

CERTIFICATION OF ENROLLMENT

SUBSTITUTE HOUSE BILL 1445

67th Legislature
2021 Regular Session

Passed by the House March 6, 2021
Yeas 98 Nays 0

**Speaker of the House of
Representatives**

Passed by the Senate April 6, 2021
Yeas 49 Nays 0

President of the Senate

Approved

Governor of the State of Washington

CERTIFICATE

I, Bernard Dean, Chief Clerk of the House of Representatives of the State of Washington, do hereby certify that the attached is **SUBSTITUTE HOUSE BILL 1445** as passed by the House of Representatives and the Senate on the dates hereon set forth.

Chief Clerk

FILED

**Secretary of State
State of Washington**

SUBSTITUTE HOUSE BILL 1445

Passed Legislature - 2021 Regular Session

State of Washington 67th Legislature 2021 Regular Session

By House Health Care & Wellness (originally sponsored by Representatives Thai, Cody, Ormsby, Pollet, and Harris-Talley)

READ FIRST TIME 02/15/21.

1 AN ACT Relating to the definition of compounding for purposes of
2 the practice of pharmacy; and reenacting and amending RCW 18.64.011.

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

4 **Sec. 1.** RCW 18.64.011 and 2016 c 148 s 1 are each reenacted and
5 amended to read as follows:

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

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

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

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

20 (4) "Closed door long-term care pharmacy" means a pharmacy that
21 provides pharmaceutical care to a defined and exclusive group of

1 patients who have access to the services of the pharmacy because they
2 are treated by or have an affiliation with a long-term care facility
3 or hospice program, and that is not a retailer of goods to the
4 general public.

5 (5) "Commission" means the pharmacy quality assurance commission.

6 (6) "Compounding" means the act of combining two or more
7 ingredients in the preparation of a prescription. Reconstitution and
8 mixing of (a) sterile products according to federal food and drug
9 administration-approved labeling does not constitute compounding if
10 prepared pursuant to a prescription and administered immediately or
11 in accordance with package labeling, and (b) nonsterile products
12 according to federal food and drug administration-approved labeling
13 does not constitute compounding if prepared pursuant to a
14 prescription.

15 (7) "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 (8) "Deliver" or "delivery" means the actual, constructive, or
19 attempted transfer from one person to another of a drug or device,
20 whether or not there is an agency relationship.

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

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

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

33 (12) "Distribute" means the delivery of a drug or device other
34 than by administering or dispensing.

35 (13) "Drug" and "devices" do not include surgical or dental
36 instruments or laboratory materials, gas and oxygen, therapy
37 equipment, X-ray apparatus or therapeutic equipment, their component
38 parts or accessories, or equipment, instruments, apparatus, or
39 contrivances used to render such articles effective in medical,
40 surgical, or dental treatment, or for use or consumption in or for

1 mechanical, industrial, manufacturing, or scientific applications or
2 purposes. "Drug" also does not include any article or mixture covered
3 by the Washington pesticide control act (chapter 15.58 RCW), as
4 enacted or hereafter amended, nor medicated feed intended for and
5 used exclusively as a feed for animals other than human beings.

6 (14) "Drugs" means:

7 (a) Articles recognized in the official United States
8 pharmacopoeia or the official homeopathic pharmacopoeia of the United
9 States;

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

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

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

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

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

32 (17) "Institutional facility" means any organization whose
33 primary purpose is to provide a physical environment for patients to
34 obtain health care services including, but not limited to, services
35 in a hospital, long-term care facility, hospice program, mental
36 health facility, drug abuse treatment center, residential
37 habilitation center, or a local, state, or federal correction
38 facility.

39 (18) "Labeling" means the process of preparing and affixing a
40 label to any drug or device container. The label must include all

1 information required by current federal and state law and pharmacy
2 rules.

3 (19) "Legend drugs" means any drugs which are required by any
4 applicable federal or state law or regulation to be dispensed on
5 prescription only or are restricted to use by practitioners only.

6 (20) "Long-term care facility" means a nursing home licensed
7 under chapter 18.51 RCW, an assisted living facility licensed under
8 chapter 18.20 RCW, or an adult family home licensed under chapter
9 70.128 RCW.

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

23 (a) The activities of a licensed pharmacy that compounds a
24 product on or in anticipation of an order of a licensed practitioner
25 for use in the course of their professional practice to administer to
26 patients, 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
32 by 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
38 requested by the patient, or the prescriber to administer to the
39 patient, or to another licensed pharmacy to dispense to the patient.

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

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

5 (24) "Person" means an individual, corporation, government,
6 governmental subdivision or agency, business trust, estate, trust,
7 partnership or association, or any other legal entity.

8 (25) "Pharmacist" means a person duly licensed by the commission
9 to engage in the practice of pharmacy.

10 (26) "Pharmacy" means every place properly licensed by the
11 commission where the practice of pharmacy is conducted.

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

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

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

31 (30) "Prescription" means an order for drugs or devices issued by
32 a practitioner duly authorized by law or rule in the state of
33 Washington to prescribe drugs or devices in the course of his or her
34 professional practice for a legitimate medical purpose.

35 (31) "Secretary" means the secretary of health or the secretary's
36 designee.

37 (32) "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 (33) "Wholesaler" means 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.

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