H-1783.1

SUBSTITUTE HOUSE BILL 1352

State of Washington 66th Legislature 2019 Regular Session

By House Health Care & Wellness (originally sponsored by Representatives Thai, Harris, Slatter, Appleton, Jinkins, and Ortiz-Self)

AN ACT Relating to drug compounding; amending RCW 18.64.270; and reenacting and amending RCW 18.64.011.

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

Sec. 1. RCW 18.64.011 and 2016 c 148 s 1 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) "Chart order" means a lawful order for a drug or device entered on the chart or medical record of an inpatient or resident of an institutional facility by a practitioner or his or her designated agent.

(4) "Closed door long-term care pharmacy" means a pharmacy that provides pharmaceutical care to a defined and exclusive group of

patients who have access to the services of the pharmacy because they are treated by or have an affiliation with a long-term care facility or hospice program, and that is not a retailer of goods to the general public.

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

(6) "Compounding" means the act of combining two or more active ingredients in the preparation of a prescription. Compounding does not include mixing, reconstitution, or other acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling.

(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.

(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.

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

(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.

(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.

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

(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.

(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.

(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, 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.

(16) "Hospice program" means a hospice program certified or paid by medicare under Title XVIII of the federal social security act, or a hospice program licensed under chapter 70.127 RCW.

(17) "Institutional facility" means any organization whose primary purpose is to provide a physical environment for patients to obtain health care services including, but not limited to, services in a hospital, long-term care facility, hospice program, mental health facility, drug abuse treatment center, residential habilitation center, or a local, state, or federal correction facility.

(18) "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.

(19) "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.

(20) "Long-term care facility" means a nursing home licensed under chapter 18.51 RCW, an assisted living facility licensed under chapter 18.20 RCW, or an adult family home licensed under chapter 70.128 RCW.

(21) "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.

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

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

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

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

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

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

(28) "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.

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

(30) "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.

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

(32) "Shared pharmacy services" means a system that allows a participating pharmacist or pharmacy pursuant to a request from another participating pharmacist or pharmacy to process or fill a prescription or drug order, which may include but is not necessarily limited to preparing, packaging, labeling, data entry, compounding for specific patients, dispensing, performing drug utilization

reviews, conducting claims adjudication, obtaining refill authorizations, reviewing therapeutic interventions, or reviewing chart orders.

(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.

Sec. 2. RCW 18.64.270 and 2013 c 146 s 2 are each amended to read as follows:

(1) Every proprietor of a wholesale or retail drug store shall be held responsible for the quality of all drugs, chemicals or medicines sold or dispensed by him or her except those sold in original packages of the manufacturer and except those articles or preparations known as patent or proprietary medicines.

(2) ((~~Any~~)) Medicinal products or preparations that are compounded for patient administration or distribution to a licensed practitioner for patient use or administration shall, at a minimum, meet the standards of the official United States pharmacopeia as it applies to nonsterile ((~~products~~)) and sterile administered products and preparations.

(3) The commission may adopt rules implementing this section.

(4) Any person who shall knowingly, willfully or fraudulently falsify or adulterate any drug or medicinal substance or preparation authorized or recognized by an official compendium or used or intended to be used in medical practice, or shall willfully, knowingly or fraudulently offer for sale, sell or cause the same to be sold for medicinal purposes, is guilty of a misdemeanor, and upon conviction thereof shall be punished by a fine in any sum not less than seventy-five nor more than one hundred and fifty dollars or by imprisonment in the county jail for a period of not less than one month nor more than three months, and any person convicted a third time for violation of this section may suffer both fine and imprisonment. In any case he or she shall forfeit to the state of Washington all drugs or preparations so falsified or adulterated.

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