SHB 2458 - H AMD **662**
By Representative Parker

ADOPTED 02/11/2016

On page 3, after line 20, insert the following:

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

(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:

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

(ii) An opened package if it contains single unit doses that remain 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.

(c) If a person collecting or distributing donated prescription drugs or supplies under this chapter receives a recall notice from the drug manufacturer or the federal food and drug administration for donated prescription drugs or supplies, the person shall immediately remove all recalled medications from stock and comply with the 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, unless the patient receiving the prescription drug is registered with the manufacturer at the time the drug is dispensed and the amount dispensed does not exceed the duration of the registration period."

Renumber the remaining sections consecutively and correct any internal references accordingly.

On page 3, after line 36, insert the following:

"**Sec. 5.** RCW 69.70.070 and 2013 c 260 s 7 are each amended to read as follows:

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

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

(b) Liability related to prescription drugs 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.

(2) Any person or entity, other than a drug manufacturer subject to subsection (1) of this section, acting in good faith in donating, accepting, or distributing prescription drugs under this chapter is immune from criminal prosecution, professional discipline, or civil liability of any kind for any injury, death, or loss to any person or property relating to such activities other than acts or omissions 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."

Renumber the remaining sections consecutively and correct any internal references accordingly.

Correct the title.

EFFECT: Allows prescription drugs that require registration with the manufacturer to be dispensed under the prescription drug donation program if the patient is registered with the manufacturer at the time the drug is dispensed and the amount dispensed does not exceed the duration of the registration period.

Specifies that immunity from liability for drug manufacturers applies to any drug donated under the prescription drug donation program. Specifies that immunity from liability for drug manufacturers includes liability related to drugs that can only be dispensed to a patient who is registered with the drug's manufacturer, in accordance with federal food and drug administration requirements.

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