

ORDER OF THE
DEPARTMENT OF HEALTH AND FAMILY SERVICES
TO ADOPT RULES

The Wisconsin Department of Health and Family Services proposes to amend ch. HFS 148 (title), 148.01, 148.02, 148.03 (1) to (3) and (13), 148.04 (1), (2) (a) (intro), (b) and (note), (3) and (note), 148.05, 148.06 (title), (1) (intro), (2) (a) (title) and (intro), (a) 1., (b) (intro) and (title), (b) 3. and (note), (3) (intro), (4) and (5), 148.07 (2), (3), (4) (c) and (4) (c) (note), 148.08 and 148.09, and 148.11 (1) and (2) (b), and to create HFS 148.03 (3m) and (14m), relating to the cancer drug repository program authorized under s. 255.056, Stats., and affecting small business.

SUMMARY OF PROPOSED RULE

Statute (s) interpreted: Section 255.056, Stats.

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

Explanation of agency authority:

Section 255.056 (2), Stats., requires the Department to establish and maintain a cancer and chronic diseases drug repository program under which a person may donate a cancer or chronic diseases drug or supplies for use by individuals who meet the eligibility requirements established by the Department in rule. Section 255.056 (7), Stats., requires the Department to promulgate rules for the administration of the cancer and chronic diseases drug repository program. Specifically, section 255.056 (7), Stats., requires the Department to promulgate rules to do all of the following:

- Establish eligibility criteria for individuals to receive drugs and supplies under the program;
- Develop forms for administering the program;
- Determine the maximum handling fee that a pharmacy or medical facility may charge a recipient for drugs or supplies received under the program; and
- Identify drugs and supplies that may and may not be accepted under the program.

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

Plain language analysis:

The Department currently manages the cancer drug repository program under s. 255.056, Stats., and ch. HFS 148, which allows pharmacies and medical facilities, including hospitals, and clinics or offices used by physicians to accept donated, unused cancer drugs and supplies for dispensation to eligible individuals. 2005 Wisconsin Act 16 expanded the cancer drug repository program effective January 1, 2006 to allow drugs and supplies for the treatment of chronic diseases to be donated and dispensed under the program. This expansion requires the Department to modify ch. HFS 148, to reflect the changes made to s. 255.056, Stats.

Through this rulemaking order, the Department proposes to modify ch. HFS 148 to insert the term “chronic disease” where appropriate. The Department also proposes to remove the alternative \$15 handling fee prescribed under s. HFS 148.08 to avoid any conflicts that may occur between this alternative amount and the Medicaid dispensing fee which is used as the basis of the handling fee amount that can be charged to persons eligible to receive drugs and supplies 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:

The Department relied on all of the following to determine the impact on small businesses, specifically pharmacies and medical facilities or to draft the proposed rules:

1. In developing the original ch. HFS 148 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 Wisconsin. The Department asked the members of the original advisory committee and contacted current participating providers under the current Cancer Drug Repository rule to provide comments on the current rule and suggest changes for these proposed rules.
2. The 2002 Economic Census – Wisconsin Geographic Series, which is compiled by the U.S. census bureau every 5 years for each year ending in “2” and “7” and is the latest available economic data compiled on businesses located in Wisconsin.
3. Criteria adopted by the Department and approved by the Wisconsin Small Business Regulatory Review Board to determine whether the Department’s proposed rules have a significant economic impact on a substantial number of small businesses. Pursuant to the Department’s criteria, a proposed rule will have a significant economic impact on a substantial number of small businesses if at least 10% of the businesses affected by the proposed rules are small businesses and if operating expenditures, including annualized capital expenditures, increase by more than the prior year’s consumer price index or reduces revenues by more than the prior year’s consumer price index. For the purposes of this rulemaking, 2005 is the index year and the rate for 2005 is 3%. The consumer price index is compiled by the U.S. Department of Labor, Bureau of Labor Statistics to measure, among other things, the rate of inflation.
4. DHFS Medicaid provider records from the Division of Health Care Financing.
5. Pharmacy Cost of Dispensing/Acquisition Cost Study prepared by David H. Kreling, PhD. Sonderegger Research Center, School of Pharmacy, University of Wisconsin – Madison.

6. Section 227.114 (1), Stats., which defines “small business” as a business entity, including its affiliates, which is independently owned and operated and not dominant in its field, and which employs 25 or fewer full-time employees or which has gross annual sales of less than \$5,000,000.

7. Section 255.056 (7), Stats., which requires the Department to promulgate rules for the drug repository program.

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

The Department currently manages the cancer drug repository program under s. 255.056, Stats., and ch. HFS 148, which allows pharmacies and medical facilities, including hospitals and clinics or offices used by physicians to elect to accept donated, unused cancer drugs and supplies for dispensation to eligible individuals. 2005 Wisconsin Act 16 expanded the cancer drug repository program effective January 1, 2006 to allow drugs and supplies for the treatment of chronic diseases to be donated and dispensed under the program. This expansion requires the Department to amend ch. HFS 148, to reflect the changes made to s. 255.056, Stats.

Through this rulemaking order, the Department will modify ch. HFS 148 to reflect the changes in s. 255.056, Stats. The Department also proposes to remove the alternative \$15 handling fee prescribed under s. HFS 148.08 to avoid any conflicts that may occur between this alternative amount and the Medicaid dispensing fee which is used as the basis of the handling fee amount that can be charged to users of the program.

The proposed expansion of the drug repository program will directly impact current and potential pharmacy or medical facility participants in the drug repository program, including those that meet the definition of small business under s. 227.114 (1), Stats. Sixteen pharmacies and no medical facilities currently participate in the cancer drug repository program. Analysis of the 2002 Economic Census (Wisconsin data) for the pharmacy industry (NAICS Code 44611), suggests that most of the pharmacies, including the current 16 pharmacy participants, are small businesses as defined under s. 227.114 (1), Stats. Medical facilities, as defined under s. 943.145, Stats., are hospitals, and clinics or offices of physicians licensed under ch. 448, Stats. An analysis of the 2002 Economic Census (Wisconsin data) for these facilities (NAICS Codes 6211- offices of physicians; 622 - hospitals; 621491- HMO medical centers; and 621493 - freestanding ambulatory surgical and emergency centers) suggests that the average facility does not meet the definition of small business under s. 227.114 (1), Stats.

Current participating entities (and potential participants) may incur additional costs for inspection, storage, dispensing, distribution, and destruction of expired donated drugs or supplies of the additional drugs and supplies. To cover these costs, entities may charge a handling fee that is up to 300% of the Medicaid dispensing fee (which is currently \$4.38) or \$13.14 per prescription. This amount is comparable to what non-participating pharmacies receive for prescription dispensing fees. A 2002 study commissioned by the Wisconsin Medicaid program found that in the year 2000, dispensing fees, which included the cost of packaging, labeling, computer systems, salaries, rent, utilities, etc., averaged between \$6.95 and \$7.35 per prescription with expected annual increases between 6 and 12 percent. Adjusting for cost increases, the Department determined that in 2005, dispensing fees could range from \$9.30 to \$11.56 per prescription.

If a participating entity chooses not to collect a handling fee, that entity will bear the costs of inspection, storage, dispensing, distribution, and destruction of expired donated drugs or supplies.

The proposed rules do not impose form requirements or requirements for reporting or recordkeeping, or performance, operational or design standards.

Effect on small business:

The expansion of the drug repository program to include chronic diseases drugs and supplies and amendment of the handling fee provision prescribed under s. HFS 148.08, will not have a significant economic impact on current or potential pharmacy or medical facility participants in the drug repository program, including those that meet the definition of small business under s. 227.114 (1), Stats.

Agency contact person:

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

Comments may be submitted to the agency contact person that is listed above and via the Wisconsin Administrative Rules website at <http://adminrules.wisconsin.gov> until 4:30 p.m. on April 12, 2006. A public hearing will be held from 9:00 a.m. to 11:00 a.m. on April 4, 2006 at 1 W. Wilson St., Room 950B, in Madison, Wisconsin. The notice of public hearing is posted on the Wisconsin Administrative Rules website at <http://adminrules.wisconsin.gov>.

TEXT OF PROPOSED RULE

SECTION 1. HFS 148 (title), 148.01 and 148.02 are amended to read:

(title) CHAPTER HFS 148, CANCER AND CHRONIC DISEASES DRUG REPOSITORY PROGRAM

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

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 and chronic diseases drug repository program.

(2) Over-the-counter medications and supplies not used to administer cancer and chronic disease 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.

SECTION 2. HFS 148.03 (1) to (3) are amended to read:

HFS 148.03 (1) “Cancer or chronic disease drug” or “drug” means a prescription drug that is used to treat any one of the following:

(a) Cancer or chronic disease or side effects of cancer or chronic disease.

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

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

(3) “Cancer or chronic diseases supply” or “supplies” means prescription and non-prescription supplies needed to administer a cancer or chronic disease drug.

SECTION 3. HFS 148.03 (3m) is created to read:

HFS 148.03 (3m) “Chronic disease” has the meaning under s. 255.056 (1) (am), Stats.

SECTION 4. HFS 148.03 (13) is amended to read:

HFS 148.03 (13) “Side effects of cancer or chronic disease” means symptoms of cancer or chronic disease.

SECTION 5. HFS 148.03 (14m) is created to read:

HFS 148.03 (14m) “Supplies” has the meaning under s. 255.056 (1) (h), Stats.

SECTION 6. HFS 148.04 (1), (2) (a) (intro), (b) and (note), (3) and (note) are amended to read:

HFS 148.04 Requirements for participation by pharmacies and medical facilities.

(1) ELIGIBILITY. To be eligible for participation in the cancer or chronic disease 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 or chronic disease drug repository program is voluntary. A pharmacy or medical facility may elect to participate in the cancer or chronic disease drug repository program by providing written notification to the department of all of the following:

(b) A pharmacy or medical facility may fully participate in the cancer or chronic disease 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 or chronic disease drug repository following the requirements under s. HFS 148.09.

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

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

Note: A notice to withdraw participation from the cancer or chronic disease drug repository program ~~can~~ should be sent to the Department of Health and Family Services, Bureau of Quality Assurance 1 West Wilson St., Madison, WI 53701.

SECTION 7. HFS 148.05 is amended to read:

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

SECTION 8. HFS 148.06 (title), (1) (intro), (2) (a) (title) and (intro), (a) 1., (b) (intro) and (title), (b) 3. and (note), (3) (intro), (4) and (5) are amended to read:

HFS 148.06 Donations of cancer or chronic disease drugs and supplies. (1) PERSONS ELIGIBLE TO DONATE DRUGS OR SUPPLIES. Any one of the following persons may donate legally obtained cancer or chronic disease 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 and chronic diseases drug repository:

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

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

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

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

Note: Cancer and chronic diseases 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 and chronic diseases drug repository program:

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

(5) STORAGE. Cancer and chronic disease drugs and supplies donated under the cancer and chronic diseases 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.

SECTION 9. HFS 148.07 (2), (3), (4) (c) and (4) (c) (note) are amended to read:

HFS 148.07 (2) The pharmacist shall inspect cancer and chronic disease 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 or chronic disease drug or supply may be dispensed to a recipient, the recipient shall sign a cancer and chronic disease drug repository recipient form and shall be orally notified that the drug or supply may have been previously dispensed.

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

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

SECTION 10. HFS 148.08 and 148.09 are amended to read:

HFS 148.08 Handling fees. A cancer and chronic disease 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 or chronic disease 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 or chronic disease drugs and supplies.

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

(2) A cancer and chronic disease 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 and chronic disease drug repository distributes drugs or supplies under sub. (1) or (2), the repository shall complete a cancer and chronic disease 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 and chronic disease drug repository at the time of distribution.

SECTION 11. HFS 148.11 (1) and (2) (b) are amended to read:

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

(2) (b) The name, strength and quantity of the cancer or chronic disease drug destroyed.

SECTION 12. 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: June 8, 2006

By: _____
Helene Nelson
Secretary

Seal: