H-1303.1				

HOUSE BILL 1800

State of Washington 63rd Legislature 2013 Regular Session

By Representatives Cody, Morrell, and Schmick

Read first time 02/11/13. Referred to Committee on Health Care & Wellness.

- AN ACT Relating to compounding of medications; reenacting and amending RCW 18.64.011; adding a new section to chapter 18.64 RCW; and
- 3 declaring an emergency.

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- 4 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:
- 5 **Sec. 1.** RCW 18.64.011 and 2009 c 549 s 1008 are each reenacted and 6 amended to read as follows:
 - Unless the context clearly requires otherwise, definitions of terms shall be as indicated when used in this chapter.
- 9 (1) "Administer" means the direct application of a drug or device, 10 whether by injection, inhalation, ingestion, or any other means, to the 11 body of a patient or research subject.
 - (2) "Board" means the Washington state board of pharmacy.
- 13 (3) "Compounding" shall be the act of combining two or more 14 ingredients in the preparation of a prescription.
 - (4) "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.
- 18 (5) "Deliver" or "delivery" means the actual, constructive, or

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attempted transfer from one person to another of a drug or device, whether or not there is an agency relationship.

- (6) "Department" means the department of health.
- (7) "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.
- (8) "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.
- (9) "Distribute" means the delivery of a drug or device other than by administering or dispensing.
- (10) The words "drug" and "devices" shall 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, nor shall the word "drug" 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.
 - (11) "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.
- (12) "Health care entity" means an organization that provides health care services in a setting that is not otherwise licensed by the

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state. Health care entity includes a freestanding outpatient surgery center or a freestanding cardiac care center. It does not include an individual practitioner's office or a multipractitioner clinic.

- (13) "Labeling" shall mean 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.
- (14) "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.
- (15) "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, prepares, compounds, packages, or labels such substance or device. The term does not include the compounding of medications for physician offices, ambulatory surgical centers, or ambulatory surgical facilities to be used by a physician for ophthalmic purposes for nonspecific patients.
- (16) "Manufacturer" shall mean a person, corporation, or other entity engaged in the manufacture of drugs or devices.
- (17) "Master license system" means the mechanism established by chapter 19.02 RCW by which master licenses, endorsed for individual state-issued licenses, are issued and renewed utilizing a master application and a master license expiration date common to each renewable license endorsement.
- (18) "Nonlegend" or "nonprescription" drugs means any drugs which may be lawfully sold without a prescription.
- 31 (19) "Person" means an individual, corporation, government, 32 governmental subdivision or agency, business trust, estate, trust, 33 partnership or association, or any other legal entity.
 - (20) "Pharmacist" means a person duly licensed by the Washington state board of pharmacy to engage in the practice of pharmacy.
 - (21) "Pharmacy" means every place properly licensed by the board of pharmacy where the practice of pharmacy is conducted.

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

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- (23)"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) "Practitioner" means a physician, dentist, veterinarian, nurse, or other person duly authorized by law or rule in the state of 17 18 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 23 24 designee.
- (27) "Wholesaler" shall mean a corporation, individual, or other 25 26 entity which buys drugs or devices for resale and distribution to 27 corporations, individuals, or entities other than consumers.
- 28 NEW SECTION. Sec. 2. A new section is added to chapter 18.64 RCW 29 to read as follows:

The board shall adopt rules to authorize the compounding of medications for physician offices and ambulatory surgical centers or ambulatory surgical facilities to be used by a physician for ophthalmic purposes for nonspecific patients. The rules must establish limits on the quantities that may be made available to the physician office, ambulatory surgical center, or ambulatory surgical facility and requirements to record the dispensing of the compounded medication,

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- including the identity of patients and the amount dispensed, and to submit the records to the board.
- NEW SECTION. Sec. 3. This act is necessary for the immediate preservation of the public peace, health, or safety, or support of the state government and its existing public institutions, and takes effect immediately.

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