

ORDER OF THE
DEPARTMENT OF HEALTH AND FAMILY SERVICES
CREATING RULES

The Wisconsin Department of Health and Family Services proposes to create ch. HFS 148, relating to the cancer drug repository program authorized under s. 255.056, Stats., and affecting small businesses.

Analysis Prepared by the Department of Health and Family Services

Statute (s) interpreted: Sections 255.056 and 450.11, Stats.

Statutory authority: Sections 227.11 (2) (a) and 255.056 (2) and (7), Stats.

Explanation of agency authority:

Section 255.056, (7) Stats., requires the Department to promulgate rules for the administration of the cancer drug repository program under which unused, donated cancer drugs and supplies may be dispensed to individuals who are diagnosed with cancer. Section 255.056, Stats., requires rules to establish eligibility requirements for participation in the program; forms for use in the administration of the program; drugs and supplies that may and may not be accepted for use under the program; and the maximum handling fee that a pharmacy or medical facility may charge a recipient for drugs or supplies received under the program.

Related statute(s) or rule(s): Sections 255.056, 450.01, 450.06, 450.05, 450.11, and 943.145 (1), Stats., and ch. Phar. 7.

Plain language analysis:

Under s. 255.056, Stats., pharmacies and medical facilities, which include hospitals, and clinics or offices used by physicians licensed under ch. 448, Stats., may elect to accept unused cancer drugs and cancer supplies for dispensation to individuals who meet eligibility criteria established by the Department in these rules. The proposed rules establish eligibility requirements for participation in the program; forms for use in the administration of the program; drugs and supplies that may and may not be accepted for use under the program; and the maximum handling fee that a pharmacy or medical facility may charge a recipient for drugs or supplies received under the program.

Summary of, and comparison with, existing or proposed federal regulations:

There are no comparable existing or proposed federal regulations.

Comparison with rules in adjacent states:

There are no comparable rules in Illinois, Iowa, Minnesota, or Michigan.

Summary of factual data and analytical methodologies:

To develop these rules, the Department formed an advisory committee that included representatives from the Wisconsin Medical Society, the Pharmacy Society of Wisconsin, the Pharmacy Examining Board, the Medical Examining Board, the American Cancer Society, Health

Care Network and the Hospice Organization, and Palliative Experts of WI. The advisory committee met over a period of three months to develop and achieve consensus on the proposed language.

Analysis and supporting documents used to determine effect on small business:

The proposed rules will affect only the pharmacies and medical facilities that elect to participate in the cancer drug repository program, including those that meet the definition of small business under s. 227.114 (1), Stats.

Anticipated costs incurred by private sector:

Medical facilities and pharmacies that elect to participate in the cancer drug repository program may incur additional costs for inspection, storage, dispensing, distribution, and destruction of expired donated drugs or supplies. The handling fee allowed under s. 255.056, and the proposed rules may help to offset these costs.

Effect on small business:

The proposed rules will affect only the pharmacies and medical facilities that elect to participate in the cancer drug repository program, including those that meet the definition of small business under s. 227.114 (1), Stats. Except for certain form requirements, the proposed rules do not impose reporting or recordkeeping requirements, or performance, operational, or design standards beyond what may be already required under s. 450.11, Stats., and ch. Phar 7 relating to pharmacies; s. HFS 124.15 relating to hospitals; and ch. Med 17 relating to physicians.

Agency contact person:

Doug Englebert, R.Ph.
Pharmacy Practice Consultant
Provider Regulation and Quality Improvement Section
Room 950, 1 West Wilson St.
Madison, WI 53701
Phone: 608-266-5388
Fax: 608-267-7119
engleda@dhfs.state.wi.us

Place where comments are to be submitted and deadline for submission:

Comments may be submitted to the contact person listed above.

SECTION 1. HFS 148 is created to read:

Chapter HFS 148

CANCER DRUG REPOSITORY PROGRAM

- HFS 148.01 Authority and purpose
- HFS 148.02 Applicability
- HFS 148.03 Definitions
- HFS 148.04 Requirements for participation by pharmacies and medical facilities
- HFS 148.05 Recipient eligibility requirements
- HFS 148.06 Donations of cancer drugs and supplies

- HFS 148.07 Dispensing requirements
- HFS 148.08 Handling fees
- HFS 148.09 Distribution of donated cancer drugs and supplies
- HFS 148.10 Re-sale of donated drugs or supplies
- HFS 148.11 Recordkeeping requirements

HFS 148.01 Authority and purpose. This chapter is promulgated under the authority of s. 255.056, Stats., to establish and maintain a cancer drug repository program under which unused cancer drugs and cancer supplies may be donated and dispensed to individuals who are diagnosed with cancer.

HFS 148.02 Applicability. (1) This chapter applies to the department and any person who donates, receives, dispenses or otherwise participates or wishes to participate in the cancer drug repository program.

(2) Over-the-counter medications and supplies not used to administer cancer drugs such as bandages or drainage bags are not subject to the provisions of this chapter. Accepting such items is at the discretion of the individual pharmacy or medical facility.

HFS 148. 03 Definitions. In this chapter:

(1) "Cancer drug" or "drug" means a prescription drug that is used to treat any one of the following:

(a) Cancer or side effects of cancer.

(b) The side effects of any prescription drug that is used to treat cancer or side effects of cancer.

(2) "Cancer drug repository" means a medical facility or pharmacy that has notified the department of its election to participate in the cancer drug repository program.

(3) "Cancer supply" or "supplies" means prescription and non-prescription supplies needed to administer a cancer drug.

(4) "Department" means the Wisconsin department of health and family services.

(5) "Dispense" has the meaning given in s. 450.01(7).

(6) "Distribute" has the meaning given in s. 450.01(8).

(7) "Distributor" has the meaning given in s. 450.01 (9).

(8) "Manufacturer" has the meaning given in s. 450.01 (12).

(9) "Medical facility" has the meaning given in s. 943.145 (1).

(10) "Pharmacist" has the meaning given in s. 450.01(15).

(11) "Pharmacy" means a pharmacy that is licensed under s. 450.06.

(12) "Prescription drug" has the meaning given in s. 450.01 (20).

(13) "Side effects of cancer" means symptoms of cancer.

(14) "Single-unit-dose packaging" means a single-unit container for articles intended for administration as a single dose, direct from the container.

(15) "Tamper-evident unit dose packaging" means a container within which a drug is sealed so that the contents cannot be opened without obvious destruction of the seal.

HFS 148.04 Requirements for participation by pharmacies and medical facilities. (1) ELIGIBILITY. To be eligible for participation in the cancer drug repository program a pharmacy or medical facility shall be in compliance with all applicable federal and state laws, and administrative rules.

(2) NOTICE OF PARTICIPATION. (a) Participation in the cancer drug repository program is voluntary. A pharmacy or medical facility may elect to participate in the cancer drug repository program by providing written notification to the department of all of the following:

1. The name, street address, and telephone number of the pharmacy or medical facility.
2. The name and telephone number of a pharmacist or another contact as determined by the pharmacist who is employed by or under contract with the pharmacy or medical facility.
3. A statement indicating that the pharmacy or medical facility meets the eligibility requirements under sub. (1), and the chosen level of participation described in par. (b).

(b) A pharmacy or medical facility may fully participate in the cancer drug repository program by accepting, storing, and dispensing donated drugs and supplies, or may limit its participation to only accepting and storing donated drugs and supplies. If a pharmacy or facility chooses to limit its participation, the pharmacy or facility shall distribute any donated drugs to a fully participating cancer drug repository following the requirements under s. HFS 148.09.

Note: Notices of participation in the cancer drug repository program can be sent to the Department of Health and Family Services, 1 West Wilson St., Madison, WI 53701.

(3) WITHDRAWAL FROM PARTICIPATION. A pharmacy or medical facility may withdraw from participation in the cancer drug repository program at any time upon written notice to the department.

Note: A notice to withdraw participation from the cancer drug repository program can be sent to the Department of Health and Family Services, 1 West Wilson St., Madison, WI 53701.

HFS 148.05 Recipient eligibility requirements. Any Wisconsin resident who is diagnosed with cancer is eligible to receive drugs or supplies under the cancer drug repository program.

HFS 148.06 Donations of cancer drugs and supplies. (1) PERSONS ELIGIBLE TO DONATE DRUGS OR SUPPLIES. Any one of the following persons may donate legally obtained cancer drugs or supplies to a cancer drug repository, if the drugs or supplies meet the requirements under sub. (2), as determined by a pharmacist who is employed by or under contract with a cancer drug repository:

(a) An individual who is 18 years old or older.

(b) A pharmacy, medical facility, manufacturer, or distributor, if the donated drugs have not been previously dispensed or administered.

(2) DRUGS AND SUPPLIES ELIGIBLE FOR DONATION. (a) *Cancer drugs*. A cancer drug is eligible for donation under the cancer drug repository program only if all of the following requirements are met:

1. The donation is accompanied by a completed cancer drug repository donor form that is signed by the person making the donation or that person's authorized representative.

2. The drug's expiration date is at least 6 months later than the date that the drug was donated.

3. The drug is in its original, unopened, tamper-evident unit dose packaging that includes the drug's lot number and expiration date. Single-unit dose drugs may be accepted if the single-unit-dose packaging is unopened.

4. The drug is not adulterated or misbranded.

(b) *Cancer supplies*. Cancer supplies are eligible for donation under the cancer drug repository program only if the supplies meet all of the following requirements:

1. The supplies are not adulterated or misbranded.

2. The supplies are in their original, unopened, sealed packaging.

3. The supplies are accompanied by a completed cancer drug repository donor form that is signed by the person making the donation or that person's authorized representative.

Note: Cancer drug repository donor forms can be obtained from the Department's website at <http://www.dhfs.wisconsin.gov/forms>.

(3) DRUGS AND SUPPLIES NOT ELIGIBLE FOR DONATION. All of the following drugs are ineligible for donation or acceptance under the cancer drug repository program:

(a) Controlled substances.

(b) Drugs and supplies that do not meet the criteria under sub. (2).

(4) LOCATIONS WHERE DONATIONS MAY BE MADE. Drugs and supplies may be donated on the premises of a cancer drug repository to a person designated by the repository. A drop box may not be used to deliver or accept donations.

(5) STORAGE. Cancer drugs and supplies donated under the cancer drug repository program shall be stored in a secure storage area under environmental conditions appropriate for the drugs or supplies being stored. Donated drugs and supplies may not be stored with non-donated inventory.

HFS 148.07 Dispensing requirements. (1) Drugs and supplies shall be dispensed by a licensed pharmacist consistent with the requirements in s. 450.11, Stats., and ch. Phar 7.

(2) The pharmacist shall inspect cancer drugs and supplies for adulteration, misbranding, and the date of expiration before dispensing. Drugs or supplies that are expired, adulterated, or misbranded may not be dispensed.

(3) Before a cancer drug or supply may be dispensed to a recipient, the recipient shall sign a cancer drug repository recipient form and shall be orally notified that the drug or supply may have been previously dispensed.

(4) Drugs and supplies shall be dispensed only to recipients who meet the eligibility requirements in s. HFS 148.05, in the following order of priority:

(a) Individuals who are uninsured.

(b) Individuals who receive or are eligible to receive Medicaid, Medicare, or other government based health care.

(c) All other individuals who are otherwise eligible under s. HFS 148.05 to receive drugs or supplies from a cancer drug repository.

Note: Cancer drug repository recipient forms can be obtained from the Department's website at <http://www.dhfs.wisconsin.gov/forms/index.htm?nav=mo> .

HFS 148.08 Handling fees. A cancer drug repository may charge the recipient of a drug or supply a handling fee of no more than 300% of the Medicaid dispensing fee or no more than \$15.00, whichever is less, for each cancer drug or supply dispensed.

Note: The Medicaid dispensing fee can be found in the Wisconsin Medicaid Pharmacy Handbook, which can be obtained from the Department's website at <http://www.dhfs.wisconsin.gov/Medicaid2/handbooks/pharmacy/index.htm>

HFS 148.09 Distribution of donated cancer drugs and supplies. (1) Cancer drug repositories may distribute drugs and supplies donated under the cancer drug repository program to other repositories if requested by a participating repository.

(2) A cancer drug repository that has elected not to dispense donated drugs or supplies shall distribute those drugs and supplies to a participating repository upon request of the repository.

(3) If a cancer drug repository distributes drugs or supplies under sub. (1) or (2), the repository shall complete a cancer drug repository donor form. The completed form and a copy of the donor form that was completed by the original donor under s. HFS 148.06 (2) (a) 1. shall be provided to the fully participating cancer drug repository at the time of distribution.

HFS 148.10 Sale of donated drugs or supplies. Donated drugs and supplies may not be sold.

HFS 148.11 Recordkeeping requirements. (1) DONOR AND RECIPIENT FORMS. Cancer drug repository donor and recipient forms shall be maintained for at least 5 years.

(2) DESTRUCTION OF DONATED DRUGS OR SUPPLIES. A record of destruction of donated drugs and supplies that are not dispensed under s. HFS 148.07 shall be maintained by the dispensing repository for at least 5 years. For each drug or supply destroyed, the record shall include all of the following information:

- (a) The date of destruction.
- (b) The name, strength and quantity of the cancer drug destroyed.
- (c) The name of the person or firm that destroyed the drug.
- (d) The source of the drugs or supplies destroyed.

SECTION 2. EFFECTIVE DATE. This rule shall take effect on the first day of the month following publication in the Wisconsin administrative register, as provided in s. 227.22 (2) (intro.), Stats.

Wisconsin Department of Health
and Family Services

Dated:

By: _____
Helene Nelson
Secretary

Seal: