HB 2879-4 (LC 3193) 5/19/15 (SCT/ps)

PROPOSED AMENDMENTS TO HOUSE BILL 2879

1 On page 1 of the printed bill, line 2, after the semicolon insert "creating 2 new provisions; amending ORS 689.005;".

3 Delete lines 4 through 30 and delete <u>page 2</u> and insert:

4 "SECTION 1. Section 2 of this 2015 Act is added to and made a part
5 of ORS chapter 689.

6 "<u>SECTION 2.</u> (1) In accordance with rules adopted by the State 7 Board of Pharmacy under ORS 689.205, a pharmacist may prescribe and 8 dispense hormonal contraceptive patches and self-administered oral 9 hormonal contraceptives to a person who is:

"(a) At least 18 years of age, regardless of whether the person has
 evidence of a previous prescription from a primary care practitioner
 for a hormonal contraceptive patch or self-administered oral hormonal
 contraceptive; or

"(b) Under 18 years of age, only if the person has evidence of a
 previous prescription from a primary care practitioner for a hormonal
 contraceptive patch or self-administered oral hormonal contraceptive.

"(2)(a) The board shall adopt rules to establish, in consultation with the Oregon Medical Board and the Oregon Health Authority, and in consideration of guidelines established by the American Congress of Obstetricians and Gynecologists, standard procedures for the prescribing and dispensing of hormonal contraceptive patches and selfadministered oral hormonal contraceptives by pharmacists. 1 "(b) The rules adopted under this subsection must require a 2 pharmacist to:

"(A) Complete a training program approved by the State Board of
 Pharmacy that is related to prescribing hormonal contraceptive
 patches 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 or self-administered oral hormonal contraceptive;
"(C) Refer the patient to the patient's primary care practitioner
upon prescribing and dispensing the hormonal contraceptive patch or
self-administered oral hormonal contraceptive;

12 "(D) Provide the patient with a written record of the hormonal 13 contraceptive patch or self-administered oral hormonal contraceptive 14 prescribed and dispensed and advise the patient to consult with a pri-15 mary care practitioner; and

"(E) 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 dispensing of a hormonal
 contraceptive patch or self-administered oral hormonal contraceptive;
 and

(B) 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 dispensation of a hormonal contraceptive patch or self-administered oral hormonal contraceptive by a pharmacist to the patient.

- "SECTION 3. ORS 689.005 is amended to read: 1
- "689.005. As used in this chapter: $\mathbf{2}$

"(1) 'Administer' means the direct application of a drug or device whether 3 by injection, inhalation, ingestion, or any other means, to the body of a pa-4 tient or research subject by: $\mathbf{5}$

"(a) A practitioner or the practitioner's authorized agent; or 6

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"(b) The patient or research subject at the direction of the practitioner.

"(2) 'Approved continuing pharmacy education program' means those 8 seminars, classes, meetings, workshops and other educational programs on 9 the subject of pharmacy approved by the board. 10

"(3) 'Board of pharmacy' or 'board' means the State Board of Pharmacy. 11

"(4) 'Continuing pharmacy education' means: 12

"(a) Professional, pharmaceutical post-graduate education in the general 13 areas of socio-economic and legal aspects of health care; 14

"(b) The properties and actions of drugs and dosage forms; and 15

"(c) The etiology, characteristics and therapeutics of the disease state. 16

(5) 'Continuing pharmacy education unit' means the unit of measurement 17 of credits for approved continuing education courses and programs. 18

"(6) 'Deliver' or 'delivery' means the actual, constructive or attempted 19 transfer of a drug or device other than by administration from one person 20to another, whether or not for a consideration. 21

"(7) 'Device' means an instrument, apparatus, implement, machine, 22contrivance, implant, in vitro reagent or other similar or related article, in-23cluding any component part or accessory, which is required under federal 24or state law to be prescribed by a practitioner and dispensed by a 25pharmacist. 26

"(8) 'Dispense' or 'dispensing' means the preparation and delivery of a 27prescription drug pursuant to a lawful order of a practitioner in a suitable 28container appropriately labeled for subsequent administration to or use by 29 a patient or other individual entitled to receive the prescription drug. 30

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

3 "(10) 'Drug' means:

4 "(a) Articles recognized as drugs in the official United States
5 Pharmacopoeia, official National Formulary, official Homeopathic
6 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;

9 "(c) Articles, other than food, intended to affect the structure or any 10 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) '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.

6 "[(15)] (16) 'Institutional drug outlet' means hospitals and inpatient care 7 facilities where medications are dispensed to another health care profes-8 sional for administration to patients served by the hospitals or facilities.

9 "[(16)] (17) 'Intern' means a person who is enrolled in or has completed 10 a course of study at a school or college of pharmacy approved by the board 11 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.

¹⁵ "[(18)] (19) 'Itinerant vendor' means a person who sells or distributes ¹⁶ nonprescription drugs by passing from house to house, or by haranguing the ¹⁷ people on the public streets or in public places, or who uses the customary ¹⁸ devices for attracting crowds, recommending their wares and offering them ¹⁹ 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 adrug:

"(a) By a practitioner as an incident to administering or dispensing of a
drug in the course of professional practice; or

5 "(b) By a practitioner or by the practitioner's authorization under super-6 vision of the practitioner for the purpose of or as an incident to research, 7 teaching or chemical analysis and not for sale.

8 "[(21)] (22) 'Manufacturer' means a person engaged in the manufacture
9 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, asso ciation 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.

²⁹ "[(28)] (29) 'Practice of pharmacy' means:

30 "(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
7 ORS 689.655;

8 "(e) The participation in drug selection and drug utilization reviews;

9 "(f) The proper and safe storage of drugs and devices and the maintenance
10 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; and

"(j) The prescribing and dispensing of hormonal contraceptive
 patches and self-administered oral hormonal contraceptives pursuant
 to section 2 of this 2015 Act.

"[(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:

25 "(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.

9 "[(32)] (33) 'Prescription' or 'prescription drug order' means a written, 10 oral or electronically transmitted direction, given by a practitioner author-11 ized to prescribe drugs, for the preparation and use of a drug. When the 12 context requires, 'prescription' also means the drug prepared under such 13 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.

"(35) '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.

"[(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.

30 "[(36)] (38) 'Wholesale drug outlet' means any person who imports, stores,

1 distributes or sells for resale any drugs including legend drugs and
2 nonprescription drugs.

"SECTION 4. (1) Section 2 of this 2015 Act and the amendments to
ORS 689.005 by section 3 of this 2015 Act become operative on January
1, 2016.

6 "(2) The State Board of Pharmacy may take any action before the 7 operative date specified in subsection (1) of this section that is neces-8 sary for the board to exercise, on and after the operative date specified 9 in subsection (1) of this section, all of the duties, function and powers 10 conferred on the board by section 2 of this 2015 Act and the amend-11 ments to ORS 689.005 by section 3 of this 2015 Act.

"SECTION 5. This 2015 Act being necessary for the immediate
 preservation of the public peace, health and safety, an emergency is
 declared to exist, and this 2015 Act takes effect on its passage.".

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