S-1113.1

SENATE BILL 5821

State of Washington 64th Legislature 2015 Regular Session

By Senators Rivers and Litzow

Read first time 02/04/15. Referred to Committee on Health Care.

AN ACT Relating to updating pharmacy provisions; amending RCW 18.64.046, 18.64.020, 69.50.302, and 69.50.310; reenacting and amending RCW 18.64.011 and 18.64.044; adding new sections to chapter 18.64 RCW; and creating a new section.

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

NEW SECTION. **Sec. 1.** The legislature finds that current legislative and regulatory laws relating to pharmacy practice in Washington state are out of date and in need of updating. Current laws must be updated in order to promote better care, which will lead to greater individual and public health.

Sec. 2. RCW 18.64.011 and 2013 c 146 s 1, 2013 c 144 s 13, and 2013 c 19 s 7 are each reenacted and 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) "Collector" means a licensed or permitted manufacturer, distributor, reverse distributor, pharmacy, or other public agency that is authorized by the commission to receive legend drugs for the purpose of destruction from an ultimate user, person lawfully entitled to dispose of an ultimate user decedent's property, or a long-term care facility on behalf of an ultimate user that resides or has resided at that facility.

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

((~~(4)~~)) (5) "Compounding" means the act of combining two or more ingredients in the preparation of a prescription.

((~~(5)~~)) (6) "Continuous quality improvement program" means a program of ongoing quality-related event identification, review, and implementation of system or process improvement to prevent further similar quality-related events.

(7) "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)~~)) (8) "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)~~)) (9) "Department" means the department of health.

((~~(8)~~)) (10) "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)~~)) (11) "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)~~)) (12) "Distribute" means the delivery of a drug or device other than by administering or dispensing.

((~~(11)~~)) (13) "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)~~)) (14) "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)~~)) (15) "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~~)) residential treatment center, emergency medical services agency, or a freestanding cardiac care center. It does not include an individual practitioner's office ((~~or a multipractitioner clinic~~)).

((~~(14)~~)) (16) "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)~~)) (17) "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)~~)) (18) "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 ((~~board [commission]~~)) 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)~~)) (19) "Manufacturer" means a person, corporation, or other entity engaged in the manufacture of drugs or devices.

((~~(18)~~)) (20) "Nonlegend" or "nonprescription" drugs means any drugs which may be lawfully sold without a prescription.

((~~(19)~~)) (21) "Person" means an individual, corporation, government, governmental subdivision or agency, business trust, estate, trust, partnership or association, or any other legal entity.

((~~(20)~~)) (22) "Pharmacist" means a person duly licensed by the commission to engage in the practice of pharmacy.

((~~(21)~~)) (23) "Pharmacy" means every place properly licensed by the commission where the practice of pharmacy is conducted.

((~~(22)~~)) (24) "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)~~)) (25) "Practice of pharmacy" includes the practice of and responsibility for: Interpreting prescription orders; the compounding, dispensing, labeling, administering, and distributing of

drugs and devices; the monitoring of drug therapy and use; the 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 participating in drug utilization reviews and drug product selection; the proper and safe storing and distributing of drugs and devices and maintenance of proper records thereof; the 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)~~)) (26) "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)~~)) (27) "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)~~)) (28) "Quality-related event" is the inappropriate dispensing or administration of a prescribed medication or the inappropriate delivery of information related to any medication dispensing or administration error; or a pharmacy system irregularity or event of pharmacy practice that placed or could have placed the safety of a patient or the health of the public at risk.

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

((~~(27)~~)) (30) "Researcher" means a person who possesses appropriate training and experience to conduct scientific research with the use of pharmaceutical drugs to include controlled substances where the commission has determined him or her to be qualified and competent and determined his or her protocol to be meritorious.

(31) "Reverse distributor" means a licensed person or firm that receives legend drugs, including either controlled substances or nonprescription drugs, or both, acquired from another licensee authorized to possess the material, a collector, or a person or firm authorized to possess the material for the purpose of:

(a) Returning unwanted, unusable, or outdated material to the manufacturer or the manufacturer's agent; or

(b) Processing such material or arranging for processing such material for disposal.

(32) "Systems-review approach" means a systematic review and assessment of operational activities, policies, and the collection of routine information regarding the performance of the medication delivery system.

(33) "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.

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

(1) Every pharmacy must establish a continuous quality improvement program that, at a minimum, documents medication errors, contributing factors to the error, and how the error was resolved. The program must help decrease the frequency of quality-related events attributable, in whole or in part, to the pharmacy, its systems and operations, or its personnel. The continuous quality improvement program must advance error prevention by conducting a systems review approach and analyzing, individually and collectively, investigative and other pertinent data collected in response to a quality-related event. The pharmacy is required to assess the cause and account for any contributing factors such as system or process failures. The program must be used to assess quality-related events that occur in the pharmacy and the pharmacy must take appropriate action to prevent a recurrence.

(2) Each pharmacy's continuous quality improvement program must be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form and available to all pharmacy personnel.

(3) Each pharmacy must use the findings of its continuous quality improvement program to develop pharmacy systems, workflow processes, staffing levels, and technological support designed to prevent quality-related events. An investigation of each quality-related event must commence as soon as is reasonably possible, but no later than two business days from the date the quality-related event is discovered. All quality-related events discovered must be reviewed.

(4) The records of the continuous quality improvement program, must be immediately retrievable in the pharmacy for at least five years. The records must demonstrate analysis of the quality-related event and remedies applied.

(5) A nonpunitive approach is encouraged in addressing quality-related events. If, however, a firm's or individual's gross negligence, knowledge or process deficit, or willful malicious intent is identified as the likely cause of the error, the commission may pursue remediation, reeducation, fines, license restriction, probation, suspension, or license revocation, or any combination thereof for the licensed firm or individuals identified as contributors to the quality-related event.

(6) The pharmacy's compliance with this section may be considered by the commission as a mitigating factor in the investigation and evaluation of a medication error or quality-related event and disciplinary action.

(7) Records generated for and maintained as a component of a pharmacy's ongoing continuous quality improvement program are considered peer review documents and are not subject to discovery in any arbitration, civil, or other proceeding, except as provided in this subsection:

(a) In the review or copying of a pharmacy's continuous quality improvement program and records maintained as part of the program by the commission as necessary to protect public health and safety, to conduct inspections, and for use in the commission's disciplinary processes concerning the pharmacy or pharmacy manager's responsibilities concerning this section; or

(b) If fraud is alleged by a governmental agency having jurisdiction over the pharmacy. Nothing in this section is construed to prohibit a patient from accessing his or her own prescription records. Nothing in this section may affect the discoverability of any records not solely generated for and maintained as a component of a pharmacy's ongoing continuous quality improvement program;

(c) In the use of summary quality-related event reports to determine industry best practices. The reports may be disclosed to another pharmacy peer review committee, appropriate state or federal agencies, national accreditation bodies, or the commission of this or another state in the furtherance of patient safety;

(d) In the event of a request for disclosure from the affected pharmacist of confidential pharmacy peer review committee information pertinent to the matter under review. The disclosure does not constitute a waiver of the confidentiality provisions provided by this section.

(8) The commission has the authority to adopt, amend, and rescind rules as are deemed necessary to carry out and implement this section.

(9) For purposes of this section, "medication error" or "quality-related event" means the inappropriate dispensing or administration of a prescribed medication, the inappropriate delivery of information related to any medication dispensing or administration error; or a pharmacy system irregularity or event of pharmacy practice that placed or could have placed the safety of a patient or the health of the public at risk.

Sec. 4. RCW 18.64.044 and 2013 c 144 s 14 and 2013 c 19 s 8 are each reenacted and amended to read as follows:

(1) A shopkeeper registered as provided in this section may sell nonprescription drugs, if such drugs are sold in the original package of the manufacturer.

(2) Every shopkeeper not a licensed ((~~pharmacist~~)) pharmacy, desiring to secure the benefits and privileges of this section, is required to register as a shopkeeper through the business licensing system established under chapter 19.02 RCW, and he or she must pay the fee determined by the secretary for registration, and on a date to be determined by the secretary thereafter the fee determined by the secretary for renewal of the registration; and must at all times keep said registration or the current renewal thereof conspicuously exposed in the location to which it applies. In event such shopkeeper's registration is not renewed by the business license expiration date, no renewal or new registration may be issued except upon payment of the registration renewal fee and the business license delinquency fee under chapter 19.02 RCW. This registration fee does not authorize the sale of legend drugs or controlled substances.

(3) The registration fees determined by the secretary under subsection (2) of this section may not exceed the cost of registering the shopkeeper.

(4) Any shopkeeper who vends or sells, or offers to sell to the public any such nonprescription drug or preparation without having registered to do so as provided in this section, is guilty of a misdemeanor and each sale or offer to sell constitutes a separate offense.

(5) A shopkeeper who is not a licensed pharmacy may purchase products containing any detectable quantity of ephedrine,

pseudoephedrine, or phenylpropanolamine, or their salts, isomers, or salts of isomers, only from a wholesaler licensed by the department under RCW 18.64.046 or from a manufacturer licensed by the department under RCW 18.64.045. The commission must issue a warning to a shopkeeper who violates this subsection, and may suspend or revoke the registration of the shopkeeper for a subsequent violation.

(6) A shopkeeper who has purchased products containing any detectable quantity of ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, isomers, or salts of isomers, in a suspicious transaction as defined in RCW 69.43.035, is subject to the following requirements:

(a) The shopkeeper may not sell any quantity of ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, isomers, or salts of isomers, if the total monthly sales of these products exceed ten percent of the shopkeeper's total prior monthly sales of nonprescription drugs in March through October. In November through February, the shopkeeper may not sell any quantity of ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, isomers, or salts of isomers, if the total monthly sales of these products exceed twenty percent of the shopkeeper's total prior monthly sales of nonprescription drugs. For purposes of this section, "monthly sales" means total dollars paid by buyers. The commission may suspend or revoke the registration of a shopkeeper who violates this subsection.

(b) The shopkeeper must maintain inventory records of the receipt and disposition of nonprescription drugs, utilizing existing inventory controls if an auditor or investigator can determine compliance with (a) of this subsection, and otherwise in the form and manner required by the commission. The records must be available for inspection by the commission or any law enforcement agency and must be maintained for two years. The commission may suspend or revoke the registration of a shopkeeper who violates this subsection. For purposes of this subsection, "disposition" means the return of product to the wholesaler or distributor.

Sec. 5. RCW 18.64.046 and 2013 c 19 s 9 are each amended to read as follows:

(1) The owner of each place of business which sells<u>, distributes, or transfers either</u> legend drugs ((~~and~~)) <u>or</u> nonprescription drugs, or ((~~nonprescription drugs at wholesale~~)) <u>both,</u> shall pay a <u>wholesale</u> license fee to be determined by the secretary, and thereafter, on or

before a date to be determined by the secretary as provided in RCW 43.70.250 and 43.70.280, a like fee to be determined by the secretary, for which the owner shall receive a license of location from the department, which shall entitle such owner to either sell, distribute, or transfer legend drugs and nonprescription drugs ((~~or nonprescription drugs at wholesale~~)) at the location specified for the period ending on a date to be determined by the secretary, and each such owner shall at the time of payment of such fee file with the department, on a blank therefor provided, a declaration of ownership and location, which declaration of ownership and location so filed as aforesaid shall be deemed presumptive evidence of the ownership of such place of business mentioned therein. It shall be the duty of the owner to notify immediately the department of any change of location and ownership and to keep the license of location or the renewal thereof properly exhibited in such place of business.

(2) Failure to conform with this section is a misdemeanor, and each day that the failure continues is a separate offense.

(3) In event the license fee remains unpaid on the date due, no renewal or new license shall be issued except upon compliance with administrative procedures, administrative requirements, and fees determined as provided in RCW 43.70.250 and 43.70.280.

(4) No wholesaler may sell, distribute, or transfer any quantity of drug products containing ephedrine, pseudoephedrine, phenylpropanolamine, or their salts, isomers, or salts of isomers, if the total monthly sales of these products to persons within the state of Washington exceed five percent of the wholesaler's total prior monthly sales of nonprescription drugs to persons within the state in March through October. In November through February, no wholesaler may sell any quantity of drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, isomers, or salts of isomers if the total monthly sales of these products to persons within the state of Washington exceed ten percent of the wholesaler's total prior monthly sales of nonprescription drugs to persons within the state. For purposes of this section, monthly sales means total dollars paid by buyers. The commission may suspend or revoke the license of any wholesaler that violates this section.

(5) The commission may exempt a wholesaler from the limitations of subsection (4) of this section if it finds that the wholesaler distributes nonprescription drugs only through transactions between divisions, subsidiaries, or related companies when the wholesaler and

the retailer are related by common ownership, and that neither the wholesaler nor the retailer has a history of suspicious transactions in precursor drugs as defined in RCW 69.43.035.

(6) The requirements for a license apply to all persons, in Washington and outside of Washington, who sell ((~~both~~))<u>, distribute, or transfer</u> legend drugs ((~~and~~)) <u>or</u> nonprescription drugs ((~~and to those who sell only nonprescription drugs, at wholesale~~)) to pharmacies, practitioners, and shopkeepers in Washington.

(7)(a) No wholesaler may sell<u>, distribute, or transfer</u> any product containing any detectable quantity of ephedrine, pseudoephedrine, phenylpropanolamine, or their salts, isomers, or salts of isomers, to any person in Washington other than a pharmacy licensed under this chapter, a shopkeeper or itinerant vendor registered under this chapter, a practitioner as defined in RCW 18.64.011, or a traditional Chinese herbal practitioner as defined in RCW 69.43.105.

(b) A violation of this subsection is punishable as a class C felony according to chapter 9A.20 RCW, and each sale in violation of this subsection constitutes a separate offense.

<u>NEW SECTION.</u> **Sec. 6.** A new section is added to chapter 18.64 RCW to read as follows:

(1) A licensed health care provider otherwise licensed by the department to proscribe and administer, or a licensed health care entity, may purchase or acquire legend and nonprescription drugs for use in the provider's or entity's own practice at the licensed location from a licensed wholesaler without acquiring a separate license. Drug administration, storage, dispensing, distribution, and recordkeeping are otherwise subject to commission rules.

(2) The licensed health care provider or health care entity may only distribute acquired drugs without a wholesaler license to a licensed reverse distributor or to the wholesaler from which the drugs were acquired, or when requested to a law enforcement or regulatory agency having authority over the drugs.

(3) The transfer of legend or nonprescription drugs between appropriately licensed health care entities under common ownership may occur with all transfers subject to commission rules.

(4) Every health care facility location where drugs are acquired, stored, or distributed are separately licensed by the commission.

Sec. 7. RCW 18.64.020 and 1979 c 90 s 6 are each amended to read as follows:

It shall hereafter be unlawful for any person to practice pharmacy or to institute or operate any pharmacy unless such person shall be a licensed pharmacist or shall place in charge of said pharmacy a licensed pharmacist((~~: PROVIDED, That~~)). However, persons licensed as manufacturers, reverse distributors, researchers, collectors or ((~~as~~)) wholesalers, and their employees, acting within the scope of their licenses, shall be exempt from this section.

Sec. 8. RCW 69.50.302 and 2013 c 19 s 98 are each amended to read as follows:

(a) Every person who manufactures, distributes, ((~~or~~)) dispenses, or exports any controlled substance within this state or who proposes to engage in the manufacture, distribution, or dispensing of any controlled substance within this state, shall obtain annually a registration issued by the department in accordance with the commission's rules.

(b) A person registered by the department under this chapter to manufacture, distribute, dispense, export, or conduct research with controlled substances may possess, manufacture, distribute, dispense, or conduct research with those substances to the extent authorized by the registration and in conformity with this Article.

(c) The following persons need not register and may lawfully possess controlled substances under this chapter:

(1) An agent or employee of any registered manufacturer, distributor, or dispenser of any controlled substance if the agent or employee is acting in the usual course of business or employment. This exemption shall not include any agent or employee distributing sample controlled substances to practitioners without an order;

(2) A common or contract carrier or warehouse operator, or an employee thereof, whose possession of any controlled substance is in the usual course of business or employment;

(3) An ultimate user or a person in possession of any controlled substance pursuant to a lawful order of a practitioner or in lawful possession of a substance included in Schedule V.

(d) The commission may waive by rule the requirement for registration of certain manufacturers, distributors, or dispensers upon finding it consistent with the public health and safety. Personal practitioners licensed or registered in the state of

Washington under the respective professional licensing acts shall not be required to be registered under this chapter unless the specific exemption is denied pursuant to RCW 69.50.305 for violation of any provisions of this chapter.

(e) A separate registration is required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances.

(f) The department may inspect the establishment of a registrant or applicant for registration in accordance with rules adopted by the commission.

Sec. 9. RCW 69.50.310 and 2013 c 19 s 104 are each amended to read as follows:

On and after September 21, 1977, a humane society and animal control agency may apply to the ((~~department~~)) commission for registration pursuant to the applicable provisions of this chapter for the sole purpose of being authorized to purchase, possess, and administer ((~~sodium pentobarbital~~)) a limited number of controlled drugs as determined by the commission to control or euthanize injured, sick, homeless, or unwanted domestic pets and animals, or nondomesticated animals. Any agency so registered shall not permit a person to administer ((~~sodium pentobarbital~~)) any authorized drug unless such person has demonstrated adequate knowledge of the potential hazards and proper techniques to be used in administering this drug.

The ((~~department~~)) commission may issue a limited registration to carry out the provisions of this section. The commission shall promulgate such rules as it deems necessary to insure strict compliance with the provisions of this section. The commission may suspend or revoke registration upon determination that the person administering ((~~sodium pentobarbital~~)) any authorized drug has not demonstrated adequate knowledge as herein provided. This authority is granted in addition to any other power to suspend or revoke registration as provided by law.

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