

Chapter DHS 148

DRUG REPOSITORY PROGRAM

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Note: Chapter HFS 148 was renumbered chapter DHS 148 under s. 13.92 (4) (b) 1., Stats., and corrections made under s. 13.92 (4) (b) 7., Stats., Register January 2009 No. 637.

DHS 148.01 Authority and purpose. This chapter is promulgated under the authority of s. 255.056, Stats., to establish and maintain a drug repository program under which unused drugs and supplies may be donated to a participating medical facility or pharmacy and dispensed to any Wisconsin resident.

History: CR 04-142: cr. Register June 2005 No. 594, eff. 7-1-05; CR 06-018: am. Register July 2006 No. 607, eff. 8-1-06; CR 10-091: am. Register December 2010 No. 660, eff. 1-1-11.

DHS 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 drug repository program.

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

History: CR 04-142: cr. Register June 2005 No. 594, eff. 7-1-05; CR 06-018: am. Register July 2006 No. 607, eff. 8-1-06; CR 10-091: am. Register December 2010 No. 660, eff. 1-1-11.

DHS 148.03 Definitions. In this chapter:

(4) “Department” means the Wisconsin department of health services.

(5) “Dispense” has the meaning given in s. 450.01 (7), Stats.

(6) “Distribute” has the meaning given in s. 450.01 (8), Stats.

(7) “Distributor” has the meaning given in s. 450.01 (9), Stats.

(7g) “Drug” has the meaning given in s. 450.01 (10), Stats.

(7r) “Drug repository” means a medical facility or pharmacy that has notified the department of its election to participate in the drug repository program.

(8) “Manufacturer” has the meaning given in s. 450.01 (12), Stats.

(9) “Medical facility” has the meaning given in s. 943.145 (1), Stats.

(10) “Pharmacist” has the meaning given in s. 450.01 (15), Stats.

(11) “Pharmacy” means a pharmacy that is licensed under s. 450.06, Stats.

(11m) “Practitioner” has the meaning given in s. Med 17.02 (2).

(12) “Prescription drug” has the meaning given in s. 450.01 (20), Stats.

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

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

(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.

History: CR 04-142: cr. Register June 2005 No. 594, eff. 7-1-05; CR 06-018: am. (1) to (3) and (13), cr. (3m) and (14m) Register July 2006 No. 607, eff. 8-1-06; correction in (4) made under s. 13.92 (4) (b) 6., Stats., Register January 2009 No. 637; CR 10-091: renum. (1) and (2) to be (7g) and (7r) and am., r. (3), (3m), (13), cr. (11m) Register December 2010 No. 660, eff. 1-1-11.

DHS 148.04 Requirements for participation by pharmacies and medical facilities. (1) ELIGIBILITY. To be eligible for participation in the 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 drug repository program is voluntary. A pharmacy or medical facility may elect to participate in the 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 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 drug repository following the requirements under s. DHS 148.09.

Note: Notices of participation in the drug repository program can be sent to the Department of Health Services, Division 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 drug repository program at any time upon written notice to the department.

Note: A notice to withdraw participation from the drug repository program should be sent to the Department of Health Services, Division of Quality Assurance, 1 West Wilson St., Madison, WI 53701.

History: CR 04-142: cr. Register June 2005 No. 594, eff. 7-1-05; CR 06-018: am. (1), (2) (a) (intro.), (b), (3) Register July 2006 No. 607, eff. 8-1-06; CR 10-091: am. (1), (2) (a) (intro.), (b), (3) Register December 2010 No. 660, eff. 1-1-11.

DHS 148.05 Recipient eligibility requirements. Any Wisconsin resident is eligible to receive drugs or supplies under the drug repository program in the order of priority established under s. DHS 148.07 (4).

History: CR 04-142: cr. Register June 2005 No. 594, eff. 7-1-05; CR 06-018: am. Register July 2006 No. 607, eff. 8-1-06; CR 10-091: am. Register December 2010 No. 660, eff. 1-1-11.

DHS 148.06 Donations of drugs and supplies. (1) PERSONS ELIGIBLE TO DONATE DRUGS OR SUPPLIES. Any one of the following persons may donate legally obtained drugs or supplies to a drug repository, if the drugs or supplies meet the require-

ments under sub. (2), as determined by a pharmacist who is employed by or under contract with a 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) *Drugs.* A drug is eligible for donation under the drug repository program only if all of the following requirements are met:

1. The donation is accompanied by a completed 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 90 days later than the date that the drug was donated.

3. The drug is in its original, unopened, tamper-evident 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) *Supplies.* Supplies are eligible for donation under the 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 drug repository donor form that is signed by the person making the donation or that person's authorized representative.

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

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

(a) Controlled substances as defined in s. 961.01 (4), Stats.

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

(c) A drug for which the U.S. food and drug administration requires that a patient using the drug be enrolled in a registry as provided under 21 USC 355-1 (f) (3) (F).

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

(5) STORAGE. Drugs and supplies donated under the 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.

History: CR 04-142: cr. Register June 2005 No. 594, eff. 7-1-05; CR 06-018: am., (1), (2) (a) (intro.), (a) 1., (b) (intro.), (b) 3., (3) (intro.), (4) and (5) Register July 2006 No. 607, eff. 8-1-06; CR 10-091: am. (title), (1) (intro.), (2) (a) (intro.), 1. to 3., (b) (intro.), 3., (3) (intro.), (a), (4), (5), cr. (3) (c) Register December 2010 No. 660, eff. 1-1-11.

DHS 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 or a practitioner consistent with the requirements in ch. Med 17.

(2) The pharmacist shall inspect 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 drug or supply may be dispensed to a recipient, the recipient shall sign a 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. DHS 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. DHS 148.05 to receive drugs or supplies from a drug repository.

Note: Drug repository recipient forms can be obtained from the Department's website at <http://www.dhs.wisconsin.gov/forms>.

History: CR 04-142: cr. Register June 2005 No. 594, eff. 7-1-05; CR 06-018: am. (2), (3) (4) (c) Register July 2006 No. 607, eff. 8-1-06; CR 10-091: am. (1), (2), (3), (4) (c) Register December 2010 No. 660, eff. 1-1-11.

DHS 148.08 Handling fees. A drug repository may charge the recipient of a drug or supply a handling fee of no more than 300% of the Medicaid dispensing fee for each 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 <https://www.forwardhealth.wi.gov/WIPortal/Online%20Handbooks/Display/tabid/152/Default.aspx>.

History: CR 04-142: cr. Register June 2005 No. 594, eff. 7-1-05; CR 06-018: am. Register July 2006 No. 607, eff. 8-1-06; CR 10-091: am. Register December 2010 No. 660, eff. 1-1-11.

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

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

History: CR 04-142: cr. Register June 2005 No. 594, eff. 7-1-05; CR 06-018: am. Register July 2006 No. 607, eff. 8-1-06; CR 10-091: am. Register December 2010 No. 660, eff. 1-1-11.

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

History: CR 04-142: cr. Register June 2005 No. 594, eff. 7-1-05.

DHS 148.11 Recordkeeping requirements.

(1) DONOR AND RECIPIENT FORMS. 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. DHS 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 drug destroyed.

(c) The name of the person or firm that destroyed the drug.

(d) The source of the drugs or supplies destroyed.

History: CR 04-142: cr. Register June 2005 No. 594, eff. 7-1-05; CR 06-018: am. (1) and (2) (b) Register July 2006 No. 607, eff. 8-1-06; CR 10-091: am. (1), (2) (b) Register December 2010 No. 660, eff. 1-1-11.