

Legislative Analysis



CANCER DRUG REPOSITORY PROGRAM

Mitchell Bean, Director
Phone: (517) 373-8080
<http://www.house.mi.gov/hfa>

House Bill 5672 as enrolled
Public Act 416 of 2006
Sponsor: Rep. Barb Vander Veen
House Committee: Health Policy
Senate Committee: Health Policy

First Analysis (2-9-07)

BRIEF SUMMARY: The bill would create the Cancer Drug Repository Program which would allow a person to donate a cancer drug or supply for use by a cancer patient.

FISCAL IMPACT: House Bill 5672, as enrolled, imposes costs on the Board of Pharmacy of the Department of Community Health to establish and maintain a Cancer Drug Repository Program, establishing program guidelines, policies and procedures and coordinating the participation of voluntary repository facilities. The bill imposes a low level of administrative oversight by the state, so additional costs may be modest. There may be some offsetting savings to the state's Medicaid and employee health plans because the donated drugs and supplies are available to any Michigan resident diagnosed with cancer, on a 3-step priority basis as established by the bill. A person receiving the drug or supply would be obligated to pay a handling fee to the repository facility of no more than five dollars.

THE APPARENT PROBLEM:

Sometimes, whether due to an early cure, an allergy, a change in medications, or death, a person may not use all of a prescribed medication. In such cases, patients are told to properly dispose of leftover medications, as it is illegal under current law to give, dispense, or sell leftover prescription drugs to someone else. In light of the price of many prescription drugs and the large numbers of people without prescription drug coverage, several states have recently created programs to allow individuals to donate unused medications. These drugs are later distributed to individuals who otherwise could not afford to purchase them. Florida and Nebraska also created a donor drug program, but restricted it to drugs and supplies used by cancer patients. Some feel that many low-income and uninsured individuals in Michigan could benefit by a similar program.

THE CONTENT OF THE BILL:

The bill would amend the Public Health Code to create an exception to the prohibition on selling, dispensing, or giving away a prescription drug that had previously been dispensed by a pharmacist and left that pharmacist's control. Under the bill, the Michigan Board of Pharmacy would be required to establish and maintain a cancer drug repository program that would allow a person to donate a prescription cancer drug or supply for use by an eligible person.

A "cancer drug" would mean a prescription drug used to treat either cancer or the side effects of cancer or the side effects of any prescription drug used to treat cancer or the side effects of cancer. "Cancer supply" or "supplies" would mean prescription and nonprescription cancer supplies needed to administer a cancer drug.

Cancer Drug Repository Program. The Michigan Board of Pharmacy would have to establish program guidelines, policies, and procedures addressing the program. Donations could be made on the premises of a licensed health facility or pharmacy. Participation in the program would be voluntary and a health facility or pharmacy could withdraw at any time from the program by giving notice to the board either by telephone or mail.

A pharmacy or health facility (defined to mean a county medical care facility, freestanding surgical outpatient facility, home for the aged, hospital, hospital long-term care unit, nursing home, and hospice) could choose to fully participate in the program by accepting, storing, and dispensing or administering the donated drugs and supplies or could choose to only accept and store the donated items. An entity with limited participation would have to distribute any donated drugs only to a fully-participating entity. A repository distributing a donated drug or supply to another repository would have to fill out a cancer drug repository donor form. A copy of that completed form, along with a copy of the donor form completed by the original donor, would have to be provided to the repository receiving the transferred cancer drug or supply at the time of the distribution.

To participate in the program, a health facility or pharmacy would have to submit a form to the board with information that included, at a minimum, the name, address, and telephone number of the entity; the name and telephone number of a pharmacist employed by or under contract with the entity, or other contact person with familiarity of the entity's participation in the program; a statement that the entity was licensed in Michigan and in compliance with all federal and state laws, rules, and regulations; and the level of participation in the program.

Donations to the Cancer Drug Repository Program. Any individual 18 years of age or older could donate lawfully obtained cancer drugs or supplies. In addition, a pharmacy or health facility could also donate cancer drugs or supplies if the drugs had not been previously dispensed. Controlled substances (i.e., narcotic pain medications) would not be eligible for donation or acceptance under the program. A manufacturer or wholesale distributor would not be eligible to be a donor under the Cancer Drug Repository Program.

Donated supplies would have to be in their original, unopened, sealed package. A donated cancer drug would have to be donated at least six months before its expiration date and be in its original, unopened, tamper-evident unit dose packaging that included the drug's lot number and expiration date. A single unit dose drug could be accepted if the single unit dose packaging was unopened. A cancer drug or supply not meeting these requirements could not be accepted into the program.

In addition, the donated cancer drug or supplies could not be adulterated or misbranded and would have to be accompanied by a cancer drug repository donor form (provided by the board and available on its website). The form would have to state that the donated drug or supply had been properly stored and never opened, used, tampered with, adulterated, or misbranded. The form would have to be signed by the person making the donation or his or her authorized representative.

Furthermore, donations could not be made to a drop box but would have to be made on the premises of a cancer drug repository (pharmacy or health facility) to a designated pharmacist. The donated drugs and supplies would have to be stored in a secure storage area under appropriate environmental conditions and could not be stored with non-donated inventory.

Eligibility criteria to receive a donated cancer drug or supply. Any resident of the state with a current diagnosis of cancer would be eligible to receive a donated cancer drug or supply under the program. Prior to receiving a cancer drug or supply, a person would have to provide verification that he or she has a current diagnosis of cancer, provide proof of his or her insurance (if any), and sign a cancer drug repository recipient form (provided by the board on its website) acknowledging that he or she understands the information stated on the form.

The cancer drug repository recipient form would have to include, at a minimum, that the drug or supply being dispensed or administered had been donated and could have been previously dispensed; that a visual inspection had been conducted by the pharmacist or dispensing prescriber to ensure that the drug had not expired, had not been adulterated or misbranded, and was in its original, unopened packaging; and that the safety of the drug or supply could not be guaranteed and that the drug or supply was determined to be safe to be dispensed or administered based on the accuracy of the donor's form submitted with the donated item and the visual inspection conducted by the pharmacist or prescriber.

The donated cancer drugs and supplies would be dispensed in the following order of priority:

- Uninsured or those whose insurance does not cover those cancer drugs or supplies.
- Individuals enrolled in Medicaid, Medicare, or other public assistance health care program.
- All other state residents diagnosed with cancer.

Dispensing donated drugs. The donated cancer drugs and supplies would have to be dispensed by a pharmacist under a prescription by a prescriber or dispensed and administered by a dispensing prescriber. Prior to being dispensed, the pharmacist or dispensing prescriber would have to visually inspect a cancer drug or supply for adulteration, misbranding, and date of expiration. An expired drug or supply or one that appeared to have been adulterated, misbranded, or tampered with in any way could not be dispensed or administered.

Fees for program participation. A cancer drug repository could charge an individual receiving a donated drug or supply a handling fee of not more than 250 percent of the Medicaid dispensing fee or \$5, whichever was less, for each drug or supply dispensed or administered.

Civil and criminal immunity. A manufacturer could not be sued or held criminally liable for an injury, death, or loss to a person or to property for the intentional or unintentional adulteration or misbranding of the drug or supply by a party not under its control; the failure of a party not under its control to transfer or communicate product or consumer information or the expiration date of the donated drug or supply; or claims for payment to government or private payers.

A health facility or pharmacy participating in the cancer drug repository program, a pharmacist dispensing a drug or supply, a prescriber dispensing or administering a drug or supply, or a donor of a cancer drug or supply would be immune from civil liability for an act or omission that caused injury to or the death of an individual to whom a cancer drug or supply was dispensed. No disciplinary action could be taken against a pharmacist or prescriber as long as the drug or supply was donated, accepted, distributed, and dispensed according to the requirements of the bill. However, the immunity would not apply if the act or omission involved reckless, wanton, or intentional misconduct or malpractice unrelated to the quality of the donated drug or supply.

Miscellaneous provisions.

-- A donated cancer drug or supply could not be resold.

-- Drugs and supplies donated under the program could only be dispensed or administered to a Michigan resident who had been diagnosed with cancer.

-- A pharmacist dispensing a donated cancer drug or supply could not submit a claim or seek reimbursement from any public or private third payer (i.e., Medicaid, Medicare, or private insurance company or HMO). A public or private third party payer could not be required to provide reimbursement for donated drugs or supplies.

-- Cancer drug repository donor and recipient forms would have to be maintained for at least five years.

-- Records of the destruction of any donated drugs and supplies not distributed or administered would also have to be maintained by the dispensing repository for at least five years. A record of destruction would have to include the date of destruction; the name, strength, and quantity of the cancer drug destroyed; the name of the person or firm that destroyed the drug; and the source of the drugs or supplies destroyed.

MCL 333.17766 and 333.17780

ARGUMENTS:

For:

The drugs used by cancer patients are very expensive. Though many pharmaceutical companies have programs that provide needed medications free or at a reduced price to low income individuals, not everyone without insurance meets the eligibility criteria. Meanwhile, some cancer patients find they may have leftover medications or supplies (e.g., tubing or syringes of heparin or saline used in the administration of IV medications) that are still useable but for which the patient no longer has a need. Under current law, these drugs and supplies must be disposed.

The bill would instead create a program that would allow a cancer patient (or his or her estate) to donate useable medications and supplies. Donated drugs and supplies would have to meet specified criteria for safety, for example, be good for at least another six months; have been stored properly (some medications must be refrigerated); are in the original, unopened, sealed package; and not be misbranded or appear to be tampered with. Each donation would be accompanied with a signed form that would identify the donor and a donated drug or supply would have to be handed directly from the donor to a pharmacist employed by or under contract with a participating pharmacy or health facility; drop boxes of any kind would be prohibited. Before dispensing a donated drug or supply, the pharmacist or dispensing provider would have to make a visual inspection of the donated item to ensure it complied with the bill's provisions. Donated cancer drugs and supplies would also have to be kept separate from a pharmacy's or health facility's inventory of medicine and supplies to prevent donated items from mingling with the non-donated items.

Furthermore, a cancer patient would have to be informed that the drug or supplies had been donated, and that though steps had been taken to determine the safety of the product, that the safety of the drug or supply could not be guaranteed. Lastly, to encourage donations, the bill would give limited protection from civil suits and criminal charges to drug manufacturers of donated goods and protection from civil suits for the donor as well as members of the repository program. However, a donor or participant in the repository program whose acts constituted reckless, wanton, or intentional misconduct could still be sued.

It is hoped that the Cancer Drug Repository Program will save lives and reduce health care costs by getting the unneeded cancer medications and supplies of some cancer patients to other individuals who couldn't otherwise afford treatment.

Response:

The bill doesn't require the donor form to inform the donee of the limitations on his or her ability to sue if he or she suffers harm from a donated drug or supply. This is important information to know before deciding to accept a donated drug or supply.

Also, it is hoped that although the bill allows a cancer drug repository to charge a handling fee per drug or supply dispensed, that the repositories would keep such handling fees to a minimum. For example, if one or more drugs were dispensed, as well as

donated tubing and several syringes of heparin or saline (used to flush an IV line), the handling fee could mount up. Instead, the handling fee should be for each dispensation – regardless of how many items were dispensed at one time.

Legislative Analyst: Susan Stutzky
Fiscal Analyst: Susan Frey

■ This analysis was prepared by nonpartisan House staff for use by House members in their deliberations, and does not constitute an official statement of legislative intent.