CERTIFICATION OF ENROLLMENT

SUBSTITUTE SENATE BILL 5148

63rd Legislature 2013 Regular Session

I, Hunter G. Goodman, Secretary of the Senate of the State of Washington, do hereby certify that the attached is SUBSTITUTE SENATE BILL 5148 as passed by the Senate and the House of Representatives or the dates hereon set forth.
BILL 5148 as passed by the Senate and the House of Representatives or
Secretary
FILED
Secretary of State State of Washington

SUBSTITUTE SENATE BILL 5148

AS AMENDED BY THE HOUSE

Passed Legislature - 2013 Regular Session

State of Washington 63rd Legislature 2013 Regular Session

By Senate Health Care (originally sponsored by Senators Keiser, Becker, Cleveland, Conway, Frockt, Parlette, Rolfes, Kohl-Welles, Schlicher, and Kline)

READ FIRST TIME 02/06/13.

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- 1 AN ACT Relating to medication access for the uninsured; adding a
- 2 new chapter to Title 69 RCW; and providing an effective date.
- 3 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:
- 4 <u>NEW SECTION.</u> **Sec. 1.** The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.
 - (1) "Department" means the department of health.
 - (2) "Drug manufacturer" means a facility licensed by the board of pharmacy under chapter 18.64 RCW that engages in the manufacture of drugs or devices.
 - (3) "Drug wholesaler" means a facility licensed by the board of pharmacy under chapter 18.64 RCW that buys drugs or devices for resale and distribution to corporations, individuals, or entities other than consumers.
- 14 (4) "Medical facility" means a hospital, pharmacy, nursing home, 15 boarding home, adult family home, or medical clinic where the 16 prescription drugs are under the control of a practitioner.
- 17 (5) "Person" means an individual, corporation, business trust, 18 estate, trust, partnership, association, joint venture, government,

- 1 governmental subdivision or agency, or any other legal or commercial entity.
 - (6) "Pharmacist" means a person licensed by the board of pharmacy under chapter 18.64 RCW to practice pharmacy.
 - (7) "Pharmacy" means a facility licensed by the board of pharmacy under chapter 18.64 RCW in which the practice of pharmacy is conducted.
 - (8) "Practitioner" has the same meaning as in RCW 69.41.010.
 - (9) "Prescribing practitioner" means a person authorized to issue orders or prescriptions for legend drugs as listed in RCW 69.41.030.
 - (10) "Prescription drugs" has the same meaning as "legend drugs" as defined in RCW 69.41.010. The term includes cancer drugs and antirejection drugs. The term does not include controlled substances.
- 13 (11) "Supplies" means the supplies necessary to administer 14 prescription drugs that are donated under the prescription drug 15 redistribution program.
- 16 NEW SECTION. Sec. 2. Any practitioner, pharmacist, medical facility, drug manufacturer, or drug wholesaler may donate prescription 17 supplies to a pharmacy for redistribution without 18 drugs and compensation or the expectation of compensation to individuals who meet 19 20 the prioritization criteria established in section 4 of this act. 21 Donations of prescription drugs and supplies may be made on the 22 premises of a pharmacy that elects to participate in the provisions of 23 this chapter. A pharmacy that receives prescription drugs or supplies 24 may distribute the prescription drugs or supplies to another pharmacy, 25 pharmacist, or prescribing practitioner for use pursuant to the 26 program.
- NEW SECTION. Sec. 3. To be eligible for the immunity in section 7 of this act, a person distributing donated prescription drugs under this chapter must:
- 30 (1) Meet all requirements in section 5 of this act and any 31 applicable rules related to the return or exchange of prescription 32 drugs or supplies adopted by the board of pharmacy;
- 33 (2) Maintain records of any prescription drugs and supplies donated 34 to the pharmacy and subsequently dispensed by the pharmacy; and
- 35 (3) Identify itself to the public as participating in this chapter.

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Sec. 4. Pharmacies, pharmacists, and prescribing 1 practitioners that elect to dispense donated prescription drugs and 2 supplies under this chapter shall give priority to individuals who are 3 uninsured and at or below two hundred percent of the federal poverty 4 If an uninsured and low-income individual has not been 5 identified as in need of available prescription drugs and supplies, 6 7 those prescription drugs and supplies may be dispensed to other 8 individuals expressing need.

- 9 <u>NEW SECTION.</u> **Sec. 5.** (1) Prescription drugs or supplies may be accepted and dispensed under this chapter if all of the following conditions are met:
 - (a) The prescription drug is in:

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- (i) Its original sealed and tamper evident packaging; or
- 14 (ii) An opened package if it contains single unit doses that remain 15 intact;
 - (b) The prescription drug bears an expiration date that is more than six months after the date the prescription drug was donated;
 - (c) The prescription drug or supplies are inspected before the prescription drug or supplies are dispensed by a pharmacist employed by or under contract with the pharmacy, and the pharmacist determines that the prescription drug or supplies are not adulterated or misbranded;
 - (d) The prescription drug or supplies are prescribed by a practitioner for use by an eligible individual and are dispensed by a pharmacist; and
 - (e) Any other safety precautions established by the department have been satisfied.
 - (2)(a) If a person who donates prescription drugs or supplies to a pharmacy under this chapter receives a notice that the donated prescription drugs or supplies have been recalled, the person shall notify the pharmacy of the recall.
 - (b) If a pharmacy that receives and distributes donated prescription drugs to another pharmacy, pharmacist, or prescribing practitioner under this chapter receives notice that the donated prescription drugs or supplies have been recalled, the pharmacy shall notify the other pharmacy, pharmacist, or prescribing practitioner of the recall.

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- 1 (c) If a person collecting or distributing donated prescription 2 drugs or supplies under this chapter receives a recall notice from the 3 drug manufacturer or the federal food and drug administration for 4 donated prescription drugs or supplies, the person shall immediately 5 remove all recalled medications from stock and comply with the 6 instructions in the recall notice.
 - (3) Prescription drugs and supplies donated under this chapter may not be resold.
 - (4) Prescription drugs and supplies dispensed under this chapter shall not be eligible for reimbursement of the prescription drug or any related dispensing fees by any public or private health care payer.
 - (5) A prescription drug that can only be dispensed to a patient registered with the manufacturer of that drug, in accordance with the requirements established by the federal food and drug administration, may not be accepted or distributed under the program.
 - NEW SECTION. Sec. 6. (1) The department must adopt rules establishing forms and procedures to: Reasonably verify eligibility and prioritize patients seeking to receive donated prescription drugs and supplies; and inform a person receiving prescription drugs donated under this program that the prescription drugs have been donated for the purposes of redistribution. A patient's eligibility may be determined by a form signed by the patient certifying that the patient is uninsured and at or below two hundred percent of the federal poverty level.
- 25 (2) The department may establish any other rules necessary to 26 implement this chapter.
- <u>NEW SECTION.</u> **Sec. 7.** (1) A drug manufacturer acting in good faith 27 28 may not, in the absence of a finding of gross negligence, be subject to 29 criminal prosecution or liability in tort or other civil action, for 30 injury, death, or loss to person or property for matters relating to the donation, acceptance, or dispensing of a drug manufactured by the 31 drug manufacturer that is donated by any person under the program 32 33 including, but not limited to, liability for failure to transfer or 34 communicate product or consumer information or the expiration date of 35 the donated prescription drug.

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- 1 (2) Any person or entity, other than a drug manufacturer subject to 2 subsection (1) of this section, acting in good faith in donating, 3 accepting, or distributing prescription drugs under this chapter is 4 immune from criminal prosecution, professional discipline, or civil 5 liability of any kind for any injury, death, or loss to any person or 6 property relating to such activities other than acts or omissions 7 constituting gross negligence or willful or wanton misconduct.
 - (3) The immunity provided under subsection (1) of this section does not absolve a drug manufacturer of a criminal or civil liability that would have existed but for the donation, nor does such donation increase the liability of the drug manufacturer in such an action.

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- NEW SECTION. Sec. 8. Access to prescription drugs and supplies under this chapter is subject to availability. Nothing in this chapter establishes an entitlement to receive prescription drugs and supplies through the program.
- NEW SECTION. Sec. 9. Nothing in this chapter restricts the use of samples by a practitioner during the course of the practitioner's duties at a medical facility or pharmacy.
- 19 <u>NEW SECTION.</u> **Sec. 10.** Nothing in this chapter authorizes the 20 resale of prescription drugs by any person.
- NEW SECTION. Sec. 11. Sections 1 through 10 of this act constitute a new chapter in Title 69 RCW.
- NEW SECTION. Sec. 12. This act takes effect July 1, 2014.

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