S-4549.1

SUBSTITUTE SENATE BILL 6467

State of Washington 64th Legislature 2016 Regular Session

By Senate Health Care (originally sponsored by Senators Rivers, Darneille, Litzow, Fain, Rolfes, Hill, Keiser, Liias, and Chase)

READ FIRST TIME 02/05/16.

AN ACT Relating to permitting pharmacists to prescribe and dispense contraceptive patches, contraceptive rings, and oral contraception; amending RCW 18.64.011; reenacting and amending RCW 69.41.030; adding a new section to chapter 18.64 RCW; and prescribing penalties.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

Sec. 1. RCW 69.41.030 and 2013 c 71 s 1 and 2013 c 12 s 1 are each reenacted and amended to read as follows:

(1) It shall be unlawful for any person to sell, deliver, or possess any legend drug except upon the order or prescription of a physician under chapter 18.71 RCW, an osteopathic physician and surgeon under chapter 18.57 RCW, an optometrist licensed under chapter 18.53 RCW who is certified by the optometry board under RCW 18.53.010, a dentist under chapter 18.32 RCW, a podiatric physician and surgeon under chapter 18.22 RCW, a veterinarian under chapter 18.92 RCW, a commissioned medical or dental officer in the United States armed forces or public health service in the discharge of his or her official duties, a duly licensed physician or dentist employed by the veterans administration in the discharge of his or her official duties, a registered nurse or advanced registered nurse practitioner under chapter 18.79 RCW when authorized by the nursing

care quality assurance commission, a pharmacist licensed under chapter 18.64 RCW to the extent permitted by drug therapy guidelines or protocols established under RCW 18.64.011 and authorized by the ((~~board of~~)) pharmacy quality assurance commission and approved by a practitioner authorized to prescribe drugs, a pharmacist licensed under chapter 18.64 RCW to the extent permitted by section 3 of this act, an osteopathic physician assistant under chapter 18.57A RCW when authorized by the board of osteopathic medicine and surgery, a physician assistant under chapter 18.71A RCW when authorized by the medical quality assurance commission, or any of the following professionals in any province of Canada that shares a common border with the state of Washington or in any state of the United States: A physician licensed to practice medicine and surgery or a physician licensed to practice osteopathic medicine and surgery, a dentist licensed to practice dentistry, a podiatric physician and surgeon licensed to practice podiatric medicine and surgery, a licensed advanced registered nurse practitioner, a licensed physician assistant, a licensed osteopathic physician assistant, or a veterinarian licensed to practice veterinary medicine: PROVIDED, HOWEVER, That the above provisions shall not apply to sale, delivery, or possession by drug wholesalers or drug manufacturers, or their agents or employees, or to any practitioner acting within the scope of his or her license, or to a common or contract carrier or warehouse operator, or any employee thereof, whose possession of any legend drug is in the usual course of business or employment: PROVIDED FURTHER, That nothing in this chapter or chapter 18.64 RCW shall prevent a family planning clinic that is under contract with the health care authority from selling, delivering, possessing, and dispensing commercially prepackaged oral contraceptives prescribed by authorized, licensed health care practitioners.

(2)(a) A violation of this section involving the sale, delivery, or possession with intent to sell or deliver is a class B felony punishable according to chapter 9A.20 RCW.

(b) A violation of this section involving possession is a misdemeanor.

Sec. 2. RCW 18.64.011 and 2015 c 234 s 3 are each amended to read as follows:

The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.

(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.

(2) "Business licensing system" means the mechanism established by chapter 19.02 RCW by which business licenses, endorsed for individual state-issued licenses, are issued and renewed utilizing a business license application and a business license expiration date common to each renewable license endorsement.

(3) "Commission" means the pharmacy quality assurance commission.

(4) "Compounding" means the act of combining two or more ingredients in the preparation of a prescription.

(5) "Controlled substance" means a drug or substance, or an immediate precursor of such drug or substance, so designated under or pursuant to the provisions of chapter 69.50 RCW.

(6) "Deliver" or "delivery" means the actual, constructive, or attempted transfer from one person to another of a drug or device, whether or not there is an agency relationship.

(7) "Department" means the department of health.

(8) "Device" means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (a) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or other animals, or (b) to affect the structure or any function of the body of human beings or other animals.

(9) "Dispense" means the interpretation of a prescription or order for a drug, biological, or device and, pursuant to that prescription or order, the proper selection, measuring, compounding, labeling, or packaging necessary to prepare that prescription or order for delivery.

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

(11) "Drug" and "devices" do not include surgical or dental instruments or laboratory materials, gas and oxygen, therapy equipment, X-ray apparatus or therapeutic equipment, their component parts or accessories, or equipment, instruments, apparatus, or contrivances used to render such articles effective in medical, surgical, or dental treatment, or for use or consumption in or for mechanical, industrial, manufacturing, or scientific applications or purposes. "Drug" also does not include any article or mixture covered by the Washington pesticide control act (chapter 15.58 RCW), as

enacted or hereafter amended, nor medicated feed intended for and used exclusively as a feed for animals other than human beings.

(12) "Drugs" means:

(a) Articles recognized in the official United States pharmacopoeia or the official homeopathic pharmacopoeia of the United States;

(b) Substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or other animals;

(c) Substances (other than food) intended to affect the structure or any function of the body of human beings or other animals; or

(d) Substances intended for use as a component of any substances specified in (a), (b), or (c) of this subsection, but not including devices or their component parts or accessories.

(13) "Health care entity" means an organization that provides health care services in a setting that is not otherwise licensed by the state to acquire or possess legend drugs. Health care entity includes a freestanding outpatient surgery center, a residential treatment facility, and a freestanding cardiac care center. "Health care entity" does not include an individual practitioner's office or a multipractitioner clinic, regardless of ownership, unless the owner elects licensure as a health care entity. "Health care entity" also does not include an individual practitioner's office or multipractitioner clinic identified by a hospital on a pharmacy application or renewal pursuant to RCW 18.64.043.

(14) "Labeling" means the process of preparing and affixing a label to any drug or device container. The label must include all information required by current federal and state law and pharmacy rules.

(15) "Legend drugs" means any drugs which are required by any applicable federal or state law or regulation to be dispensed on prescription only or are restricted to use by practitioners only.

(16) "Manufacture" means the production, preparation, propagation, compounding, or processing of a drug or other substance or device or the packaging or repackaging of such substance or device, or the labeling or relabeling of the commercial container of such substance or device, but does not include the activities of a practitioner who, as an incident to his or her administration or dispensing such substance or device in the course of his or her professional practice, personally prepares, compounds, packages, or

labels such substance or device. "Manufacture" includes the distribution of a licensed pharmacy compounded drug product to other state licensed persons or commercial entities for subsequent resale or distribution, unless a specific product item has approval of the commission. The term does not include:

(a) The activities of a licensed pharmacy that compounds a product on or in anticipation of an order of a licensed practitioner for use in the course of their professional practice to administer to patients, either personally or under their direct supervision;

(b) The practice of a licensed pharmacy when repackaging commercially available medication in small, reasonable quantities for a practitioner legally authorized to prescribe the medication for office use only;

(c) The distribution of a drug product that has been compounded by a licensed pharmacy to other appropriately licensed entities under common ownership or control of the facility in which the compounding takes place; or

(d) The delivery of finished and appropriately labeled compounded products dispensed pursuant to a valid prescription to alternate delivery locations, other than the patient's residence, when requested by the patient, or the prescriber to administer to the patient, or to another licensed pharmacy to dispense to the patient.

(17) "Manufacturer" means a person, corporation, or other entity engaged in the manufacture of drugs or devices.

(18) "Nonlegend" or "nonprescription" drugs means any drugs which may be lawfully sold without a prescription.

(19) "Person" means an individual, corporation, government, governmental subdivision or agency, business trust, estate, trust, partnership or association, or any other legal entity.

(20) "Pharmacist" means a person duly licensed by the commission to engage in the practice of pharmacy.

(21) "Pharmacy" means every place properly licensed by the commission where the practice of pharmacy is conducted.

(22) "Poison" does not include any article or mixture covered by the Washington pesticide control act (chapter 15.58 RCW), as enacted or hereafter amended.

(23) "Practice of pharmacy" includes the practice of and responsibility for:

(a) Interpreting prescription orders; ((~~the~~))

(b) Compounding, dispensing, labeling, administering, and distributing of drugs and devices; ((~~the~~))

(c) Monitoring of drug therapy and use; ((~~the~~))

(d) Initiating or modifying of drug therapy in accordance with written guidelines or protocols previously established and approved for his or her practice by a practitioner authorized to prescribe drugs; ((~~the~~))

(e) Prescribing and dispensing contraceptive patches, contraceptive rings, and oral contraceptives as provided in section 3 of this act;

(f) Participating in drug utilization reviews and drug product selection; ((~~the~~))

(g) Proper and safe storing and distributing of drugs and devices and maintenance of proper records thereof; ((~~the~~)) and

(h) Providing of information on legend drugs which may include, but is not limited to, the advising of therapeutic values, hazards, and the uses of drugs and devices.

(24) "Practitioner" means a physician, dentist, veterinarian, nurse, or other person duly authorized by law or rule in the state of Washington to prescribe drugs.

(25) "Prescription" means an order for drugs or devices issued by a practitioner duly authorized by law or rule in the state of Washington to prescribe drugs or devices in the course of his or her professional practice for a legitimate medical purpose.

(26) "Secretary" means the secretary of health or the secretary's designee.

(27) "Wholesaler" means a corporation, individual, or other entity which buys drugs or devices for resale and distribution to corporations, individuals, or entities other than consumers.

(28) "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.

(29) "Contraceptive ring" means a flexible vaginal ring that releases a continuous low dose of hormones that is approved by the United States food and drug administration to prevent pregnancy.

(30) "Oral contraceptive" means a progestin-only drug or 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.

NEW SECTION. **Sec. 3.** A new section is added to chapter 18.64 RCW to read as follows:

(1) A pharmacist may prescribe and dispense contraceptive patches, contraceptive rings, and oral contraceptives to a person who is:

(a) At least eighteen 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 contraceptive patch, contraceptive ring, or oral contraceptive; or

(b) Under eighteen years of age, only if the person has evidence of a previous prescription for a contraceptive patch, contraceptive ring, or oral contraceptive.

(2) The commission must adopt rules to establish, in consultation with the medical quality assurance commission and the nursing quality assurance commission, and in consideration of guidelines established by the American congress of obstetricians and gynecologists, standard procedures for the prescribing of contraceptive patches, contraceptive rings, and oral contraceptives by pharmacists. The rules adopted must require a pharmacist to:

(a) Complete a training program approved by the commission that is related to prescribing contraceptive patches, contraceptive rings, and oral contraceptives;

(b) Provide a self-screening risk assessment tool that the patient must use before the pharmacist prescribes the contraceptive patch, contraceptive ring, or oral contraceptive. The self-screening risk assessment tool must assist the pharmacist in determining which contraceptive option is the most appropriate to meet the patient's needs if the patient is a candidate for hormonal contraception;

(c) Select a contraceptive product based exclusively on the needs of the patient and not on the impact of the selection on the pharmacy business;

(d) Refer the patient to the patient's primary care practitioner or women's health care practitioner upon prescribing and dispensing the contraceptive patch, contraceptive ring, or oral contraceptive;

(e) Provide the patient with a written record of the contraceptive patch, contraceptive ring, or oral contraceptive

prescribed and dispensed and advise the patient to consult with a primary care practitioner or women's health care practitioner; and

(f) Dispense the contraceptive patch, contraceptive ring, or oral contraceptive to the patient as soon as practicable after the pharmacist issues the prescription.

(3) When prescribing or dispensing contraceptive patches, contraceptive rings, or oral contraceptives, a pharmacist may not:

(a) Require a patient to schedule an appointment with the pharmacist for the prescribing or dispensing of a contraceptive patch, contraceptive ring, or oral contraceptive;

(b) Prescribe and dispense a contraceptive patch, contraceptive ring, or oral 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 contraceptive patch, contraceptive ring, or oral contraceptive by a pharmacist to a patient; and

(c) Select a contraceptive product based on preferential profitability or reimbursement or be influenced by preferential profitability or reimbursement in his or her selection of the product that is most appropriate for each patient.

(4) In accordance with RCW 48.43.094, benefits may not be denied for services performed by a pharmacist under this section. This includes reimbursement for prescription drugs or products prescribed or dispensed under this section and for consultation services provided by the pharmacist and as required by this section.

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