

CERTIFICATION OF ENROLLMENT

HOUSE BILL 1800

Chapter 146, Laws of 2013

63rd Legislature
2013 Regular Session

PHARMACISTS--DRUG COMPOUNDING--DISTRIBUTION OR RESALE

EFFECTIVE DATE: 05/07/13

Passed by the House April 22, 2013
Yeas 95 Nays 0

FRANK CHOPP

Speaker of the House of Representatives

Passed by the Senate April 17, 2013
Yeas 48 Nays 0

BRAD OWEN

President of the Senate

Approved May 7, 2013, 2:02 p.m.

JAY INSLEE

Governor of the State of Washington

CERTIFICATE

I, Barbara Baker, Chief Clerk of the House of Representatives of the State of Washington, do hereby certify that the attached is **HOUSE BILL 1800** as passed by the House of Representatives and the Senate on the dates hereon set forth.

BARBARA BAKER

Chief Clerk

FILED

May 7, 2013

**Secretary of State
State of Washington**

HOUSE BILL 1800

AS AMENDED BY THE SENATE

Passed Legislature - 2013 Regular Session

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.

1 AN ACT Relating to compounding of medications; amending RCW
2 18.64.270; reenacting and amending RCW 18.64.011; and declaring an
3 emergency.

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:

7 Unless the context clearly requires otherwise, definitions of terms
8 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.

12 (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.

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

18 (5) "Deliver" or "delivery" means the actual, constructive, or

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

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

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

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

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

15 (10) The words "drug" and "devices" shall not include surgical or
16 dental instruments or laboratory materials, gas and oxygen, therapy
17 equipment, X-ray apparatus or therapeutic equipment, their component
18 parts or accessories, or equipment, instruments, apparatus, or
19 contrivances used to render such articles effective in medical,
20 surgical, or dental treatment, or for use or consumption in or for
21 mechanical, industrial, manufacturing, or scientific applications or
22 purposes, nor shall the word "drug" include any article or mixture
23 covered by the Washington pesticide control act (chapter 15.58 RCW), as
24 enacted or hereafter amended, nor medicated feed intended for and used
25 exclusively as a feed for animals other than human beings.

26 (11) "Drugs" means:

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

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

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

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

36 (12) "Health care entity" means an organization that provides
37 health care services in a setting that is not otherwise licensed by the

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

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

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

11 (15) "Manufacture" means the production, preparation, propagation,
12 compounding, or processing of a drug or other substance or device or
13 the packaging or repackaging of such substance or device, or the
14 labeling or relabeling of the commercial container of such substance or
15 device, but does not include the activities of a practitioner who, as
16 an incident to his or her administration or dispensing such substance
17 or device in the course of his or her professional practice, personally
18 prepares, compounds, packages, or labels such substance or device.
19 "Manufacture" includes the distribution of a licensed pharmacy
20 compounded drug product to other state licensed persons or commercial
21 entities for subsequent resale or distribution, unless a specific
22 product item has approval of the board. The term does not include:

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

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

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

35 (d) The delivery of finished and appropriately labeled compounded
36 products dispensed pursuant to a valid prescription to alternate
37 delivery locations, other than the patient's residence, when requested

1 by the patient, or the prescriber to administer to the patient, or to
2 another licensed pharmacy to dispense to the patient.

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

5 (17) "Master license system" means the mechanism established by
6 chapter 19.02 RCW by which master licenses, endorsed for individual
7 state-issued licenses, are issued and renewed utilizing a master
8 application and a master license expiration date common to each
9 renewable license endorsement.

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

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

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

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

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

22 (23) "Practice of pharmacy" includes the practice of and
23 responsibility for: Interpreting prescription orders; the compounding,
24 dispensing, labeling, administering, and distributing of drugs and
25 devices; the monitoring of drug therapy and use; the initiating or
26 modifying of drug therapy in accordance with written guidelines or
27 protocols previously established and approved for his or her practice
28 by a practitioner authorized to prescribe drugs; the participating in
29 drug utilization reviews and drug product selection; the proper and
30 safe storing and distributing of drugs and devices and maintenance of
31 proper records thereof; the providing of information on legend drugs
32 which may include, but is not limited to, the advising of therapeutic
33 values, hazards, and the uses of drugs and devices.

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

37 (25) "Prescription" means an order for drugs or devices issued by

1 a practitioner duly authorized by law or rule in the state of
2 Washington to prescribe drugs or devices in the course of his or her
3 professional practice for a legitimate medical purpose.

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

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

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

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

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

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

34 NEW SECTION. **Sec. 3.** This act is necessary for the immediate
35 preservation of the public peace, health, or safety, or support of the

1 state government and its existing public institutions, and takes effect
2 immediately.

Passed by the House April 22, 2013.

Passed by the Senate April 17, 2013.

Approved by the Governor May 7, 2013.

Filed in Office of Secretary of State May 7, 2013.