HOUSE RESEARCH

Bill Summary

FILE NUMBER: H.F. 127 **DATE:** March 11, 2005

Version: First engrossment

Authors: Abeler and others

Subject: Cancer Drug Repository Program

Analyst: Janelle Taylor, 651-296-5808

Overview

This bill establishes a voluntary cancer drug repository program. The program allows the donation of cancer drugs and supplies to participating pharmacies and medical facilities. The pharmacies and medical facilities may either distribute the drugs to other participating pharmacies and medical facilities or dispense the drugs to eligible individuals.

Section

1 **Cancer drug repository program.** Adds § 144.707. Creates a cancer drug repository program.

Subd. 1. Definitions. Defines "cancer drug," "cancer drug repository," "cancer supply," "commissioner," "dispense," "distribute," "medical facility," "medical supplies," "pharmacist," "pharmacy," "practitioner," "prescription drug," "side effects of cancer," "single-unit-dose packaging," and "tamper-evident unit dose packaging" for the purposes of the program.

Subd. 2. Establishment . Directs the commissioner of health to establish and maintain a cancer drug repository program where cancer drugs and supplies may be donated for use by individuals meeting eligibility requirements established in subdivision 4. The drugs and supplies may be donated on the premises of a participating medical facility or pharmacy meeting the requirements of subdivision 3.

Section

Subd. 3. Requirements for participation by pharmacies and medical facilities. Establishes several requirements that must be met in order for pharmacies and medical facilities to participate in the program in the following paragraphs:

(a) A pharmacy or medical facility must be licensed and in compliance with all applicable federal and state laws and administrative rules.

(b) A pharmacy or medical facility volunteering to participate (the program is voluntary) must submit the following information to the commissioner of health: their name, address, and telephone number; the name and telephone number of a pharmacist or other person knowledgeable of the pharmacy's or medical facility's participation in the program; and a statement that they meet the eligibility requirements in paragraph (a) and the chosen level of participation under paragraph (c).

(c) A pharmacy or medical facility may participate by either accepting, storing and dispensing the drugs and supplies OR accepting and storing the drugs and supplies and donating them to a participating pharmacy or medical facility that dispenses the drugs and supplies.

(d) A pharmacy or medical facility may withdraw from the program at anytime upon notification of the commissioner of health by telephone or mail.

Subd. 4. Individual eligibility requirements. States that any Minnesota resident diagnosed with cancer is eligible to receive drugs or supplies under the program according to the priorities established in subdivision 6.

Subd. 5. Donations of cancer drugs and supplies. Paragraph (a) states that legally obtained cancer drugs and supplies may be donated by an individual age 18 years or older OR a pharmacy, medical facility, drug manufacturer, or wholesale drug distributor if the drugs or supplies have not been previously dispensed. The cancer drugs and supplies must meet the requirements in paragraph (b) or (c) in order to be donated.

Paragraph (b) sets the criteria for cancer drugs. ***Cancer drugs*** must: (1) be accompanied by a cancer drug repository donor form signed by the person making the donation (or their authorized representative) as required in paragraph (d); (2) have an expiration date at least six months later than the date the drug was donated; (3) be in their original, unopened, tamper-evident unit dose packaging that includes the drug's lot number and expiration date (singe unit doses may be accepted if the single unit dose packaging is unopened); and (4) not be adulterated or misbranded.

Paragraph (c) sets the criteria for cancer supplies. ***Cancer supplies*** must: (1) not be adulterated; (2) be in their original, unopened, sealed packaging; and (3) be accompanied by a cancer drug repository donor form signed by the person making the donation (or their authorized representative) as required in paragraph (d).

Section

Paragraph (d) requires that a cancer drug repository donor form be provided by the commissioner of health and made available on the department's website. The form must state, to the best of the donor's knowledge, that the donated drug or supply has been properly stored and that the drug or supply has never been opened, used, tampered with, adulterated, or misbranded.

Paragraph (e) states that drugs and supplies not meeting the requirements of this subdivision are not eligible for donation or acceptance under the program.

Paragraph (f) states that drugs and supplies may be donated on the premises of a cancer drug repository to a pharmacist designated by the repository. A drop box may not be used.

Paragraph (g) states that donated cancer drugs and supplies must: (1) be stored separately from nondonated drugs and supplies; and (2) be stored in a secure area with the appropriate environmental conditions appropriate for the drugs and supplies.

Subd. 6. Dispensing requirements. Establishes requirements for dispensing the drugs and supplies, including:

- requiring that the drugs and supplies be dispensed by a licensed pharmacist, pursuant to a prescription, and in accordance with Minnesota Statutes, chapter 151;

- requiring that the drugs be inspected by the pharmacist for adulteration, misbranding and the expiration date (drugs that have expired or appear to be adulterated, tampered with or misbranded, may not by dispensed);

- requiring recipients of the donated cancer drugs and supplies to sign a form provided by the commissioner of health (and made available on the department's website) that states that the recipient understands that: (1) the drugs and supplies have been donated and may have been previously dispensed; (2) a pharmacist has inspected the drugs; (3) the pharmacist, the repository, the Department of Health, and any other program participant cannot guarantee the safety of the drug; and (4) the pharmacist has determined that the drug is safe based on visual inspection and the accuracy of the form submitted by the donor; and

- requiring that drugs and supplies be dispensed to individuals meeting the eligibility requirements of subdivision 4 in the following order of priority: (1) uninsured, (2) enrolled in MA, GAMC, MinnesotaCare, Medicare, or other public assistance health care, and (3) all other eligible individuals.

Subd. 7. Handling fees. Allows a cancer drug repository to charge individuals receiving a drug or supply a handling fee of no more than 250 percent of the MA program dispensing fee for each cancer drug or supply dispensed. (The current pharmacy dispensing fee is $3.65, with some exceptions (Minn. Stat. § 256B.0625,

Section

subd. 13e.))

Subd. 8. Distribution of donated cancer drugs and supplies. States that cancer drug repositories may distribute donated drugs and supplies to another repository if requested by the other repository. Any repository electing not to dispense drugs and supplies shall distribute any donated drugs and supplies to a participating repository at the request of the other repository. Repositories distributing drugs and supplies under this subdivision shall complete a cancer drug repository form (provided by the commissioner) and provide the original donor form (required under subdivision 5) to the receiving repository at the time of the distribution.

Subd. 9. Resale of donated drugs or supplies. States that donated drugs and supplies may not be resold.

Subd. 10. Record-keeping requirements. Requires that cancer drug repository donor and recipient forms be maintained for at least five years. Also requires a record of the destruction of drugs and supplies that were not dispensed to be maintained for at least five years. The record of the destruction must include: the date of destruction; the name, strength, and quantity of the drug destroyed; the name of the person/firm that destroyed the drug; and the source of the drugs or supplies.

Subd. 11. Liability. Exempts manufacturers of drugs and supplies (unless they exercise bad faith) from civil or criminal liabilities for injury, death, or loss to a person or property related to the donation, acceptance or dispensing of drugs and supplies under the cancer drug repository program. Exempts medical facilities, pharmacies, pharmacists, practitioners, or donors participating in the program from civil liability for injuries or deaths of individuals to whom cancer drugs or supplies were dispensed. States that no disciplinary action shall be taken for unprofessional conduct related to donating, accepting, distributing or dispensing cancer drugs or supplies unless there was reckless, wanton, or intentional misconduct.