

HB 1800 - S COMM AMD
By Committee on Health Care

NOT ADOPTED 04/17/2013

1 Strike everything after the enacting clause and insert the
2 following:

3 "Sec. 1. RCW 18.64.011 and 2009 c 549 s 1008 are each reenacted
4 and amended to read as follows:

5 Unless the context clearly requires otherwise, definitions of terms
6 shall be as indicated when used in this chapter.

7 (1) "Administer" means the direct application of a drug or device,
8 whether by injection, inhalation, ingestion, or any other means, to the
9 body of a patient or research subject.

10 (2) "Board" means the Washington state board of pharmacy.

11 (3) "Compounding" shall be the act of combining two or more
12 ingredients in the preparation of a prescription.

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

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

19 (6) "Department" means the department of health.

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

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

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

1 (10) The words "drug" and "devices" shall not include surgical or
2 dental instruments or laboratory materials, gas and oxygen, therapy
3 equipment, X-ray apparatus or therapeutic equipment, their component
4 parts or accessories, or equipment, instruments, apparatus, or
5 contrivances used to render such articles effective in medical,
6 surgical, or dental treatment, or for use or consumption in or for
7 mechanical, industrial, manufacturing, or scientific applications or
8 purposes, nor shall the word "drug" include any article or mixture
9 covered by the Washington pesticide control act (chapter 15.58 RCW), as
10 enacted or hereafter amended, nor medicated feed intended for and used
11 exclusively as a feed for animals other than human beings.

12 (11) "Drugs" means:

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

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

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

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

22 (12) "Health care entity" means an organization that provides
23 health care services in a setting that is not otherwise licensed by the
24 state. Health care entity includes a freestanding outpatient surgery
25 center or a freestanding cardiac care center. It does not include an
26 individual practitioner's office or a multipractitioner clinic.

27 (13) "Labeling" shall mean the process of preparing and affixing a
28 label to any drug or device container. The label must include all
29 information required by current federal and state law and pharmacy
30 rules.

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

34 (15) "Manufacture" means the production, preparation, propagation,
35 compounding, or processing of a drug or other substance or device or
36 the packaging or repackaging of such substance or device, or the
37 labeling or relabeling of the commercial container of such substance or
38 device, but does not include the activities of a practitioner who, as

1 an incident to his or her administration or dispensing such substance
2 or device in the course of his or her professional practice, personally
3 prepares, compounds, packages, or labels such substance or device. The
4 term does not include:

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

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

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

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

22 (e) The distribution of a drug that has been compounded by a
23 licensed pharmacy to other licensed persons or commercial entities for
24 subsequent resale or distribution, without specific product item
25 approval of the board.

26 (16) "Manufacturer" shall mean a person, corporation, or other
27 entity engaged in the manufacture of drugs or devices.

28 (17) "Master license system" means the mechanism established by
29 chapter 19.02 RCW by which master licenses, endorsed for individual
30 state-issued licenses, are issued and renewed utilizing a master
31 application and a master license expiration date common to each
32 renewable license endorsement.

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

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

1 (20) "Pharmacist" means a person duly licensed by the Washington
2 state board of pharmacy to engage in the practice of pharmacy.

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

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

8 (23) "Practice of pharmacy" includes the practice of and
9 responsibility for: Interpreting prescription orders; the compounding,
10 dispensing, labeling, administering, and distributing of drugs and
11 devices; the monitoring of drug therapy and use; the initiating or
12 modifying of drug therapy in accordance with written guidelines or
13 protocols previously established and approved for his or her practice
14 by a practitioner authorized to prescribe drugs; the participating in
15 drug utilization reviews and drug product selection; the proper and
16 safe storing and distributing of drugs and devices and maintenance of
17 proper records thereof; the providing of information on legend drugs
18 which may include, but is not limited to, the advising of therapeutic
19 values, hazards, and the uses of drugs and devices.

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

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

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

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

32 **Sec. 2.** RCW 18.64.270 and 2003 c 53 s 137 are each amended to read
33 as follows:

34 (1) Every proprietor of a wholesale or retail drug store shall be
35 held responsible for the quality of all drugs, chemicals or medicines
36 sold or dispensed by him or her except those sold in original packages

1 of the manufacturer and except those articles or preparations known as
2 patent or proprietary medicines.

3 (2) Any medicinal products that are compounded or prepared for
4 patient administration or distribution to a licensed practitioner for
5 patient use or administration shall, at a minimum, meet the standards
6 of the official United States pharmacopeia as it applies to oral
7 products and parenteral administered products.

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

21 NEW SECTION. **Sec. 3.** This act is necessary for the immediate
22 preservation of the public peace, health, or safety, or support of the
23 state government and its existing public institutions, and takes effect
24 immediately."

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25 On page 1, line 1 of the title, after "medications;" strike the
26 remainder of the title and insert "amending RCW 18.67.270; reenacting
27 and amending RCW 18.64.011; and declaring an emergency."

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