

ESHB 2228 - S COMM AMD

By Committee on Health & Long-Term Care

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 3 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 this chapter. A
11 pharmacy that receives prescription drugs or supplies may distribute
12 the prescription drugs or supplies to another pharmacy, pharmacist, or
13 prescribing practitioner for use pursuant to the program.

14 NEW SECTION. **Sec. 3.** Pharmacies, pharmacists, and prescribing
15 practitioners that elect to dispense donated prescription drugs and
16 supplies under this chapter shall give priority to individuals who are
17 uninsured and at or below two hundred percent of the federal poverty
18 level. If an uninsured and low-income individual has not been
19 identified as in need of available prescription drugs and supplies,
20 those prescription drugs and supplies may be dispensed to other
21 individuals expressing need.

22 NEW SECTION. **Sec. 4.** (1) The department must adopt rules
23 establishing forms and procedures to reasonably verify eligibility and
24 prioritize patients seeking to receive donated prescription drugs and
25 supplies. A patient's eligibility may be determined by a form signed
26 by the patient certifying that the patient is uninsured and at or below
27 two hundred percent of the federal poverty level.

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

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

33 (a) The prescription drug is in:

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

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

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

5 (c) The prescription drug or supplies are inspected before the
6 prescription drug or supplies are dispensed by a pharmacist employed by
7 or under contract with the pharmacy, and the pharmacist determines that
8 the prescription drug or supplies are not adulterated or misbranded;

9 (d) The prescription drug or supplies are prescribed by a
10 practitioner for use by an eligible individual and are dispensed by a
11 pharmacist; and

12 (e) Any other safety precautions established by the department have
13 been satisfied.

14 (2)(a) If a person who donates prescription drugs or supplies to a
15 pharmacy under this chapter receives a notice that the donated
16 prescription drugs or supplies have been recalled, the person shall
17 notify the pharmacy of the recall.

18 (b) If a pharmacy that receives and distributes donated
19 prescription drugs to another pharmacy, pharmacist, or prescribing
20 practitioner under this chapter receives notice that the donated
21 prescription drugs or supplies have been recalled, the pharmacy shall
22 notify the other pharmacy, pharmacist, or prescribing practitioner of
23 the recall.

24 (c) If a person collecting or distributing donated prescription
25 drugs or supplies under this chapter receives a recall notice from the
26 drug manufacturer or the federal food and drug administration for
27 donated prescription drugs or supplies, the person shall immediately
28 remove all recalled medications from stock and comply with the
29 instructions in the recall notice.

30 (3) A person receiving donated prescription drugs or supplies under
31 this chapter must be notified that the drug was donated.

32 (4) Prescription drugs and supplies donated under this chapter may
33 not be resold.

34 (5) Prescription drugs and supplies dispensed under this chapter
35 shall not be eligible for reimbursement under the medical assistance
36 program.

1 NEW SECTION. **Sec. 6.** (1) Any practitioner, pharmacist, or medical
2 facility who donates prescription drugs or supplies under this chapter
3 shall not, in the absence of a finding of gross negligence, be subject
4 to criminal prosecution, civil liability, or professional disciplinary
5 action, for injury, death, or loss to person or property relating to
6 the donation of the prescription drug or supply.

7 (2) Any drug manufacturer or drug wholesaler who donates
8 prescription drugs or supplies under this chapter shall not, in the
9 absence of a finding of gross negligence, be subject to criminal
10 prosecution or civil liability, for injury, death, or loss to person or
11 property relating to the donation of the prescription drug or supply,
12 failure to transfer or communicate product or consumer information, or
13 failure to communicate the expiration date of the donated prescription
14 drug or supply.

15 (3) Any pharmacist, pharmacy, or prescribing practitioner who
16 accepts or dispenses prescription drugs or supplies under this chapter
17 shall not, in the absence of a finding of gross negligence, be subject
18 to criminal prosecution, civil liability, or professional disciplinary
19 action, for injury, death, or loss to person or property relating to
20 accepting or dispensing the prescription drug or supply if the
21 pharmacist, pharmacy, or prescribing practitioner: Meets all the
22 requirements of section 5 of this act; maintains records of any
23 prescription drugs and supplies donated and dispensed under this
24 chapter; and identifies itself to the public as participating in this
25 chapter.

26 (4) The immunity provided under this section does not absolve a
27 drug manufacturer of a criminal or civil liability that would have
28 existed but for the donation, nor shall such donation, increase the
29 liability of the drug manufacturer in such an action.

30 NEW SECTION. **Sec. 7.** Access to prescription drugs and supplies
31 under this chapter is subject to availability. Nothing in this chapter
32 establishes an entitlement to receive prescription drugs or supplies
33 through the program.

34 NEW SECTION. **Sec. 8.** Nothing in this chapter restricts the use of
35 samples by a practitioner during the course of the practitioner's
36 duties at a medical facility or pharmacy.

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

3 NEW SECTION. **Sec. 10.** Sections 1 through 9 of this act constitute
4 a new chapter in Title 69 RCW.

5 NEW SECTION. **Sec. 11.** This act takes effect July 1, 2013."

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6 On page 1, line 1 of the title, after "uninsured;" strike the
7 remainder of the title and insert "adding a new chapter to Title 69
8 RCW; and providing an effective date."

EFFECT: (1) Provides that donors and dispensers are provided with immunity from criminal or civil actions, unless there is a finding of gross negligence. (Rather than a "good faith" standard for drug manufacturers and a "reasonable care" standard for other entities.) This immunity applies to drug manufacturers for failure to transfer or communicate product or consumer information or expiration dates. This immunity does not apply to actions against a drug manufacturer that would have existed but for the donation.

(2) Provides that a recipient of donated drugs must be informed that the drug was donated.

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