

SENATE BILL REPORT

SB 6049

As Reported by Senate Committee On:
Health & Long-Term Care, January 23, 2012

Title: An act relating to requiring the department of health to establish a cancer drug repository program.

Brief Description: Requiring the department of health to establish a cancer drug repository program.

Sponsors: Senators Kastama and Shin.

Brief History:

Committee Activity: Health & Long-Term Care: 1/11/12, 1/23/12 [DPS-WM].

SENATE COMMITTEE ON HEALTH & LONG-TERM CARE

Majority Report: That Substitute Senate Bill No. 6049 be substituted therefor, and the substitute bill do pass and be referred to Committee on Ways & Means.

Signed by Senators Keiser, Chair; Becker, Ranking Minority Member; Frockt, Kline and Pflug.

Staff: Kathleen Buchli (786-7488)

Background: At least 38 states have enacted laws to create prescription drug recycling, repository, or redistribution programs for unused medication. In general, drug redistribution programs allow the return of prescription drugs in single-use or sealed packaging from state programs, nursing homes, and other medical facilities. The medicines are then redistributed for use to needy residents who cannot afford to purchase their prescribed drugs. The scope of prescription drug programs varies by state and may include the following provisions: direct the financial terms of the donations or regulate resale; assure purity, safety, and freshness of the products; restrict the donation of expired drugs; prohibit the donation of controlled substances; require a state-licensed pharmacist or pharmacy to be part of the verification and distribution process; require patients to possess a valid prescription for the drugs they receive; limit donations to cancer drugs; limit donations to within long-term care facilities; or limit program participation to correctional facilities.

Summary of Bill (Recommended Substitute): The Department of Health (DOH) must establish a cancer drug repository program for accepting donated cancer drugs and

This analysis was prepared by non-partisan legislative staff for the use of legislative members in their deliberations. This analysis is not a part of the legislation nor does it constitute a statement of legislative intent.

dispensing these drugs to authorized Washington residents. DOH must consult with the Board of Pharmacy in adopting rules that establish the following: eligibility criteria and other standards and procedures for participating facilities that accept and distribute or dispense donated cancer drugs; forms for program administration; handling fees; categories of cancer drugs that will be accepted by the program; and a participating facility registry. Any person or entity, including drug manufacturers and health care facilities, may donate cancer drugs.

Cancer drugs may only be donated to, accepted by, or dispensed under the program if the drug is in unopened, sealed, and tamper-evident unit dose packaging. Single-unit dose packaging may be donated if unopened. Cancer drugs may not be donated if they are expired, adulterated, or misbranded. Cancer drugs donated to the program may only be dispensed pursuant to a prescription issued by a prescribing practitioner or may be distributed to another participating facility for dispensing. Handling fees, as determined by DOH rule, may be charged by participating facilities, but donated cancer drugs may not be resold.

A person or entity that donates, accepts, or dispenses prescription drugs shall not, in the absence of negligence, be subject to criminal prosecution, liability in tort or other civil action for injury, death, or loss to person or property, or professional disciplinary action; this applies to drug manufacturers, including for liability for failure to transfer or communicate product or consumer information or the expiration date of the donated drug.

DOH must maintain a participating facility registry that is to be available to any entity wishing to donate cancer drugs to the program.

EFFECT OF CHANGES MADE BY HEALTH & LONG-TERM CARE COMMITTEE (Recommended Substitute): People, practitioners, health care facilities, pharmacies, and drug manufacturers may donate cancer drugs that are in tamper-evident packaging. The DOH must adopt rules, including rules requiring the inspection of donated drugs to determine that the packaging is tamper-evident and the donated drug is safe for redistribution. Drugs may be donated if they are in original, sealed, and tamper-evident unit dose packaging or in single-unit dose packaging. Only pharmacies and health care practitioners may accept and redistribute donated cancer drugs. Handling fees may not be charged, in whole or in part, to any third party. A person or entity that donates, accepts, or dispenses prescription drugs shall not, in the absence of negligence, be subject to criminal prosecution, liability in tort or other civil action for injury, death, or loss to person or property, or professional disciplinary action; this applies to drug manufacturers, including for liability for failure to transfer or communicate product or consumer information or the expiration date of the donated drug.

Appropriation: None.

Fiscal Note: Available.

Committee/Commission/Task Force Created: No.

Effective Date: Ninety days after adjournment of session in which bill is passed.

Staff Summary of Public Testimony: PRO: We are looking at ways to make transformational changes in the delivery of health care, this is a step in the right direction. 38 States have drug redistribution programs of some kind, seven states have similar cancer drug programs. This is an important step forward and to help people to respond to the cut in copay assistance for Medicaid Part D. Senior citizens sometimes choose between filling their prescriptions or cutting their pills in half to make them last longer. It is also important to get information about these programs out to the community. This program would help with prescription abuse prevention. There is a population of cancer patients who are unable to access their medicine. This program would allow donation and safe redistribution of cancer drugs. Pharmacists are trained to identify the substances they are dispensing and can help with the program by asking questions on how the drug has been stored and determine whether it meets donation criteria. The program is voluntary and current programs do not meet the need of all patients; some patients do not qualify for certain programs or lose time during the application process, which makes a difference in the stage of cancer that is being treated. Cancer medicines are expensive. While there is a risk to the patient, patients can evaluate that risk and their need for the program. The risk of no drugs is greater than the risk of misbranding.

OTHER: We share the concerns about high costs of drugs and of wasted drugs and support the concept of reducing costs if safety is considered. A criteria of this program should be to protect the integrity of drugs, and to track the source of drugs along with the expiration date. Handling rules should be developed and pharmacists should be involved to evaluate drugs. Ohio has a model for liability language that the Committee should consider.

Persons Testifying: PRO: Senator Kastama, prime sponsor; Mary Clogston, American Assoc. of Retired Persons; Seth Dawson, Washington Assoc. for Substance Abuse Prevention; Abbey Horner, Peace Health Southwest Medical Center.

OTHER: Steven Saxe, DOH; Jeff Gombosky, Pharmaceutical Research and Manufacturers of America.