

ESSB 5460 - H AMD TO HCW COMM AMD (H2478.1) 337
By Representative Cody

ADOPTED 4/13/2015

1 On page 2, after line 40 of the amendment, insert the following:

2 "NEW SECTION. **Sec. 2.** A new section is added to chapter 70.41
3 RCW to read as follows:

4 (1) The legislature recognizes that in order for hospitals to
5 ensure drugs are accessible to patients and the public to meet
6 hospital and community health care needs, certain transfers of drugs
7 must be authorized between hospitals and their affiliated or related
8 companies under common ownership and control of the corporate entity
9 and for emergency medical reasons.

10 (2) A licensed hospital pharmacy is permitted, without a
11 wholesaler license, to:

12 (a) Engage in intracompany sales, being defined as any
13 transaction or transfer between any division, subsidiary, parent
14 company, affiliated company, or related company under common
15 ownership and control of the corporate entity, unless the transfer
16 occurs between a wholesale distributor and a health care entity or
17 practitioner; and

18 (b) Sell, purchase, or trade a drug or offer to sell, purchase,
19 or trade a drug for emergency medical reasons. For the purposes of
20 this subsection, "emergency medical reasons" includes transfers of
21 prescription drugs to alleviate a temporary shortage, except that the
22 gross dollar value of the transfers may not exceed five percent of
23 the total prescription drug sale revenue of either the transferor or
24 transferee pharmacy during any twelve consecutive month period.

25 **Sec. 3.** RCW 18.64.011 and 2013 c 146 s 1, 2013 c 144 s 13, and
26 2013 c 19 s 7 are each reenacted and amended to read as follows:

27 The definitions in this section apply throughout this chapter
28 unless the context clearly requires otherwise.

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

1 (2) "Business licensing system" means the mechanism established
2 by chapter 19.02 RCW by which business licenses, endorsed for
3 individual state-issued licenses, are issued and renewed utilizing a
4 business license application and a business license expiration date
5 common to each renewable license endorsement.

6 (3) "Commission" means the pharmacy quality assurance commission.

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

9 (5) "Controlled substance" means a drug or substance, or an
10 immediate precursor of such drug or substance, so designated under or
11 pursuant to the provisions of chapter 69.50 RCW.

12 (6) "Deliver" or "delivery" means the actual, constructive, or
13 attempted transfer from one person to another of a drug or device,
14 whether or not there is an agency relationship.

15 (7) "Department" means the department of health.

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

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

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

29 (11) "Drug" and "devices" do not include surgical or dental
30 instruments or laboratory materials, gas and oxygen, therapy
31 equipment, X-ray apparatus or therapeutic equipment, their component
32 parts or accessories, or equipment, instruments, apparatus, or
33 contrivances used to render such articles effective in medical,
34 surgical, or dental treatment, or for use or consumption in or for
35 mechanical, industrial, manufacturing, or scientific applications or
36 purposes. "Drug" also does not include any article or mixture covered
37 by the Washington pesticide control act (chapter 15.58 RCW), as
38 enacted or hereafter amended, nor medicated feed intended for and
39 used exclusively as a feed for animals other than human beings.

40 (12) "Drugs" means:

1 (a) Articles recognized in the official United States
2 pharmacopoeia or the official homeopathic pharmacopoeia of the United
3 States;

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

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

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

12 (13) "Health care entity" means an organization that provides
13 health care services in a setting that is not otherwise licensed by
14 the state to acquire or possess legend drugs. Health care entity
15 includes a freestanding outpatient surgery center ~~((or))~~, a
16 residential treatment facility, and a freestanding cardiac care
17 center. ~~((It))~~ "Health care entity" does not include an individual
18 practitioner's office or a multipractitioner clinic, regardless of
19 ownership, unless the owner elects licensure as a health care entity.
20 "Health care entity" also does not include an individual
21 practitioner's office or multipractitioner clinic identified by a
22 hospital on a pharmacy application or renewal pursuant to RCW
23 18.64.043.

24 (14) "Labeling" means the process of preparing and affixing a
25 label to any drug or device container. The label must include all
26 information required by current federal and state law and pharmacy
27 rules.

28 (15) "Legend drugs" means any drugs which are required by any
29 applicable federal or state law or regulation to be dispensed on
30 prescription only or are restricted to use by practitioners only.

31 (16) "Manufacture" means the production, preparation,
32 propagation, compounding, or processing of a drug or other substance
33 or device or the packaging or repackaging of such substance or
34 device, or the labeling or relabeling of the commercial container of
35 such substance or device, but does not include the activities of a
36 practitioner who, as an incident to his or her administration or
37 dispensing such substance or device in the course of his or her
38 professional practice, personally prepares, compounds, packages, or
39 labels such substance or device. "Manufacture" includes the
40 distribution of a licensed pharmacy compounded drug product to other

1 state licensed persons or commercial entities for subsequent resale
2 or distribution, unless a specific product item has approval of the
3 (~~board [commission]~~) commission. The term does not include:

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

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

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

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

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

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

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

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

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

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

35 (23) "Practice of pharmacy" includes the practice of and
36 responsibility for: Interpreting prescription orders; the
37 compounding, dispensing, labeling, administering, and distributing of
38 drugs and devices; the monitoring of drug therapy and use; the
39 initiating or modifying of drug therapy in accordance with written
40 guidelines or protocols previously established and approved for his

1 or her practice by a practitioner authorized to prescribe drugs; the
2 participating in drug utilization reviews and drug product selection;
3 the proper and safe storing and distributing of drugs and devices and
4 maintenance of proper records thereof; the providing of information
5 on legend drugs which may include, but is not limited to, the
6 advising of therapeutic values, hazards, and the uses of drugs and
7 devices.

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

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

15 (26) "Secretary" means the secretary of health or the secretary's
16 designee.

17 (27) "Wholesaler" means a corporation, individual, or other
18 entity which buys drugs or devices for resale and distribution to
19 corporations, individuals, or entities other than consumers.

20 **Sec. 4.** RCW 18.64.043 and 1996 c 191 s 43 are each amended to
21 read as follows:

22 (1) The owner of each pharmacy shall pay an original license fee
23 to be determined by the secretary, and annually thereafter, on or
24 before a date to be determined by the secretary, a fee to be
25 determined by the secretary, for which he or she shall receive a
26 license of location, which shall entitle the owner to operate such
27 pharmacy at the location specified, or such other temporary location
28 as the secretary may approve, for the period ending on a date to be
29 determined by the secretary as provided in RCW 43.70.250 and
30 43.70.280, and each such owner shall at the time of filing proof of
31 payment of such fee as provided in RCW 18.64.045 as now or hereafter
32 amended, file with the department on a blank therefor provided, a
33 declaration of ownership and location, which declaration of ownership
34 and location so filed as aforesaid shall be deemed presumptive
35 evidence of ownership of the pharmacy mentioned therein. For a
36 hospital licensed under chapter 70.41 RCW, the license of location
37 provided under this section may include any individual practitioner's
38 office or multipractitioner clinic owned and operated by a hospital,
39 and identified by the hospital on the pharmacy application or

1 renewal. A hospital that elects to include one or more offices or
2 clinics under this subsection on its pharmacy application must
3 maintain the office or clinic under its pharmacy license through at
4 least one pharmacy inspection or twenty-four months. However, the
5 department may, in its discretion, allow a change in licensure at an
6 earlier time. The secretary may adopt rules to establish an
7 additional reasonable fee for any such office or clinic.

8 (2) It shall be the duty of the owner to immediately notify the
9 department of any change of location or ownership and to keep the
10 license of location or the renewal thereof properly exhibited in said
11 pharmacy.

12 (3) Failure to comply with this section shall be deemed a
13 misdemeanor, and each day that said failure continues shall be deemed
14 a separate offense.

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

19 Renumber the remaining section consecutively, correct any
20 internal references accordingly, and correct the title.

21 On page 3, line 1 of the amendment, after "**Sec. 2.**" strike "This"
22 and insert "Section 1 of this"

EFFECT: Allows hospital pharmacies that do not have a wholesaler license to engage in intracompany sales and the sale, purchase, or trade of a drug for emergency medical reasons. Defines an intracompany sale as a transfer or transaction between any component of a company under common ownership and control of the corporate entity. Clarifies that "emergency medical reasons" include transfers of a drug to alleviate a temporary shortage, except that the value of the transfers cannot have a gross value that is more than five percent of the total annual drug sales revenue of either the transferor or transferee.

Allows a hospital that receives a pharmacy license to include under its license any individual practitioner's office or multipractitioner clinic that is owned and operated by the hospital and listed on the hospital's initial or renewal pharmacy application. Requires hospitals with additional offices or clinics under its pharmacy license to keep those entities on the license through at least one inspection or for 24 months. Authorizes the Secretary of Health to establish fees for offices or clinics under the hospital's pharmacy license.

Adds residential treatment facilities to the definition of "health care entity." Excludes individual practitioners and multipractitioner clinics, whether or not they are hospital-based, from the definition of "health care entity." Allows a nonhospital-

based individual practitioner or multipractitioner clinic to elect to become licensed as a health care entity.

--- END ---