

CERTIFICATION OF ENROLLMENT
ENGROSSED SUBSTITUTE SENATE BILL 6203

Chapter 148, Laws of 2016

64th Legislature
2016 Regular Session

PRACTICE OF PHARMACY--LONG-TERM CARE SETTINGS

EFFECTIVE DATE: 6/9/2016

Passed by the Senate March 7, 2016
Yeas 48 Nays 0

BRAD OWEN

President of the Senate

Passed by the House March 3, 2016
Yeas 97 Nays 0

FRANK CHOPP

Speaker of the House of Representatives

Approved March 31, 2016 4:52 PM

JAY INSLEE

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 6203** as passed by Senate and the House of Representatives on the dates hereon set forth.

HUNTER G. GOODMAN

Secretary

FILED

April 1, 2016

**Secretary of State
State of Washington**

ENGROSSED SUBSTITUTE SENATE BILL 6203

AS AMENDED BY THE HOUSE

Passed Legislature - 2016 Regular Session

State of Washington 64th Legislature 2016 Regular Session

By Senate Health Care (originally sponsored by Senators Parlette, Becker, Keiser, and Conway)

READ FIRST TIME 02/05/16.

1 AN ACT Relating to updating statutes relating to the practice of
2 pharmacy including the practice of pharmacy in long-term care
3 settings; amending RCW 18.64.011, 69.50.308, 74.42.230, 69.41.032,
4 69.41.042, 69.41.044, 69.41.055, 69.41.220, 18.64.245, and 18.64.500;
5 reenacting and amending RCW 69.41.010 and 69.41.030; adding new
6 sections to chapter 18.64 RCW; and adding a new section to chapter
7 69.41 RCW.

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

9 **Sec. 1.** RCW 18.64.011 and 2015 c 234 s 3 are each amended to
10 read as follows:

11 The definitions in this section apply throughout this chapter
12 unless the context clearly requires otherwise.

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

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

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

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

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

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

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

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

16 (9) "Dispense" means the interpretation of a prescription or
17 order for a drug, biological, or device and, pursuant to that
18 prescription or order, the proper selection, measuring, compounding,
19 labeling, or packaging necessary to prepare that prescription or
20 order for delivery.

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

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

34 (12) "Drugs" means:

35 (a) Articles recognized in the official United States
36 pharmacopoeia or the official homeopathic pharmacopoeia of the United
37 States;

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

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

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

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

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

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

24 (16) "Manufacture" means the production, preparation,
25 propagation, compounding, or processing of a drug or other substance
26 or device or the packaging or repackaging of such substance or
27 device, or the labeling or relabeling of the commercial container of
28 such substance or device, but does not include the activities of a
29 practitioner who, as an incident to his or her administration or
30 dispensing such substance or device in the course of his or her
31 professional practice, personally prepares, compounds, packages, or
32 labels such substance or device. "Manufacture" includes the
33 distribution of a licensed pharmacy compounded drug product to other
34 state licensed persons or commercial entities for subsequent resale
35 or distribution, unless a specific product item has approval of the
36 commission. The term does not include:

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

1 (b) The practice of a licensed pharmacy when repackaging
2 commercially available medication in small, reasonable quantities for
3 a practitioner legally authorized to prescribe the medication for
4 office use only;

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

9 (d) The delivery of finished and appropriately labeled compounded
10 products dispensed pursuant to a valid prescription to alternate
11 delivery locations, other than the patient's residence, when
12 requested by the patient, or the prescriber to administer to the
13 patient, or to another licensed pharmacy to dispense to the patient.

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

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

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

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

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

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

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

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

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

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

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

13 (28) "Chart order" means a lawful order for a drug or device
14 entered on the chart or medical record of an inpatient or resident of
15 an institutional facility by a practitioner or his or her designated
16 agent.

17 (29) "Closed door long-term care pharmacy" means a pharmacy that
18 provides pharmaceutical care to a defined and exclusive group of
19 patients who have access to the services of the pharmacy because they
20 are treated by or have an affiliation with a long-term care facility
21 or hospice program, and that is not a retailer of goods to the
22 general public.

23 (30) "Hospice program" means a hospice program certified or paid
24 by medicare under Title XVIII of the federal social security act, or
25 a hospice program licensed under chapter 70.127 RCW.

26 (31) "Institutional facility" means any organization whose
27 primary purpose is to provide a physical environment for patients to
28 obtain health care services including, but not limited to, services
29 in a hospital, long-term care facility, hospice program, mental
30 health facility, drug abuse treatment center, residential
31 habilitation center, or a local, state, or federal correction
32 facility.

33 (32) "Long-term care facility" means a nursing home licensed
34 under chapter 18.51 RCW, an assisted living facility licensed under
35 chapter 18.20 RCW, or an adult family home licensed under chapter
36 70.128 RCW.

37 (33) "Shared pharmacy services" means a system that allows a
38 participating pharmacist or pharmacy pursuant to a request from
39 another participating pharmacist or pharmacy to process or fill a
40 prescription or drug order, which may include but is not necessarily

1 limited to preparing, packaging, labeling, data entry, compounding
2 for specific patients, dispensing, performing drug utilization
3 reviews, conducting claims adjudication, obtaining refill
4 authorizations, reviewing therapeutic interventions, or reviewing
5 chart orders.

6 NEW SECTION. Sec. 2. A new section is added to chapter 18.64
7 RCW to read as follows:

8 (1) A chart order must be considered a prescription if it
9 contains:

10 (a) The full name of the patient;

11 (b) The date of issuance;

12 (c) The name, strength, and dosage form of the drug prescribed;

13 (d) Directions for use; and

14 (e) An authorized signature:

15 (i) For written orders, the order must contain the prescribing
16 practitioner's signature or the signature of the practitioner's
17 authorized agent, including the name of the prescribing practitioner;
18 or

19 (ii) For electronic or digital orders, the order must contain the
20 prescribing practitioner's electronic or digital signature, or the
21 electronic or digital signature of the practitioner's authorized
22 agent, including the name of the prescribing practitioner.

23 (2) A licensed nurse, pharmacist, or physician practicing in a
24 long-term care facility or hospice program may act as the
25 practitioner's agent for purposes of this chapter, without need for a
26 written agency agreement, to document a chart order in the patient's
27 medical record on behalf of the prescribing practitioner pending the
28 prescribing practitioner's signature; or to communicate a
29 prescription to a pharmacy whether telephonically, via facsimile, or
30 electronically. The communication of a prescription to a dispenser by
31 the prescriber's agent has the same force and effect as if
32 communicated directly by the authorized practitioner.

33 (3) Nothing in this chapter prevents an authorized credentialed
34 employee of a long-term care facility from transmitting a chart order
35 pursuant to RCW 74.42.230, or transmitting a prescription on behalf
36 of a resident to the extent otherwise authorized by law.

37 NEW SECTION. Sec. 3. A new section is added to chapter 18.64
38 RCW to read as follows:

1 (1) A pharmacy or pharmacist may provide a limited quantity of
2 drugs to a nursing home or hospice program without a prescription for
3 emergency administration by authorized personnel of the facility or
4 program pursuant to a valid prescription. The drugs so provided must
5 be limited to those required to meet the immediate therapeutic needs
6 of residents or patients and may not be available from another
7 authorized source in sufficient time to prevent risk of harm by delay
8 resulting from obtaining drugs from another source. Emergency kits
9 must be secured in a locked room, container, or device to prevent
10 unauthorized access and to ensure the proper environment for
11 preservation of the drugs.

12 (2) In addition to or in connection with the emergency kit
13 authorized under subsection (1) of this section, a nursing home that
14 employs a unit dose drug distribution system may maintain a
15 supplemental dose kit for supplemental nonemergency drug therapy.
16 Supplemental dose kits must be secured in a locked room, container,
17 or device to prevent unauthorized access, and to ensure the proper
18 environment for preservation of the drugs. Administration of drugs
19 from a supplemental dose kit must be under a valid prescription or
20 chart order.

21 (3) The types and quantity of drugs appropriate to serve the
22 resident or patient population of a nursing home or hospice program
23 using an emergency kit or supplemental dose kit and procedures for
24 the proper storage and security of drugs must be determined by a
25 pharmaceutical services committee that includes a pharmacist licensed
26 under this chapter, a physician licensed under chapter 18.71 RCW, an
27 osteopathic physician licensed under chapter 18.57 RCW, or an
28 advanced registered nurse practitioner licensed under chapter 18.79
29 RCW, and appropriate clinical or administrative personnel of the
30 nursing home or hospice program as set forth in rules adopted by the
31 pharmacy quality assurance commission.

32 (4) A registered nurse or licensed practical nurse operating
33 under appropriate direction and supervision by a pharmacist may
34 restock an emergency kit or supplemental dose kit to provide for safe
35 and timely patient access.

36 NEW SECTION. **Sec. 4.** A new section is added to chapter 18.64
37 RCW to read as follows:

38 (1) A pharmacy may resupply a legend drug to a patient at a long-
39 term care facility or hospice program pursuant to a valid chart order

1 that is signed by the prescribing practitioner, is not time limited,
2 and has not been discontinued.

3 (2) A pharmacy may outsource shared pharmacy services for a long-
4 term care facility or hospice program to another pharmacy if the
5 outsourcing pharmacy:

6 (a) Obtains approval from the long-term care facility or hospice
7 program to outsource shared pharmacy services for the facility's or
8 program's residents or patients; and

9 (b) Provides a copy of the prescription or order to the pharmacy
10 providing the shared pharmacy services.

11 (3) Shared pharmacy services may be used for, but are not limited
12 to, the purpose of ensuring that drugs or devices are attainable to
13 meet the immediate needs of residents of the long-term care facility
14 or hospice program, or when the outsourcing pharmacy cannot provide
15 services on an ongoing basis. Where a pharmacy uses shared pharmacy
16 services to have a second pharmacy provide a first dose or partial
17 fill of a prescription or drug order to meet a patient's or
18 resident's immediate needs, the second supplying pharmacy may
19 dispense the first dose or partially filled prescription on a
20 satellite basis without the outsourcing pharmacy being required to
21 fully transfer the prescription to the supplying pharmacy. The
22 supplying pharmacy must retain a copy of the prescription or order on
23 file, a copy of the dispensing record or fill, and must notify the
24 outsourcing pharmacy of the service and quantity provided.

25 (4) A pharmacy may repackage and dispense unused drugs returned
26 by a long-term care facility or hospice program to the pharmacy in
27 per-use, blister packaging, whether in unit dose or modified unit
28 dose form, except as prohibited by federal law. The commission must
29 adopt rules providing for the safe and efficient repackaging, reuse,
30 and disposal of unused drugs returned to a pharmacy from a long-term
31 care facility or hospice program. In adopting rules, the commission
32 must take into consideration the acceptance and dispensing
33 requirements of RCW 69.70.050 (1), (2), and (5).

34 NEW SECTION. **Sec. 5.** A new section is added to chapter 18.64
35 RCW to read as follows:

36 The commission must adopt reasonable, task-based standards
37 regarding the ratio of pharmacists to pharmacy technicians in a
38 closed door long-term care pharmacy. For the purpose of such
39 standards, a pharmacy technician licensed under chapter 18.64A RCW

1 may not be considered to be practicing as a pharmacy technician while
2 performing administrative tasks not associated with immediate
3 dispensing of drugs that may lawfully be performed by a registered
4 pharmacy assistant. Administrative tasks not associated with
5 immediate dispensing of drugs include but are not necessarily limited
6 to medical records maintenance, billing, prepackaging unit dose
7 drugs, inventory control, delivery, and processing returned drugs.

8 NEW SECTION. **Sec. 6.** A new section is added to chapter 18.64
9 RCW to read as follows:

10 The commission may adopt rules implementing sections 2 through 5
11 of this act.

12 NEW SECTION. **Sec. 7.** A new section is added to chapter 69.41
13 RCW to read as follows:

14 (1) A pharmacy may dispense legend drugs to the resident of a
15 long-term care facility or hospice program on the basis of a written
16 or digitally signed prescription or chart order sent via facsimile
17 copy by the prescriber to the long-term care facility or hospice
18 program, and communicated or transmitted to the pharmacy pursuant to
19 section 2 of this act.

20 (2) For the purpose of this section, the terms "long-term care
21 facility," "hospice program," and "chart order" have the meanings
22 provided in RCW 18.64.011.

23 **Sec. 8.** RCW 69.50.308 and 2013 c 276 s 3 are each amended to
24 read as follows:

25 (a) A controlled substance may be dispensed only as provided in
26 this section. Prescriptions electronically communicated must also
27 meet the requirements under RCW 69.50.312.

28 (b) Except when dispensed directly by a practitioner authorized
29 to prescribe or administer a controlled substance, other than a
30 pharmacy, to an ultimate user, a substance included in Schedule II
31 may not be dispensed without the written or electronically
32 communicated prescription of a practitioner.

33 (1) Schedule II narcotic substances may be dispensed by a
34 pharmacy pursuant to a facsimile prescription under the following
35 circumstances:

36 (i) The facsimile prescription is transmitted by a practitioner
37 to the pharmacy; and

1 (ii) The facsimile prescription is for a patient in a long-term
2 care facility or a hospice program (~~(certified or paid by medicare~~
3 ~~under Title XVIII of the federal social security act. "Long-term care~~
4 ~~facility" means nursing homes licensed under chapter 18.51 RCW,~~
5 ~~assisted living facilities licensed under chapter 18.20 RCW, and~~
6 ~~adult family homes licensed under chapter 70.128 RCW; or~~

7 ~~(iii) The facsimile prescription is for a patient of a hospice~~
8 ~~program licensed by the state)); and~~

9 ((~~(iv)~~)) (iii) The practitioner or the practitioner's agent notes
10 on the facsimile prescription that the patient is a long-term care or
11 hospice patient.

12 (2) Injectable Schedule II narcotic substances that are to be
13 compounded for patient use may be dispensed by a pharmacy pursuant to
14 a facsimile prescription if the facsimile prescription is transmitted
15 by a practitioner to the pharmacy.

16 (3) Under (1) and (2) of this subsection the facsimile
17 prescription shall serve as the original prescription and shall be
18 maintained as other Schedule II narcotic substances prescriptions.

19 (c) In emergency situations, as defined by rule of the
20 commission, a substance included in Schedule II may be dispensed upon
21 oral prescription of a practitioner, reduced promptly to writing and
22 filed by the pharmacy. Prescriptions shall be retained in conformity
23 with the requirements of RCW 69.50.306.

24 (d) A prescription for a substance included in Schedule II may
25 not be refilled. A prescription for a substance included in Schedule
26 II may not be filled more than six months after the date the
27 prescription was issued.

28 (e) Except when dispensed directly by a practitioner authorized
29 to prescribe or administer a controlled substance, other than a
30 pharmacy, to an ultimate user, a substance included in Schedule III,
31 IV, or V, which is a prescription drug as determined under RCW
32 69.04.560, may not be dispensed without a written, oral, or
33 electronically communicated prescription of a practitioner. Any oral
34 prescription must be promptly reduced to writing.

35 (f) A written, oral, or electronically communicated prescription
36 for a substance included in Schedule III, IV, or V, which is a
37 prescription drug as determined under RCW 69.04.560, for a resident
38 in a long-term care facility or hospice program may be communicated
39 to the pharmacy by an authorized agent of the prescriber. A
40 registered nurse, pharmacist, or physician practicing in a long-term

1 care facility or hospice program may act as the practitioner's agent
2 for purposes of this section, without need for a written agency
3 agreement.

4 (g) The prescription for a substance included in Schedule III,
5 IV, or V may not be filled or refilled more than six months after the
6 date issued by the practitioner or be refilled more than five times,
7 unless renewed by the practitioner.

8 ~~((g))~~ (h) A valid prescription or lawful order of a
9 practitioner, in order to be effective in legalizing the possession
10 of controlled substances, must be issued in good faith for a
11 legitimate medical purpose by one authorized to prescribe the use of
12 such controlled substance. An order purporting to be a prescription
13 not in the course of professional treatment is not a valid
14 prescription or lawful order of a practitioner within the meaning and
15 intent of this chapter; and the person who knows or should know that
16 the person is filling such an order, as well as the person issuing
17 it, can be charged with a violation of this chapter.

18 ~~((h))~~ (i) A substance included in Schedule V must be distributed
19 or dispensed only for a medical purpose.

20 ~~((i))~~ (j) A practitioner may dispense or deliver a controlled
21 substance to or for an individual or animal only for medical
22 treatment or authorized research in the ordinary course of that
23 practitioner's profession. Medical treatment includes dispensing or
24 administering a narcotic drug for pain, including intractable pain.

25 ~~((j))~~ (k) No administrative sanction, or civil or criminal
26 liability, authorized or created by this chapter may be imposed on a
27 pharmacist for action taken in reliance on a reasonable belief that
28 an order purporting to be a prescription was issued by a practitioner
29 in the usual course of professional treatment or in authorized
30 research.

31 ~~((k))~~ (l) An individual practitioner may not dispense a
32 substance included in Schedule II, III, or IV for that individual
33 practitioner's personal use.

34 (4) For the purposes of this section, the terms "long-term care
35 facility" and "hospice program" have the meaning provided in RCW
36 18.64.011.

37 **Sec. 9.** RCW 74.42.230 and 1994 sp.s. c 9 s 751 are each amended
38 to read as follows:

1 (1) The resident's attending or staff physician or authorized
2 practitioner approved by the attending physician shall order all
3 medications for the resident. The order may be oral or written and
4 shall ~~((be limited by time))~~ continue in effect until discontinued by
5 a physician or other authorized prescriber, unless the order is
6 specifically limited by time. An "authorized practitioner," as used
7 in this section, is a registered nurse under chapter 18.79 RCW when
8 authorized by the nursing care quality assurance commission, an
9 osteopathic physician assistant under chapter 18.57A RCW when
10 authorized by the committee of osteopathic examiners, ~~((or))~~ a
11 physician assistant under chapter 18.71A RCW when authorized by the
12 medical quality assurance commission, or a pharmacist under chapter
13 18.64 RCW when authorized by the pharmacy quality assurance
14 commission.

15 (2) An oral order shall be given only to a licensed nurse,
16 pharmacist, or another physician. The oral order shall be recorded
17 and physically or electronically signed immediately by the person
18 receiving the order. The attending physician shall sign the record of
19 the oral order in a manner consistent with good medical practice.

20 (3) A licensed nurse, pharmacist, or another physician receiving
21 and recording an oral order may, if so authorized by the physician or
22 authorized practitioner, communicate that order to a pharmacy on
23 behalf of the physician or authorized practitioner. The order may be
24 communicated verbally by telephone, by facsimile manually signed by
25 the person receiving the order pursuant to subsection (2) of this
26 section, or by electronic transmission pursuant to RCW 69.41.055. The
27 communication of a resident's order to a pharmacy by a licensed
28 nurse, pharmacist, or another physician acting at the prescriber's
29 direction has the same force and effect as if communicated directly
30 by the delegating physician or authorized practitioner. Nothing in
31 this provision limits the authority of a licensed nurse, pharmacist,
32 or physician to delegate to an authorized agent, including but not
33 limited to delegation of operation of a facsimile machine by
34 credentialed facility staff, to the extent consistent with his or her
35 professional license.

36 **Sec. 10.** RCW 69.41.010 and 2013 c 276 s 1 and 2013 c 19 s 55 are
37 each reenacted and amended to read as follows:

38 As used in this chapter, the following terms have the meanings
39 indicated unless the context clearly requires otherwise:

1 (1) "Administer" means the direct application of a legend drug
2 whether by injection, inhalation, ingestion, or any other means, to
3 the body of a patient or research subject by:

4 (a) A practitioner; or

5 (b) The patient or research subject at the direction of the
6 practitioner.

7 (2) "Community-based care settings" include: Community
8 residential programs for persons with developmental disabilities,
9 certified by the department of social and health services under
10 chapter 71A.12 RCW; adult family homes licensed under chapter 70.128
11 RCW; and assisted living facilities licensed under chapter 18.20 RCW.
12 Community-based care settings do not include acute care or skilled
13 nursing facilities.

14 (3) "Deliver" or "delivery" means the actual, constructive, or
15 attempted transfer from one person to another of a legend drug,
16 whether or not there is an agency relationship.

17 (4) "Department" means the department of health.

18 (5) "Dispense" means the interpretation of a prescription or
19 order for a legend drug and, pursuant to that prescription or order,
20 the proper selection, measuring, compounding, labeling, or packaging
21 necessary to prepare that prescription or order for delivery.

22 (6) "Dispenser" means a practitioner who dispenses.

23 (7) "Distribute" means to deliver other than by administering or
24 dispensing a legend drug.

25 (8) "Distributor" means a person who distributes.

26 (9) "Drug" means:

27 (a) Substances recognized as drugs in the official United States
28 pharmacopoeia, official homeopathic pharmacopoeia of the United
29 States, or official national formulary, or any supplement to any of
30 them;

31 (b) Substances intended for use in the diagnosis, cure,
32 mitigation, treatment, or prevention of disease in human beings or
33 animals;

34 (c) Substances (other than food, minerals or vitamins) intended
35 to affect the structure or any function of the body of human beings
36 or animals; and

37 (d) Substances intended for use as a component of any article
38 specified in (a), (b), or (c) of this subsection. It does not include
39 devices or their components, parts, or accessories.

1 (10) "Electronic communication of prescription information" means
2 the transmission of a prescription or refill authorization for a drug
3 of a practitioner using computer systems. The term does not include a
4 prescription or refill authorization transmitted verbally by
5 telephone nor a facsimile manually signed by the practitioner.

6 (11) "In-home care settings" include an individual's place of
7 temporary and permanent residence, but does not include acute care or
8 skilled nursing facilities, and does not include community-based care
9 settings.

10 (12) "Legend drugs" means any drugs which are required by state
11 law or regulation of the pharmacy quality assurance commission to be
12 dispensed on prescription only or are restricted to use by
13 practitioners only.

14 (13) "Legible prescription" means a prescription or medication
15 order issued by a practitioner that is capable of being read and
16 understood by the pharmacist filling the prescription or the nurse or
17 other practitioner implementing the medication order. A prescription
18 must be hand printed, typewritten, or electronically generated.

19 (14) "Medication assistance" means assistance rendered by a
20 nonpractitioner to an individual residing in a community-based care
21 setting or in-home care setting to facilitate the individual's self-
22 administration of a legend drug or controlled substance. It includes
23 reminding or coaching the individual, handing the medication
24 container to the individual, opening the individual's medication
25 container, using an enabler, or placing the medication in the
26 individual's hand, and such other means of medication assistance as
27 defined by rule adopted by the department. A nonpractitioner may help
28 in the preparation of legend drugs or controlled substances for self-
29 administration where a practitioner has determined and communicated
30 orally or by written direction that such medication preparation
31 assistance is necessary and appropriate. Medication assistance shall
32 not include assistance with intravenous medications or injectable
33 medications, except prefilled insulin syringes.

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

37 (16) "Practitioner" means:

38 (a) A physician under chapter 18.71 RCW, an osteopathic physician
39 or an osteopathic physician and surgeon under chapter 18.57 RCW, a
40 dentist under chapter 18.32 RCW, a podiatric physician and surgeon

1 under chapter 18.22 RCW, a veterinarian under chapter 18.92 RCW, a
2 registered nurse, advanced registered nurse practitioner, or licensed
3 practical nurse under chapter 18.79 RCW, an optometrist under chapter
4 18.53 RCW who is certified by the optometry board under RCW
5 18.53.010, an osteopathic physician assistant under chapter 18.57A
6 RCW, a physician assistant under chapter 18.71A RCW, a naturopath
7 licensed under chapter 18.36A RCW, a pharmacist under chapter 18.64
8 RCW, or, when acting under the required supervision of a dentist
9 licensed under chapter 18.32 RCW, a dental hygienist licensed under
10 chapter 18.29 RCW;

11 (b) A pharmacy, hospital, or other institution licensed,
12 registered, or otherwise permitted to distribute, dispense, conduct
13 research with respect to, or to administer a legend drug in the
14 course of professional practice or research in this state; and

15 (c) A physician licensed to practice medicine and surgery or a
16 physician licensed to practice osteopathic medicine and surgery in
17 any state, or province of Canada, which shares a common border with
18 the state of Washington.

19 (17) "Secretary" means the secretary of health or the secretary's
20 designee.

21 (18) "Commission" means the pharmacy quality assurance
22 commission.

23 **Sec. 11.** RCW 69.41.030 and 2013 c 71 s 1 and 2013 c 12 s 1 are
24 each reenacted and amended to read as follows:

25 (1) It shall be unlawful for any person to sell, deliver, or
26 possess any legend drug except upon the order or prescription of a
27 physician under chapter 18.71 RCW, an osteopathic physician and
28 surgeon under chapter 18.57 RCW, an optometrist licensed under
29 chapter 18.53 RCW who is certified by the optometry board under RCW
30 18.53.010, a dentist under chapter 18.32 RCW, a podiatric physician
31 and surgeon under chapter 18.22 RCW, a veterinarian under chapter
32 18.92 RCW, a commissioned medical or dental officer in the United
33 States armed forces or public health service in the discharge of his
34 or her official duties, a duly licensed physician or dentist employed
35 by the veterans administration in the discharge of his or her
36 official duties, a registered nurse or advanced registered nurse
37 practitioner under chapter 18.79 RCW when authorized by the nursing
38 care quality assurance commission, a pharmacist licensed under
39 chapter 18.64 RCW to the extent permitted by drug therapy guidelines

1 or protocols established under RCW 18.64.011 and authorized by the
2 (~~board of pharmacy~~) commission and approved by a practitioner
3 authorized to prescribe drugs, an osteopathic physician assistant
4 under chapter 18.57A RCW when authorized by the board of osteopathic
5 medicine and surgery, a physician assistant under chapter 18.71A RCW
6 when authorized by the medical quality assurance commission, or any
7 of the following professionals in any province of Canada that shares
8 a common border with the state of Washington or in any state of the
9 United States: A physician licensed to practice medicine and surgery
10 or a physician licensed to practice osteopathic medicine and surgery,
11 a dentist licensed to practice dentistry, a podiatric physician and
12 surgeon licensed to practice podiatric medicine and surgery, a
13 licensed advanced registered nurse practitioner, a licensed physician
14 assistant, a licensed osteopathic physician assistant, or a
15 veterinarian licensed to practice veterinary medicine: PROVIDED,
16 HOWEVER, That the above provisions shall not apply to sale, delivery,
17 or possession by drug wholesalers or drug manufacturers, or their
18 agents or employees, or to any practitioner acting within the scope
19 of his or her license, or to a common or contract carrier or
20 warehouse operator, or any employee thereof, whose possession of any
21 legend drug is in the usual course of business or employment:
22 PROVIDED FURTHER, That nothing in this chapter or chapter 18.64 RCW
23 shall prevent a family planning clinic that is under contract with
24 the health care authority from selling, delivering, possessing, and
25 dispensing commercially prepackaged oral contraceptives prescribed by
26 authorized, licensed health care practitioners.

27 (2)(a) A violation of this section involving the sale, delivery,
28 or possession with intent to sell or deliver is a class B felony
29 punishable according to chapter 9A.20 RCW.

30 (b) A violation of this section involving possession is a
31 misdemeanor.

32 **Sec. 12.** RCW 69.41.032 and 1987 c 41 s 2 are each amended to
33 read as follows:

34 This chapter shall not prevent a medicare-approved dialysis
35 center or facility operating a medicare-approved home dialysis
36 program from selling, delivering, possessing, or dispensing directly
37 to its dialysis patients, in case or full shelf lots, if prescribed
38 by a physician licensed under chapter 18.57 or 18.71 RCW, those
39 legend drugs determined by the (~~board~~) commission pursuant to rule.

1 **Sec. 13.** RCW 69.41.042 and 1989 1st ex.s. c 9 s 405 are each
2 amended to read as follows:

3 A pharmaceutical manufacturer, wholesaler, pharmacy, or
4 practitioner who purchases, dispenses, or distributes legend drugs
5 shall maintain invoices or such other records as are necessary to
6 account for the receipt and disposition of the legend drugs.

7 The records maintained pursuant to this section shall be
8 available for inspection by the ((~~board~~)) commission and its
9 authorized representatives and shall be maintained for two years.

10 **Sec. 14.** RCW 69.41.044 and 2005 c 274 s 328 are each amended to
11 read as follows:

12 All records, reports, and information obtained by the ((~~board~~))
13 commission or its authorized representatives from or on behalf of a
14 pharmaceutical manufacturer, representative of a manufacturer,
15 wholesaler, pharmacy, or practitioner who purchases, dispenses, or
16 distributes legend drugs under this chapter are confidential and
17 exempt from public inspection and copying under chapter 42.56 RCW.
18 Nothing in this section restricts the investigations or the
19 proceedings of the ((~~board~~)) commission so long as the ((~~board~~))
20 commission and its authorized representatives comply with the
21 provisions of chapter 42.56 RCW.

22 **Sec. 15.** RCW 69.41.055 and 1998 c 222 s 2 are each amended to
23 read as follows:

24 (1) Information concerning an original prescription or
25 information concerning a prescription refill for a legend drug may be
26 electronically communicated between an authorized practitioner and a
27 pharmacy of the patient's choice with no intervening person having
28 access to the prescription drug order pursuant to the provisions of
29 this chapter if the electronically communicated prescription
30 information complies with the following:

31 (a) Electronically communicated prescription information must
32 comply with all applicable statutes and rules regarding the form,
33 content, recordkeeping, and processing of a prescription or order for
34 a legend drug;

35 (b) The system used for transmitting electronically communicated
36 prescription information and the system used for receiving
37 electronically communicated prescription information must be approved
38 by the ((~~board~~)) commission. This subsection does not apply to

1 currently used facsimile equipment transmitting an exact visual image
2 of the prescription. The ((~~board~~)) commission shall maintain and
3 provide, upon request, a list of systems used for electronically
4 communicating prescription information currently approved by the
5 ((~~board~~)) commission;

6 (c) An explicit opportunity for practitioners must be made to
7 indicate their preference on whether or not a therapeutically
8 equivalent generic drug or interchangeable biological product may be
9 substituted. This section does not limit the ability of practitioners
10 and pharmacists to permit substitution by default under a prior-
11 consent authorization;

12 (d) Prescription drug orders are confidential health information,
13 and may be released only to the patient or the patient's authorized
14 representative, the prescriber or other authorized practitioner then
15 caring for the patient, or other persons specifically authorized by
16 law to receive such information;

17 (e) To maintain confidentiality of prescription records, the
18 electronic system shall have adequate security and systems safeguards
19 designed to prevent and detect unauthorized access, modification, or
20 manipulation of these records. The pharmacist in charge shall
21 establish or verify the existence of policies and procedures which
22 ensure the integrity and confidentiality of prescription information
23 transmitted to the pharmacy by electronic means. All managers,
24 employees, and agents of the pharmacy are required to read, sign, and
25 comply with the established policies and procedures; and

26 (f) The pharmacist shall exercise professional judgment regarding
27 the accuracy, validity, and authenticity of the prescription drug
28 order received by way of electronic transmission, consistent with
29 federal and state laws and rules and guidelines of the ((~~board~~))
30 commission.

31 (2) The electronic or digital signature of the prescribing
32 practitioner's agent on behalf of the prescribing practitioner for a
33 resident in a long-term care facility or hospice program, pursuant to
34 a valid order and authorization under section 2 of this act,
35 constitutes a valid electronic communication of prescription
36 information. Such an authorized signature and transmission by an
37 agent in a long-term care facility or hospice program does not
38 constitute an intervening person having access to the prescription
39 drug order.

1 (3) The ((board)) commission may adopt rules implementing this
2 section.

3 **Sec. 16.** RCW 69.41.220 and 1989 1st ex.s. c 9 s 428 are each
4 amended to read as follows:

5 Each manufacturer and distributor shall publish and provide to
6 the ((board)) commission by filing with the department printed
7 material which will identify each current imprint used by the
8 manufacturer or distributor. The ((board)) commission shall be
9 notified of any change by the filing of any change with the
10 department. This information shall be provided by the department to
11 all pharmacies licensed in the state of Washington, poison control
12 centers, and hospital emergency rooms.

13 **Sec. 17.** RCW 18.64.245 and 2013 c 19 s 17 are each amended to
14 read as follows:

15 (1) Every proprietor or manager of a pharmacy shall keep readily
16 available a suitable record of prescriptions which shall preserve for
17 a period of not less than two years the record of every prescription
18 dispensed at such pharmacy which shall be numbered, dated, and filed,
19 and shall produce the same in court or before any grand jury whenever
20 lawfully required to do so. The record shall be maintained either
21 separately from all other records of the pharmacy or in such form
22 that the information required is readily retrievable from ordinary
23 business records of the pharmacy. All recordkeeping requirements for
24 controlled substances must be complied with. Such record of
25 prescriptions shall be for confidential use in the pharmacy, only.
26 The record of prescriptions shall be open for inspection by the
27 commission or any officer of the law, who is authorized to enforce
28 this chapter ((18.64)) or chapter 69.41((7)) or 69.50 RCW.

29 (2) When a pharmacy receives a prescription in digital or
30 electronic format through facsimile equipment transmitting an exact
31 visual image of the prescription, or through electronic communication
32 of prescription information, the digital or electronic record of
33 every such prescription dispensed at the pharmacy constitutes a
34 suitable record of prescriptions, provided that the original or
35 direct copy of the prescription is electronically or digitally
36 numbered or referenced, dated, and filed in a form that permits the
37 information required to be readily retrievable.

38 (3) A person violating this section is guilty of a misdemeanor.

1 **Sec. 18.** RCW 18.64.500 and 2013 c 19 s 30 are each amended to
2 read as follows:

3 (1) (~~Effective July 1, 2010,~~) Every prescription written in
4 this state by a licensed practitioner must be written on a tamper-
5 resistant prescription pad or paper approved by the commission.

6 (2) A pharmacist may not fill a written prescription from a
7 licensed practitioner unless it is written on an approved tamper-
8 resistant prescription pad or paper, except that a pharmacist may
9 provide emergency supplies in accordance with the commission and
10 other insurance contract requirements.

11 (3) If a hard copy of an electronic prescription is given
12 directly to the patient, the manually signed hard copy prescription
13 must be on approved tamper-resistant paper that meets the
14 requirements of this section.

15 (4) For the purposes of this section, "tamper-resistant
16 prescription pads or paper" means a prescription pad or paper that
17 has been approved by the commission for use and contains the
18 following characteristics:

19 (a) One or more industry-recognized features designed to prevent
20 unauthorized copying of a completed or blank prescription form;

21 (b) One or more industry-recognized features designed to prevent
22 the erasure or modification of information written on the
23 prescription form by the practitioner; and

24 (c) One or more industry-recognized features designed to prevent
25 the use of counterfeit prescription forms.

26 (5) Practitioners shall employ reasonable safeguards to assure
27 against theft or unauthorized use of prescriptions.

28 (6) All vendors must have their tamper-resistant prescription
29 pads or paper approved by the commission prior to the marketing or
30 sale of pads or paper in Washington state.

31 (7) The commission shall create a seal of approval that confirms
32 that a pad or paper contains all three industry-recognized
33 characteristics required by this section. The seal must be affixed to
34 all prescription pads or paper used in this state.

35 (8) The commission may adopt rules necessary for the
36 administration of chapter 328, Laws of 2009.

37 (9) The tamper-resistant prescription pad or paper requirements
38 in this section shall not apply to:

39 (a) Prescriptions that are transmitted to the pharmacy by
40 telephone, facsimile, or electronic means; or

1 (b) Prescriptions written for inpatients of a hospital,
2 outpatients of a hospital, residents of a (~~nursing home~~) long-term
3 care facility, patients of a hospice program, inpatients or residents
4 of a mental health facility, or individuals incarcerated in a local,
5 state, or federal correction facility, when the health care
6 practitioner authorized to write prescriptions, or his or her
7 authorized agent, writes the order into the patient's medical or
8 clinical record, the order is given directly to the pharmacy, and the
9 patient never has the opportunity to handle the written order.

10 (10) All acts related to the prescribing, dispensing, and records
11 maintenance of all prescriptions shall be in compliance with
12 applicable federal and state laws, rules, and regulations.

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