HB 4124-2
(LC 181)
2/3/16 (SCT/ps)

Requested by Representative WILLIAMSON

PROPOSED AMENDMENTS TO
HOUSE BILL 4124

On page 1 of the printed bill, line 2, after "431A.865" delete the rest of the line and insert ", 689.005, 689.681 and 689.683; and".

On page 5, after line 11, 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) 'Clinical pharmacy agreement' means an agreement between a pharmacist or pharmacy and a health care organization or a physician as defined in ORS 677.010 that permits the pharmacist to engage in the practice of clinical pharmacy for the benefit of the patients of the health care organization or physician.

"(5) '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.

"(6) 'Continuing pharmacy education unit' means the unit of measurement of credits for approved continuing education courses and programs.

"(7) '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.

"(8) '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.

"(9) '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.

"(10) 'Distribute' means the delivery of a drug other than by administering or dispensing.

"(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.

"(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.

"(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.

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

"(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.

"[*(16) 'Hormonal contraceptive patch' means a transdermal patch applied to the skin of a patient, by the patient or by a practitioner, that releases a drug composed of a combination of hormones that is approved by the United States Food and Drug Administration to prevent pregnancy.*]

"**(16) 'Hormonal contraceptive injection' means an injection, administered to a patient by a practitioner, that releases a drug composed of a combination of hormones that is approved by the United States Food and Drug Administration to prevent pregnancy.**

"(17) '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.

"(18) '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.

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

"(20) '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.

"(21) '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.

"(22) '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.

"(23) 'Manufacturer' means a person engaged in the manufacture of drugs.

"(24) 'Nonprescription drug outlet' means shopkeepers and itinerant vendors registered under ORS 689.305.

"(25) '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.

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

"(27) 'Pharmacist' means an individual licensed by this state to engage in the practice of pharmacy or to engage in the practice of clinical pharmacy.

"(28) '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.

"(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.

"(30) 'Practice of clinical pharmacy' means:

"(a) The health science discipline in which, in conjunction with the patient's other practitioners, a pharmacist provides patient care to optimize medication therapy and to promote disease prevention and the patient's health and wellness;

"(b) The provision of patient care services, including but not limited to post-diagnostic disease state management services; and

"(c) The practice of pharmacy by a pharmacist pursuant to a clinical pharmacy agreement.

"(31) '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 and the providing of patient care services 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;

"(i) The optimizing of drug therapy through the practice of clinical pharmacy;

"(j) Patient care services, including medication therapy management and comprehensive medication review;

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

"**(L) The prescribing and administering of hormonal contraceptive injections pursuant to ORS 689.683; and**

"[*(L)*] **(m)** The prescribing and dispensing of [*hormonal contraceptive patches and*] self-administered [*oral*] hormonal contraceptives pursuant to ORS 689.683.

"(32) '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 Sub-

stances Act.

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

"(34) '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.

"(35) '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.

"(36) '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.

"(37) 'Self-administered [*oral*] hormonal contraceptive' means a drug composed of a combination of hormones that is approved by the United States Food and Drug Administration to prevent pregnancy and that the patient to whom the drug is prescribed may take orally **or may otherwise self-administer**.

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

"(39) '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.

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

"SECTION 6. ORS 689.683 is amended to read:

"689.683. (1)**(a)** In accordance with **paragraph (b) of this subsection and** rules adopted by the State Board of Pharmacy under ORS 689.205, a pharmacist may**:**

"(A) Prescribe and administer hormonal contraceptive injections; and

"(B) Prescribe and dispense [*hormonal contraceptive patches and*] self-administered [*oral*] hormonal contraceptives**.**

"(b) A pharmacist may prescribe and administer hormonal contraceptive injections and prescribe and dispense self-administered hormonal contraceptives to a person who is:

"[*(a)*] **(A)** At least 18 years of age, regardless of whether the person has evidence of a previous prescription from a primary care practitioner or women's health care practitioner for a hormonal contraceptive [*patch*] **injection** or self-administered [*oral*] hormonal contraceptive; or

"[*(b)*] **(B)** Under 18 years of age, only if the person has evidence of a previous prescription from a primary care practitioner or women's health care practitioner for a hormonal contraceptive [*patch*] **injection** or self-administered [*oral*] hormonal contraceptive.

"(2)(a) The board shall adopt rules to establish, in consultation with the Oregon Medical Board, the Oregon State Board of Nursing and the Oregon Health Authority, and in consideration of guidelines established by the American Congress of Obstetricians and Gynecologists, standard procedures for the prescribing of hormonal contraceptive [*patches*] **injections** and self-

administered [*oral*] hormonal contraceptives by pharmacists.

"(b) The rules adopted under this subsection must require a pharmacist to:

"(A) Complete a training program approved by the State Board of Pharmacy that is related to prescribing hormonal contraceptive [*patches*] **injections** and self-administered [*oral*] hormonal contraceptives;

"(B) Provide a self-screening risk assessment tool that the patient must use prior to the pharmacist's prescribing the hormonal contraceptive [*patch*] **injection** or self-administered [*oral*] hormonal contraceptive;

"**(C) Provide counseling to the patient about hormonal contraceptive injections and self-administered hormonal contraceptives;**

"[*(C)*] **(D)** Refer the patient to the patient's primary care practitioner or women's health care practitioner upon prescribing and **administering the hormonal contraceptive injection or prescribing and** dispensing the [*hormonal contraceptive patch or*] self-administered [*oral*] hormonal contraceptive;

"[*(D)*] **(E)** Provide the patient with a written record of the hormonal contraceptive [*patch*] **injection prescribed and administered** or **the** self-administered [*oral*] hormonal contraceptive prescribed and dispensed and advise the patient to consult with a primary care practitioner or women's health care practitioner; and

"[*(E)*] **(F) Administer the hormonal contraceptive injection or** dispense the [*hormonal contraceptive patch or*] self-administered [*oral*] hormonal contraceptive to the patient as soon as practicable after the pharmacist issues the prescription.

"(c) The rules adopted under this subsection must prohibit a pharmacist from:

"(A) Requiring a patient to schedule an appointment with the pharmacist for the prescribing or **administering of a hormonal contraceptive in-**

jection or the prescribing or dispensing of a [*hormonal contraceptive patch or*] self-administered [*oral*] hormonal contraceptive; and

"(B) Prescribing and **administering a hormonal contraceptive injection or prescribing and** dispensing a [*hormonal contraceptive patch or*] self-administered [*oral*] hormonal contraceptive to a patient who does not have evidence of a clinical visit for women's health within the three years immediately following the initial prescription and **administration of a hormonal contraceptive injection or the initial prescription and** dispensation of a [*hormonal contraceptive patch or*] self-administered [*oral*] hormonal contraceptive by a pharmacist to the patient.

"(3) All state and federal laws governing insurance coverage of contraceptive drugs, devices, products and services shall apply to hormonal contraceptive [*patches*] **injections** and self-administered [*oral*] hormonal contraceptives prescribed by a pharmacist under this section.

"SECTION 7. ORS 689.683, as amended by section 3, chapter 649, Oregon Laws 2015, is amended to read:

"689.683. (1) In accordance with rules adopted by the State Board of Pharmacy under ORS 689.205, a pharmacist may**:**

"**(a) Prescribe and administer hormonal contraceptive injections; and**

"(b) Prescribe and dispense [*hormonal contraceptive patches and*] self-administered [*oral*] hormonal contraceptives.

"(2)(a) The board shall adopt rules to establish, in consultation with the Oregon Medical Board, the Oregon State Board of Nursing and the Oregon Health Authority, and in consideration of guidelines established by the American Congress of Obstetricians and Gynecologists, standard procedures for the prescribing of hormonal contraceptive [*patches*] **injections** and self-administered [*oral*] hormonal contraceptives by pharmacists.

"(b) The rules adopted under this subsection must require a pharmacist to:

"(A) Complete a training program approved by the State Board of Pharmacy that is related to prescribing hormonal contraceptive [*patches*] **injections** and self-administered [*oral*] hormonal contraceptives;

"(B) Provide a self-screening risk assessment tool that the patient must use prior to the pharmacist's prescribing the hormonal contraceptive [*patch*] **injection** or self-administered [*oral*] hormonal contraceptive;

"**(C) Provide counseling to the patient about hormonal contraceptive injections and self-administered hormonal contraceptives;**

"[*(C)*] **(D)** Refer the patient to the patient's primary care practitioner or women's health care practitioner upon prescribing and **administering the hormonal contraceptive injection or prescribing and** dispensing the [*hormonal contraceptive patch or*] self-administered [*oral*] hormonal contraceptive;

"[*(D)*] **(E)** Provide the patient with a written record of the hormonal contraceptive [*patch*] **injection prescribed and administered** or **the** self-administered [*oral*] hormonal contraceptive prescribed and dispensed and advise the patient to consult with a primary care practitioner or women's health care practitioner; and

"[*(E)*] **(F) Administer the hormonal contraceptive injection or** dispense the [*hormonal contraceptive patch or*] self-administered [*oral*] hormonal contraceptive to the patient as soon as practicable after the pharmacist issues the prescription.

"(c) The rules adopted under this subsection must prohibit a pharmacist from:

"(A) Requiring a patient to schedule an appointment with the pharmacist for the prescribing or **administering of a hormonal contraceptive injection or the prescribing or** dispensing of a [*hormonal contraceptive patch or*] self-administered [*oral*] hormonal contraceptive; and

"(B) Prescribing and **administering a hormonal contraceptive in-**

jection or prescribing and dispensing a [*hormonal contraceptive patch or*] self-administered [*oral*] hormonal contraceptive to a patient who does not have evidence of a clinical visit for women's health within the three years immediately following the initial prescription and **administration of a hormonal contraceptive injection or the initial prescription and** dispensation of a [*hormonal contraceptive patch or*] self-administered [*oral*] hormonal contraceptive by a pharmacist to the patient.

"(3) All state and federal laws governing insurance coverage of contraceptive drugs, devices, products and services shall apply to hormonal contraceptive [*patches*] **injections** and self-administered [*oral*] hormonal contraceptives prescribed by a pharmacist under this section.".

In line 12, delete "5" and insert "8".
