

CERTIFICATION OF ENROLLMENT
ENGROSSED SUBSTITUTE HOUSE BILL 2458

Chapter 43, Laws of 2016

64th Legislature
2016 Regular Session

PRESCRIPTION DRUG DONATION PROGRAM--PARTICIPATION REQUIREMENTS

EFFECTIVE DATE: 1/1/2017

Passed by the House March 7, 2016
Yeas 96 Nays 0

FRANK CHOPP

Speaker of the House of Representatives

Passed by the Senate March 2, 2016
Yeas 47 Nays 0

BRAD OWEN

President of the Senate

Approved March 29, 2016 3:45 PM

JAY INSLEE

Governor of the State of Washington

CERTIFICATE

I, Barbara Baker, Chief Clerk of the House of Representatives of the State of Washington, do hereby certify that the attached is **ENGROSSED SUBSTITUTE HOUSE BILL 2458** as passed by House of Representatives and the Senate on the dates hereon set forth.

BARBARA BAKER

Chief Clerk

FILED

March 30, 2016

**Secretary of State
State of Washington**

ENGROSSED SUBSTITUTE HOUSE BILL 2458

AS AMENDED BY THE SENATE

Passed Legislature - 2016 Regular Session

State of Washington **64th Legislature** **2016 Regular Session**

By House Health Care & Wellness (originally sponsored by Representatives Parker, Cody, Riccelli, Holy, and Tharinger)

READ FIRST TIME 02/02/16.

1 AN ACT Relating to participation in the prescription drug
2 donation program; amending RCW 69.70.010, 69.70.020, 69.70.040,
3 69.70.050, 69.70.060, and 69.70.070; creating a new section; and
4 providing an effective date.

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

6 **Sec. 1.** RCW 69.70.010 and 2013 c 260 s 1 are each amended to
7 read as follows:

8 The definitions in this section apply throughout this chapter
9 unless the context clearly requires otherwise.

10 (1) "Department" means the department of health.

11 (2) "Drug manufacturer" means a facility licensed by the (~~board~~
12 ~~of~~) pharmacy quality assurance commission under chapter 18.64 RCW
13 that engages in the manufacture of drugs or devices.

14 (3) "Drug wholesaler" means a facility licensed by the (~~board~~
15 ~~of~~) pharmacy quality assurance commission under chapter 18.64 RCW
16 that buys drugs or devices for resale and distribution to
17 corporations, individuals, or entities other than consumers.

18 (4) "Medical facility" means a hospital, pharmacy, nursing home,
19 boarding home, adult family home, or medical clinic where the
20 prescription drugs are under the control of a practitioner.

1 (5) "Person" means an individual, corporation, business trust,
2 estate, trust, partnership, association, joint venture, government,
3 governmental subdivision or agency, or any other legal or commercial
4 entity.

5 (6) "Pharmacist" means a person licensed by the (~~board of~~)
6 pharmacy quality assurance commission under chapter 18.64 RCW to
7 practice pharmacy.

8 (7) "Pharmacy" means a facility licensed by the (~~board of~~)
9 pharmacy quality assurance commission under chapter 18.64 RCW in
10 which the practice of pharmacy is conducted.

11 (8) "Practitioner" has the same meaning as in RCW 69.41.010.

12 (9) "Prescribing practitioner" means a person authorized to issue
13 orders or prescriptions for legend drugs as listed in RCW 69.41.030.

14 (10) "Prescription drugs" has the same meaning as "legend drugs"
15 as defined in RCW 69.41.010. The term includes cancer drugs and
16 antirejection drugs. The term does not include controlled substances.

17 (11) "Supplies" means the supplies necessary to administer
18 prescription drugs that are donated under the prescription drug
19 redistribution program.

20 (12) "Time temperature indicator" means a device or smart label
21 that shows the accumulated time-temperature history of a product by
22 providing a nonreversible, accurate record of temperature exposure
23 through the entire supply chain.

24 (13) "Uninsured" means a person who:

25 (a) Does not have private or public health insurance; or

26 (b) Has health insurance, but the health insurance does not
27 provide coverage for a particular drug that has been prescribed to
28 the person.

29 **Sec. 2.** RCW 69.70.020 and 2013 c 260 s 2 are each amended to
30 read as follows:

31 (1) Any practitioner, pharmacist, medical facility, drug
32 manufacturer, or drug wholesaler may donate prescription drugs and
33 supplies to a pharmacy for redistribution without compensation or the
34 expectation of compensation to individuals who meet the
35 prioritization criteria established in RCW 69.70.040. Donations of
36 prescription drugs and supplies may be made on the premises of a
37 pharmacy that elects to participate in the provisions of this
38 chapter. A pharmacy that receives prescription drugs or supplies may
39 distribute the prescription drugs or supplies to another pharmacy,

1 pharmacist, or prescribing practitioner for use pursuant to the
2 program.

3 (2) The person to whom a prescription drug was prescribed, or the
4 person's representative, may donate prescription drugs under
5 subsection (1) of this section if, as determined by the professional
6 judgment of a pharmacist, the prescription drugs were stored under
7 required temperature conditions using the prescription drugs' time
8 temperature indicator information and the person, or the person's
9 representative, has completed and signed a donor form, adopted by the
10 department, to release the prescription drug for distribution under
11 this chapter and certifying that the donated prescription drug has
12 never been opened, used, adulterated, or misbranded.

13 **Sec. 3.** RCW 69.70.040 and 2013 c 260 s 4 are each amended to
14 read as follows:

15 Pharmacies, pharmacists, and prescribing practitioners that elect
16 to dispense donated prescription drugs and supplies under this
17 chapter shall give priority to individuals who are uninsured (~~and at~~
18 ~~or below two hundred percent of the federal poverty level~~). If an
19 uninsured (~~and low income~~) individual has not been identified as in
20 need of available prescription drugs and supplies, those prescription
21 drugs and supplies may be dispensed to other individuals expressing
22 need.

23 **Sec. 4.** RCW 69.70.050 and 2013 c 260 s 5 are each amended to
24 read as follows:

25 (1) Prescription drugs or supplies may be accepted and dispensed
26 under this chapter if all of the following conditions are met:

27 (a) The prescription drug is in:

28 (i) Its original sealed and tamper evident packaging; or

29 (ii) An opened package if it contains single unit doses that
30 remain intact;

31 (b) The prescription drug bears an expiration date that is more
32 than six months after the date the prescription drug was donated;

33 (c) The prescription drug or supplies are inspected before the
34 prescription drug or supplies are dispensed by a pharmacist employed
35 by or under contract with the pharmacy, and the pharmacist determines
36 that the prescription drug or supplies are not adulterated or
37 misbranded;

1 (d) The prescription drug or supplies are prescribed by a
2 practitioner for use by an eligible individual and are dispensed by a
3 pharmacist; and

4 (e) Any other safety precautions established by the department
5 have been satisfied.

6 (2)(a) If a person who donates prescription drugs or supplies to
7 a pharmacy under this chapter receives a notice that the donated
8 prescription drugs or supplies have been recalled, the person shall
9 notify the pharmacy of the recall.

10 (b) If a pharmacy that receives and distributes donated
11 prescription drugs to another pharmacy, pharmacist, or prescribing
12 practitioner under this chapter receives notice that the donated
13 prescription drugs or supplies have been recalled, the pharmacy shall
14 notify the other pharmacy, pharmacist, or prescribing practitioner of
15 the recall.

16 (c) If a person collecting or distributing donated prescription
17 drugs or supplies under this chapter receives a recall notice from
18 the drug manufacturer or the federal food and drug administration for
19 donated prescription drugs or supplies, the person shall immediately
20 remove all recalled medications from stock and comply with the
21 instructions in the recall notice.

22 (3) Prescription drugs and supplies donated under this chapter
23 may not be resold.

24 (4) Prescription drugs and supplies dispensed under this chapter
25 shall not be eligible for reimbursement of the prescription drug or
26 any related dispensing fees by any public or private health care
27 payer.

28 (5) A prescription drug that can only be dispensed to a patient
29 registered with the manufacturer of that drug, in accordance with the
30 requirements established by the federal food and drug administration,
31 may not be ~~((accepted or))~~ distributed under the program, unless the
32 patient receiving the prescription drug is registered with the
33 manufacturer at the time the drug is dispensed and the amount
34 dispensed does not exceed the duration of the registration period.

35 **Sec. 5.** RCW 69.70.060 and 2013 c 260 s 6 are each amended to
36 read as follows:

37 ~~((1) The department must adopt rules establishing forms and~~
38 ~~procedures to: Reasonably verify eligibility and prioritize patients~~
39 ~~seeking to receive donated prescription drugs and supplies; and~~

1 inform a person receiving prescription drugs donated under this
2 program that the prescription drugs have been donated for the
3 purposes of redistribution. A patient's eligibility may be determined
4 by a form signed by the patient certifying that the patient is
5 uninsured and at or below two hundred percent of the federal poverty
6 level.

7 ~~(2) The department may establish any other rules necessary to~~
8 ~~implement this chapter.)~~ The department shall develop a form for
9 persons to use when releasing prescription drugs for distribution and
10 certifying the condition of the drugs, as provided in RCW
11 69.70.020(2).

12 **Sec. 6.** RCW 69.70.070 and 2013 c 260 s 7 are each amended to
13 read as follows:

14 (1) A drug manufacturer acting in good faith may not, in the
15 absence of a finding of gross negligence, be subject to criminal
16 prosecution or liability in tort or other civil action, for injury,
17 death, or loss to person or property for matters relating to the
18 donation, acceptance, or dispensing of ((a)) any drug manufactured by
19 the drug manufacturer that is donated by any person under the program
20 including, but not limited to((τ)):

21 (a) Liability for failure to transfer or communicate product or
22 consumer information or the expiration date of the donated
23 prescription drug; and

24 (b) Liability related to prescription drugs that can only be
25 dispensed to a patient registered with the manufacturer of that drug,
26 in accordance with the requirements established by the federal food
27 and drug administration.

28 (2) Any person or entity, other than a drug manufacturer subject
29 to subsection (1) of this section, acting in good faith in donating,
30 accepting, or distributing prescription drugs under this chapter is
31 immune from criminal prosecution, professional discipline, or civil
32 liability of any kind for any injury, death, or loss to any person or
33 property relating to such activities other than acts or omissions
34 constituting gross negligence or willful or wanton misconduct.

35 (3) The immunity provided under subsection (1) of this section
36 does not absolve a drug manufacturer of a criminal or civil liability
37 that would have existed but for the donation, nor does such donation
38 increase the liability of the drug manufacturer in such an action.

1 NEW SECTION. **Sec. 7.** This act may be known and cited as the
2 cancer can't charitable pharmacy act.

3 NEW SECTION. **Sec. 8.** This act takes effect January 1, 2017.

Passed by the House March 7, 2016.

Passed by the Senate March 2, 2016.

Approved by the Governor March 29, 2016.

Filed in Office of Secretary of State March 30, 2016.

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