C) Reimburse pharmacies or pharmacists for prescribing a drug.

"(d) Provide, for the previous calendar year or the pharmacy benefit manager's previous fiscal year, an accounting of:

"(A) All rebate revenue received by the pharmacy benefit manager from pharmaceutical manufacturers or subsidiaries of pharmaceutical manufacturers;

"(B) All revenue derived from collecting the difference between the

amount reimbursed by the pharmacy benefit manager to a pharmacy or pharmacist for a prescribed drug and the amount reimbursed by the insurance plan that provides coverage for that drug to the pharmacy benefit manager;

"(C) All revenue derived from substituting a different drug of similar therapeutic value for a prescribed drug; and

"(D) All revenue derived from dispensing and distributing drugs by mail.

"(e) Submit or provide an accounting of any other information required by the board by rule.

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

"(a) Pay a renewal fee, not to exceed $____, adopted by the board.

"(b) Update any formulas or explanations submitted under subsection (2)(c) of this section or required by rule under subsection (2)(e) of this section.

"(c) Provide, for the previous calendar year or the pharmacy benefit manager's previous fiscal year, an accounting of all information described in subsection (2)(d) of this section or required by rule under subsection (2)(e) of this section.

"(d) Disclose, for the previous period of licensure, the number of times that the pharmacy benefit manager adjusted each maximum allowable cost specified on a payment schedule.

"(e) Renew the license by the date specified in subsection (4) of this section.

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

"(A) By March 1, if the pharmacy benefit manager provides an accounting of the information described in subsection (2)(d) of this section for the previous calendar year; or

"(B) Within two months of the date on which the pharmacy benefit manager's fiscal year ends, if the pharmacy benefit manager provides an accounting of the information described in subsection (2)(d) of this section for the pharmacy benefit manager's previous fiscal year.

"(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 90 days.

"(5) A pharmacy benefit manager that provides services to the state for purposes related to the state's medical assistance program is exempt from the requirements of this section with respect to the provision of those services.

"(6) 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.

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

In line 25, after "submitted" insert "or provided".

In line 29, after "submit" insert "or provide".

In line 41, after "submitted" insert "or provided".

In line 44, delete "prescription drug claims" and insert "claims for prescribed drugs".

In line 45, after "submitted" insert "or provided".

On page 3, line 4, delete "pharmacist,".

In line 5, delete "prescription drug claims" and insert "claims for prescribed drugs".

Delete line 7 and insert "(Definitions)".

Delete lines 9 through 45 and delete pages 4 and 5.

On page 6, delete lines 1 through 16 and insert:

"**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 facili-

ties 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) 'Maximum allowable cost' means the maximum amount, as established by a pharmacy benefit manager, to be paid for a unit of a drug or a unit of an ingredient in a drug.**

"[*(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.

"**(28)(a) 'Pharmacy benefit manager' means a nongovernmental entity that serves as the contractor between a network of pharmacies or pharmacists and a provider of health insurance coverage and that:**

"(A) Contracts with pharmacies or pharmacists for the procurement of prescribed drugs;

"(B) Processes claims for prescribed drugs for, or provides retail network management for, pharmacies or pharmacists;

"(C) Makes payments for claims for prescribed drugs to pharmacies or pharmacists;

"(D) Negotiates rebates with drug manufacturers for drugs procured or paid for as described in subparagraphs (A) and (C) of this paragraph;

"(E) Manages preferred drug lists;

"(F) Dispenses and distributes drugs by mail;

"(G) Substitutes drugs of similar therapeutic value for prescribed drugs; or

"(H) Conducts programs related to disease management, patient compliance or therapeutic intervention.

"(b) 'Pharmacy benefit manager' does not include a provider of health insurance coverage that performs any of the services described in paragraph (a) of this subsection.

"[*(27)*] **(29)** '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)*] **(30)** '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)*] **(31)** '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)*] **(32)** 'Preceptor' means a pharmacist or a person licensed by the board to supervise the internship training of a licensed intern.

"[*(31)*] **(33)** '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)*] **(34)** '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)*] **(35)** '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)*] **(36)** 'Shopkeeper' means a business or other establishment, open to the general public, for the sale or nonprofit distribution of drugs.

"[*(35)*] **(37)** '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)*] **(38)** 'Wholesale drug outlet' means any person who imports, stores, distributes or sells for resale any drugs including legend drugs and nonprescription drugs.".