

CERTIFICATION OF ENROLLMENT
ENGROSSED SUBSTITUTE SENATE BILL 5460

64th Legislature
2015 Regular Session

Passed by the Senate April 16, 2015
Yeas 47 Nays 0

President of the Senate

Passed by the House April 13, 2015
Yeas 93 Nays 4

Speaker of the House of Representatives

Approved

Governor of the State of Washington

CERTIFICATE

I, Hunter G. Goodman, Secretary of the Senate of the State of Washington, do hereby certify that the attached is **ENGROSSED SUBSTITUTE SENATE BILL 5460** as passed by Senate and the House of Representatives on the dates hereon set forth.

Secretary

FILED

**Secretary of State
State of Washington**

ENGROSSED SUBSTITUTE SENATE BILL 5460

AS AMENDED BY THE HOUSE

Passed Legislature - 2015 Regular Session

State of Washington 64th Legislature 2015 Regular Session

By Senate Health Care (originally sponsored by Senators Parlette, Cleveland, Rivers, Keiser, Angel, Chase, and Bailey)

READ FIRST TIME 02/10/15.

1 AN ACT Relating to pharmacy services in hospital emergency rooms
2 and hospital clinics; amending RCW 18.64.043; reenacting and amending
3 RCW 18.64.011; adding new sections to chapter 70.41 RCW; and
4 declaring an emergency.

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

6 NEW SECTION. **Sec. 1.** A new section is added to chapter 70.41
7 RCW to read as follows:

8 (1) The legislature finds that high quality, safe, and
9 compassionate health care services for patients of Washington state
10 must be available at all times. The legislature further finds that
11 there is a need for patients being released from hospital emergency
12 departments to maintain access to emergency medications when
13 community or hospital pharmacy services are not available. It is the
14 intent of the legislature to accomplish this objective by allowing
15 practitioners with prescriptive authority to prescribe limited
16 amounts of prepackaged emergency medications to patients being
17 discharged from hospital emergency departments when access to
18 community or outpatient hospital pharmacy services is not otherwise
19 available.

20 (2) A hospital may allow a practitioner to prescribe prepackaged
21 emergency medications and allow a practitioner or a registered nurse

1 licensed under chapter 18.79 RCW to distribute prepackaged emergency
2 medications to patients being discharged from a hospital emergency
3 department during times when community or outpatient hospital
4 pharmacy services are not available within fifteen miles by road or
5 when, in the judgment of the practitioner and consistent with
6 hospital policies and procedures, a patient has no reasonable ability
7 to reach the local community or outpatient pharmacy. A hospital may
8 only allow this practice if: The director of the hospital pharmacy,
9 in collaboration with appropriate hospital medical staff, develops
10 policies and procedures regarding the following:

11 (a) Development of a list, preapproved by the pharmacy director,
12 of the types of emergency medications to be prepackaged and
13 distributed;

14 (b) Assurances that emergency medications to be prepackaged
15 pursuant to this section are prepared by a pharmacist or under the
16 supervision of a pharmacist licensed under chapter 18.64 RCW;

17 (c) Development of specific criteria under which emergency
18 prepackaged medications may be prescribed and distributed consistent
19 with the limitations of this section;

20 (d) Assurances that any practitioner authorized to prescribe
21 prepackaged emergency medication or any nurse authorized to
22 distribute prepackaged emergency medication is trained on the types
23 of medications available and the circumstances under which they may
24 be distributed;

25 (e) Procedures to require practitioners intending to prescribe
26 prepackaged emergency medications pursuant to this section to
27 maintain a valid prescription either in writing or electronically in
28 the patient's records prior to a medication being distributed to a
29 patient;

30 (f) Establishment of a limit of no more than a forty-eight hour
31 supply of emergency medication as the maximum to be dispensed to a
32 patient, except when community or hospital pharmacy services will not
33 be available within forty-eight hours. In no case may the policy
34 allow a supply exceeding ninety-six hours be dispensed;

35 (g) Assurances that prepackaged emergency medications will be
36 kept in a secure location in or near the emergency department in such
37 a manner as to preclude the necessity for entry into the pharmacy;
38 and

1 (h) Assurances that nurses or practitioners will distribute
2 prepackaged emergency medications to patients only after a
3 practitioner has counseled the patient on the medication.

4 (3) The delivery of a single dose of medication for immediate
5 administration to the patient is not subject to the requirements of
6 this section.

7 (4) For purposes of this section:

8 (a) "Emergency medication" means any medication commonly
9 prescribed to emergency room patients, including those drugs,
10 substances or immediate precursors listed in schedules II through V
11 of the uniform controlled substances act, chapter 69.50 RCW, as now
12 or hereafter amended.

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

15 (c) "Practitioner" means any person duly authorized by law or
16 rule in the state of Washington to prescribe drugs as defined in RCW
17 18.64.011(24).

18 (d) "Nurse" means a registered nurse as defined in RCW 18.79.020.

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

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

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

29 (a) Engage in intracompany sales, being defined as any
30 transaction or transfer between any division, subsidiary, parent
31 company, affiliated company, or related company under common
32 ownership and control of the corporate entity, unless the transfer
33 occurs between a wholesale distributor and a health care entity or
34 practitioner; and

35 (b) Sell, purchase, or trade a drug or offer to sell, purchase,
36 or trade a drug for emergency medical reasons. For the purposes of
37 this subsection, "emergency medical reasons" includes transfers of
38 prescription drugs to alleviate a temporary shortage, except that the
39 gross dollar value of the transfers may not exceed five percent of

1 the total prescription drug sale revenue of either the transferor or
2 transferee pharmacy during any twelve consecutive month period.

3 **Sec. 3.** RCW 18.64.011 and 2013 c 146 s 1, 2013 c 144 s 13, and
4 2013 c 19 s 7 are each reenacted and amended to read as follows:

5 The definitions in this section apply throughout this chapter
6 unless the context clearly requires otherwise.

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

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

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

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

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

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

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

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

31 (9) "Dispense" means the interpretation of a prescription or
32 order for a drug, biological, or device and, pursuant to that
33 prescription or order, the proper selection, measuring, compounding,
34 labeling, or packaging necessary to prepare that prescription or
35 order for delivery.

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

38 (11) "Drug" and "devices" do not include surgical or dental
39 instruments or laboratory materials, gas and oxygen, therapy

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

10 (12) "Drugs" means:

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

14 (b) Substances intended for use in the diagnosis, cure,
15 mitigation, treatment, or prevention of disease in human beings or
16 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 (13) "Health care entity" means an organization that provides
23 health care services in a setting that is not otherwise licensed by
24 the state to acquire or possess legend drugs. Health care entity
25 includes a freestanding outpatient surgery center ~~((or))~~, a
26 residential treatment facility, and a freestanding cardiac care
27 center. ~~((It))~~ "Health care entity" does not include an individual
28 practitioner's office or a multipractitioner clinic, regardless of
29 ownership, unless the owner elects licensure as a health care entity.
30 "Health care entity" also does not include an individual
31 practitioner's office or multipractitioner clinic identified by a
32 hospital on a pharmacy application or renewal pursuant to RCW
33 18.64.043.

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

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

1 (16) "Manufacture" means the production, preparation,
2 propagation, compounding, or processing of a drug or other substance
3 or device or the packaging or repackaging of such substance or
4 device, or the labeling or relabeling of the commercial container of
5 such substance or device, but does not include the activities of a
6 practitioner who, as an incident to his or her administration or
7 dispensing such substance or device in the course of his or her
8 professional practice, personally prepares, compounds, packages, or
9 labels such substance or device. "Manufacture" includes the
10 distribution of a licensed pharmacy compounded drug product to other
11 state licensed persons or commercial entities for subsequent resale
12 or distribution, unless a specific product item has approval of the
13 (~~board [commission]~~) commission. The term does not include:

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

18 (b) The practice of a licensed pharmacy when repackaging
19 commercially available medication in small, reasonable quantities for
20 a practitioner legally authorized to prescribe the medication for
21 office use only;

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

26 (d) The delivery of finished and appropriately labeled compounded
27 products dispensed pursuant to a valid prescription to alternate
28 delivery locations, other than the patient's residence, when
29 requested by the patient, or the prescriber to administer to the
30 patient, or to another licensed pharmacy to dispense to the patient.

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

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.

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

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

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

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

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

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

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

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

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

33 (1) The owner of each pharmacy shall pay an original license fee
34 to be determined by the secretary, and annually thereafter, on or
35 before a date to be determined by the secretary, a fee to be
36 determined by the secretary, for which he or she shall receive a
37 license of location, which shall entitle the owner to operate such
38 pharmacy at the location specified, or such other temporary location
39 as the secretary may approve, for the period ending on a date to be

1 determined by the secretary as provided in RCW 43.70.250 and
2 43.70.280, and each such owner shall at the time of filing proof of
3 payment of such fee as provided in RCW 18.64.045 as now or hereafter
4 amended, file with the department on a blank therefor provided, a
5 declaration of ownership and location, which declaration of ownership
6 and location so filed as aforesaid shall be deemed presumptive
7 evidence of ownership of the pharmacy mentioned therein. For a
8 hospital licensed under chapter 70.41 RCW, the license of location
9 provided under this section may include any individual practitioner's
10 office or multipractitioner clinic owned and operated by a hospital,
11 and identified by the hospital on the pharmacy application or
12 renewal. A hospital that elects to include one or more offices or
13 clinics under this subsection on its pharmacy application must
14 maintain the office or clinic under its pharmacy license through at
15 least one pharmacy inspection or twenty-four months. However, the
16 department may, in its discretion, allow a change in licensure at an
17 earlier time. The secretary may adopt rules to establish an
18 additional reasonable fee for any such office or clinic.

19 (2) It shall be the duty of the owner to immediately notify the
20 department of any change of location or ownership and to keep the
21 license of location or the renewal thereof properly exhibited in said
22 pharmacy.

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

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

30 NEW SECTION. Sec. 5. Section 1 of this act is necessary for the
31 immediate preservation of the public peace, health, or safety, or
32 support of the state government and its existing public institutions,
33 and takes effect immediately.

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