



Senate Fiscal Agency
P. O. Box 30036
Lansing, Michigan 48909-7536



BILL ANALYSIS

Telephone: (517) 373-5383
Fax: (517) 373-1986
TDD: (517) 373-0543

House Bill 5672 (Substitute H-2 as passed by the House)
Sponsor: Representative Barb Vander Veen
House Committee: Health Policy
Senate Committee: Health Policy

Date Completed: 9-5-06

CONTENT

The bill would amend the Public Health Code to do the following:

- **Require the Board of Pharmacy to create a cancer drug donation program.**
- **Allow an individual who was at least 18 years old to donate legally obtained cancer drugs or supplies to a cancer drug repository, and allow donations by a pharmacy, health facility, manufacturer, or wholesale distributor.**
- **Permit any licensed health facility or pharmacy that was in compliance with Federal and State laws, rules, and regulations to participate as a repository.**
- **Allow a repository to accept and store donated drugs and supplies, or accept, store, dispense, and administer donated drugs and supplies.**
- **Require an individual who received a cancer drug or supply to provide verification that he or she had a current diagnosis of cancer.**
- **Establish priorities for dispensing donated drugs and supplies.**
- **Allow a repository to charge a handling fee for each cancer drug or supply dispensed or administered.**
- **Establish record-keeping requirements for a repository.**
- **Provide criminal and civil immunity for drug manufacturers for certain actions by a party not under the manufacturers' control, and provide civil immunity for program participants in certain situations.**

Program Establishment

Under the bill, the Board of Pharmacy would have to establish and maintain a cancer drug repository program that would allow a person to donate a cancer drug for supply or for use by an individual who met the eligibility criteria. The Board would have to establish program guidelines, policies, and procedures addressing the cancer drug repository program. Under the program, donations could be made on the premises of a health facility or pharmacy that elected to participate and met the specified requirements.

"Cancer drug repository" would mean a health facility or pharmacy that notified the Board of its election to participate in the cancer drug repository program. "Health facility" would mean a facility licensed in accordance with Article 17 of the Act (facilities and agencies) as a county medical care facility, freestanding surgical outpatient facility, home for the aged, hospital, hospital long-term care unit, nursing home, and hospice. "Cancer drug" would mean a prescription drug that is used to treat either cancer or the side effects of cancer; or the side effects of any prescription drug that is used to treat cancer or its side effects.

Donations; Program Participation

An individual who was at least 18 years of age could donate legally obtained cancer drugs or supplies to a cancer drug repository. If the donated drugs had not been previously dispensed, a pharmacy, health facility, manufacturer, or wholesale

distributor also could donate cancer drugs or supplies to a repository. Donated drugs or supplies would be acceptable for donation if they were determined to be eligible by a pharmacist who was employed by or under contract with a cancer drug repository.

Any health facility or pharmacy that was licensed and in compliance with all Federal and State laws, rules, and regulations would be eligible to participate in the cancer drug repository program. Participation would be voluntary and a pharmacy or health facility could withdraw from participation at any time upon notification to the Board. A notice to withdraw could be given by telephone or regular mail.

A pharmacy or health facility could choose to participate fully in the program by accepting, storing, and dispensing or administering donated drugs and supplies, or the pharmacy or health facility could limit its participation to only accepting and storing donated drugs and supplies. If a pharmacy or health facility chose to limit its participation, it would have to distribute any donated drugs to a fully participating cancer drug repository.

A pharmacy or health facility that elected to participate in the program would have to submit the following information to the Board in a form provided by the Board that included, at minimum, each of the following:

- The name, street address, and telephone number of the pharmacy or health facility.
- The name and telephone number of a pharmacist who was employed by or under contract with the pharmacy or health facility, or other contact person who was familiar with the pharmacy's or health facility's participation in the cancer drug repository program.
- A statement indicating that the pharmacy or health facility was located in the State and in compliance with all Federal and State laws, rules, and regulations and the chosen level of participation in the program.

Eligible Drugs & Supplies

A cancer drug would be eligible for donation under the cancer drug repository program only if all of the following requirements were met:

- The donation was accompanied by a cancer drug repository donor form that was provided by the Board and stated that to the best of the donor's knowledge the donated drug had been properly stored and had never been opened, used, tampered with, adulterated, or misbranded.
- The drug's expiration date was at least six months later than the date the drug was donated.
- The drug was in its original, unopened, tamper-evident unit dose packaging that included the drug's lot number and expiration date. Single unit dose drugs could be accepted if the single unit dose packaging were unopened.
- The drug was not adulterated or misbranded.

Cancer supplies (prescription and nonprescription supplies needed to administer a cancer drug) would be eligible for donation under the program only if all of the following requirements were met:

- The supplies were not adulterated or misbranded.
- The supplies were in their original, unopened, sealed package.
- The donation was accompanied by a cancer drug repository donor form that was provided by the Board and stated that to the best of the donor's knowledge the donated supply had been properly stored and had never been opened, used, tampered with, adulterated, or misbranded.

The Board would have to make the cancer drug repository donor form available on the its website. The form would have to be signed by the person making the donation or that person's authorized representative.

Controlled substances would not be eligible for donation or acceptance under the program. Cancer drugs and supplies that did not meet the criteria for donation would not be eligible for donation or acceptance under the program.

Cancer drugs and supplies could be donated on the premises of a cancer drug repository to a pharmacist designated by the repository. A drop box could not be used to deliver or accept donations. Donated drugs and supplies would have to be stored in a secure storage area under environmental

conditions appropriate for the drugs or supplies being stored. Donated drugs and supplies could not be stored with nondonated inventory.

Donated drugs and supplies would have to be dispensed by a pharmacist pursuant to a prescription by a prescriber or could be dispensed or administered by a dispensing prescriber. Before being dispensed or administered, the drugs and supplies would have to be visually inspected by the pharmacist or dispensing prescriber for adulteration, misbranding, and date of expiration. Drugs or supplies that had expired or appeared upon visual inspection to be adulterated, misbranded, or tampered with in any way could not be dispensed or administered.

Dispensation/Administration

Any resident of the State who was diagnosed with cancer would be eligible to receive drugs or supplies under the cancer drug repository program. Donated drugs and supplies could not be resold and could only be dispensed or administered to residents of the State who were diagnosed with cancer.

Before a cancer drug or supply could be dispensed or administered to an individual, the individual would have to provide verification that he or she had 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 acknowledging that the individual understood the information stated on the form. The form would have to be made available to the public on the Board's website and, at minimum, include the following information:

- 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.
- That the pharmacist, the dispensing or administering prescriber, the cancer drug repository, the Board, and any other participant of the cancer drug repository program could not guarantee the safety of the drug or supply being dispensed or

administered and that the pharmacist or prescriber had determined that the drug or supply was safe to dispense or administer based on the accuracy of the donor's form submitted with the donated drug or supply and the visual inspection required to be performed by the pharmacist or prescriber before dispensing or administering.

A pharmacist who dispensed drugs and supplies donated under the program could not submit a claim or otherwise seek reimbursement from any public or private third party payer for drugs or supplies dispensed to any eligible individual in accordance with the program, nor could a public or private third party payer be required to provide reimbursement for donated drugs or supplies dispensed by a pharmacist to an eligible individual in accordance with the program.

Cancer drugs and supplies dispensed under the program would have to be dispensed in the following order of priority:

- Individuals who were uninsured or did not have insurance coverage for those cancer drugs or supplies.
- Individuals who were enrolled in Medicaid, Medicare, or any other public assistance health care program.
- All other individuals who were residents of the State and diagnosed with cancer.

Repositories

A cancer drug repository could charge the individual receiving a drug or supply a handling fee of not more than 250% of the Medicaid dispensing fee or \$5, whichever was less, for each cancer drug or supply dispensed or administered. Cancer drug repositories could distribute drugs and supplies donated under the program to other repositories if requested by a participating repository.

A cancer drug repository that had elected not to dispense donated drugs or supplies would have to distribute any donated drugs and supplies to a participating repository upon request of the repository. If a repository distributed drugs or supplies to another participating repository, the repository would have to complete a cancer drug repository donor form provided by the Board. The completed form and copy of the

donor form that was completed by the original donor would have to be provided to the fully participating cancer drug repository at the time of distribution.

Cancer drug repository donor and recipient forms would have to be maintained for at least five years. A record of destruction of donated drugs and supplies that were not dispensed would have to be maintained by the dispensing repository for at least five years. For each drug or supply destroyed, the record would have to include the following information:

- The date of destruction.
- The name, strength, and quantity of the drug destroyed.
- The name of the person or firm that destroyed the drug.
- The source of the drugs or supplies destroyed.

Immunity

A manufacturer would not be subject to criminal or civil liability for injury, death, or loss to a person or to property for either the intentional or unintentional alteration of the drug or supply by a party not under the manufacturer's control; or the failure of a party not under the manufacturer's control to transfer or communicate product or consumer information or the expiration date of the donated drug or supply.

A health facility or pharmacy participating in the cancer drug repository program, a pharmacist dispensing a drug or supply pursuant to the program, a prescriber dispensing or administering a drug or supply pursuant to the program, 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 the cancer drug or supply was dispensed, and 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 bill's requirements. The immunity would not apply if the act or omission involved reckless, wanton, or intentional misconduct, or malpractice unrelated to the quality of the cancer drug or supply.

MCL 333.17766 et al.

Legislative Analyst: J.P. Finet

FISCAL IMPACT

The bill would create a moderate, indeterminate increase in administrative cost for the Department of Community Health through the establishment and maintenance of the cancer drug repository program. It is likely that this administrative cost would be offset by decreased expenditures for pharmaceutical products through the Medicaid program and State and local governmental employee health plans. The extent of savings to State and local government associated with this program would depend upon the number of participating facilities and the number of individuals receiving Medicaid benefits or State and local employee health coverage who would participate in the program.

Fiscal Analyst: David Fosdick

S0506\S5672sa

This analysis was prepared by nonpartisan Senate staff for use by the Senate in its deliberations and does not constitute an official statement of legislative intent.