

SSB 5148 - H COMM AMD

By Committee on Health Care & Wellness

ADOPTED 04/09/2013

1 Strike everything after the enacting clause and insert the
2 following:

3 "NEW SECTION. **Sec. 1.** The definitions in this section apply
4 throughout this chapter unless the context clearly requires otherwise.

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

6 (2) "Drug manufacturer" means a facility licensed by the board of
7 pharmacy under chapter 18.64 RCW that engages in the manufacture of
8 drugs or devices.

9 (3) "Drug wholesaler" means a facility licensed by the board of
10 pharmacy under chapter 18.64 RCW that buys drugs or devices for resale
11 and distribution to corporations, individuals, or entities other than
12 consumers.

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

16 (5) "Person" means an individual, corporation, business trust,
17 estate, trust, partnership, association, joint venture, government,
18 governmental subdivision or agency, or any other legal or commercial
19 entity.

20 (6) "Pharmacist" means a person licensed by the board of pharmacy
21 under chapter 18.64 RCW to practice pharmacy.

22 (7) "Pharmacy" means a facility licensed by the board of pharmacy
23 under chapter 18.64 RCW in which the practice of pharmacy is conducted.

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

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

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

1 (11) "Supplies" means the supplies necessary to administer
2 prescription drugs that are donated under the prescription drug
3 redistribution program.

4 NEW SECTION. **Sec. 2.** Any practitioner, pharmacist, medical
5 facility, drug manufacturer, or drug wholesaler may donate prescription
6 drugs and supplies to a pharmacy for redistribution without
7 compensation or the expectation of compensation to individuals who meet
8 the prioritization criteria established in section 4 of this act.
9 Donations of prescription drugs and supplies may be made on the
10 premises of a pharmacy that elects to participate in the provisions of
11 this chapter. A pharmacy that receives prescription drugs or supplies
12 may distribute the prescription drugs or supplies to another pharmacy,
13 pharmacist, or prescribing practitioner for use pursuant to the
14 program.

15 NEW SECTION. **Sec. 3.** To be eligible for the immunity in section
16 7 of this act, a person distributing donated prescription drugs under
17 this chapter must:

18 (1) Meet all requirements in section 5 of this act and any
19 applicable rules related to the return or exchange of prescription
20 drugs or supplies adopted by the board of pharmacy;

21 (2) Maintain records of any prescription drugs and supplies donated
22 to the pharmacy and subsequently dispensed by the pharmacy; and

23 (3) Identify itself to the public as participating in this chapter.

24 NEW SECTION. **Sec. 4.** Pharmacies, pharmacists, and prescribing
25 practitioners that elect to dispense donated prescription drugs and
26 supplies under this chapter shall give priority to individuals who are
27 uninsured and at or below two hundred percent of the federal poverty
28 level. If an uninsured and low-income individual has not been
29 identified as in need of available prescription drugs and supplies,
30 those prescription drugs and supplies may be dispensed to other
31 individuals expressing need.

32 NEW SECTION. **Sec. 5.** (1) Prescription drugs or supplies may be
33 accepted and dispensed under this chapter if all of the following
34 conditions are met:

1 (a) The prescription drug is in:
2 (i) Its original sealed and tamper evident packaging; or
3 (ii) An opened package if it contains single unit doses that remain
4 intact;
5 (b) The prescription drug bears an expiration date that is more
6 than six months after the date the prescription drug was donated;
7 (c) The prescription drug or supplies are inspected before the
8 prescription drug or supplies are dispensed by a pharmacist employed by
9 or under contract with the pharmacy, and the pharmacist determines that
10 the prescription drug or supplies are not adulterated or misbranded;
11 (d) The prescription drug or supplies are prescribed by a
12 practitioner for use by an eligible individual and are dispensed by a
13 pharmacist; and
14 (e) Any other safety precautions established by the department have
15 been satisfied.
16 (2)(a) If a person who donates prescription drugs or supplies to a
17 pharmacy under this chapter receives a notice that the donated
18 prescription drugs or supplies have been recalled, the person shall
19 notify the pharmacy of the recall.
20 (b) If a pharmacy that receives and distributes donated
21 prescription drugs to another pharmacy, pharmacist, or prescribing
22 practitioner under this chapter receives notice that the donated
23 prescription drugs or supplies have been recalled, the pharmacy shall
24 notify the other pharmacy, pharmacist, or prescribing practitioner of
25 the recall.
26 (c) If a person collecting or distributing donated prescription
27 drugs or supplies under this chapter receives a recall notice from the
28 drug manufacturer or the federal food and drug administration for
29 donated prescription drugs or supplies, the person shall immediately
30 remove all recalled medications from stock and comply with the
31 instructions in the recall notice.
32 (3) Prescription drugs and supplies donated under this chapter may
33 not be resold.
34 (4) Prescription drugs and supplies dispensed under this chapter
35 shall not be eligible for reimbursement of the prescription drug or any
36 related dispensing fees by any public or private health care payer.
37 (5) A prescription drug that can only be dispensed to a patient

1 registered with the manufacturer of that drug, in accordance with the
2 requirements established by the federal food and drug administration,
3 may not be accepted or distributed under the program.

4 NEW SECTION. **Sec. 6.** (1) The department must adopt rules
5 establishing forms and procedures to: Reasonably verify eligibility
6 and prioritize patients seeking to receive donated prescription drugs
7 and supplies; and inform a person receiving prescription drugs donated
8 under this program that the prescription drugs have been donated for
9 the purposes of redistribution. A patient's eligibility may be
10 determined by a form signed by the patient certifying that the patient
11 is uninsured and at or below two hundred percent of the federal poverty
12 level.

13 (2) The department may establish any other rules necessary to
14 implement this chapter.

15 NEW SECTION. **Sec. 7.** (1) A drug manufacturer acting in good faith
16 may not, in the absence of a finding of gross negligence, be subject to
17 criminal prosecution or liability in tort or other civil action, for
18 injury, death, or loss to person or property for matters relating to
19 the donation, acceptance, or dispensing of a drug manufactured by the
20 drug manufacturer that is donated by any person under the program
21 including, but not limited to, liability for failure to transfer or
22 communicate product or consumer information or the expiration date of
23 the donated prescription drug.

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

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

1 NEW SECTION. **Sec. 8.** Access to prescription drugs and supplies
2 under this chapter is subject to availability. Nothing in this chapter
3 establishes an entitlement to receive prescription drugs and supplies
4 through the program.

5 NEW SECTION. **Sec. 9.** Nothing in this chapter restricts the use of
6 samples by a practitioner during the course of the practitioner's
7 duties at a medical facility or pharmacy.

8 NEW SECTION. **Sec. 10.** Nothing in this chapter authorizes the
9 resale of prescription drugs by any person.

10 NEW SECTION. **Sec. 11.** Sections 1 through 10 of this act
11 constitute a new chapter in Title 69 RCW.

12 NEW SECTION. **Sec. 12.** This act takes effect July 1, 2014."

13 Correct the title.

EFFECT: (1) Specifies that drugs and supplies donated under the program are not eligible for reimbursement for either the item or the dispensing fee under any public or private program (rather than just Medicaid).

(2) Prohibits the acceptance or distribution under the program of prescription drugs that the federal Food and Drug Administration has determined may only be dispensed to patients registered with the drugs' manufacturers.

(3) Applies immunity for failure to transfer or communicate product or consumer information or the expiration date of the donated item to only drug manufacturers, rather than all program participants. Removes the listed elements of what does not constitute "gross negligence" (although similar requirements must be met in order for immunity to apply).

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