

Pharmaceutical Waste at Non-Hospital Health Care Facilities

DNR/DHS Consensus on Regulation

Publication WA1214

Revised June 2016



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This document clarifies the terminology used by the state of Wisconsin to describe various types of non-hospital health care facilities and how they are regulated with respect to the disposal of pharmaceutical waste.

People who collect pharmaceutical waste from households may use this document to determine the circumstances under which they can accept pharmaceutical waste from non-hospital health care facilities. Similarly, non-hospital health care facilities may use the document to assist in determining their regulatory status, if they are considering taking pharmaceutical waste to household collection programs.

Household hazardous waste is regulated as a hazardous waste in Wisconsin when it is separately collected at a household hazardous waste collection facility. The Wisconsin Department of Natural Resources has issued a document conditionally exempting household pharmaceutical hazardous waste from these requirements. The document, ***Hazardous Waste and Solid Waste Requirements Pertaining to Collected Household Pharmaceuticals*** ([publication WA1052](#), also known as the “enforcement discretion” document), prohibits persons collecting household pharmaceutical waste from accepting wastes from businesses and institutions. Hazardous waste regulations are found in chs. NR 660-679 of the Wisconsin Administrative Code.

The DNR advises health care facilities to contact the organizers of a household pharmaceutical waste collection program before bringing any pharmaceutical waste to the collection site to ensure that it can be accepted and to make any other necessary arrangements.

2016 update

Since this consensus document was adopted in 2008, two regulatory developments have occurred that have or may affect how non-hospital health care facilities manage pharmaceutical waste:

1. DEA rules: In October 2014, the federal Drug Enforcement Administration adopted new rules about the disposal of controlled substances. The new rules allow pharmacies to set up collection receptacles within residential health care facilities for household waste. ***Business waste may not be placed in collection receptacles intended for household waste.***

2. EPA proposed rules: In mid-2015, the U.S. Environmental Protection Agency proposed changes to hazardous waste regulations that would apply to disposal of pharmaceuticals in health care. The proposed rules would prohibit all health care facilities, regardless of size, from flushing unused medications and would allow “Very Small Quantity Generators” of pharmaceutical waste to manage their wastes differently than in the past. ***Until EPA and DNR regulations change, this DNR/DHS Consensus on Regulation is still current.***

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This document represents a joint effort by the Wisconsin DNR Waste and Materials Management Program and the Wisconsin Department of Health Services, Division of Quality Assurance.

Purpose

This document provides a summary of non-hospital health care facility definitions, as they pertain to pharmaceutical waste, in order to establish a basis for each type of facility to determine how its pharmaceutical waste should be handled. Please read the notes under the table for more information.

Summary of DNR/DHS Consensus on Regulation	
Nursing homes	Business / non-household
Community-based residential facility	Business / non-household
Residential care apartment complex	Household <i>Exception: RCACs that purchase, store, distribute or otherwise centrally manage medications on behalf of tenants are considered businesses, regardless of the number of tenants or units.</i>
Adult family home	Household
Hospice care	In-patient: business
	In-home: household
	In-other-facility: see above for each represented facility

Nursing homes

- Serve 5 or more residents.
- Prescription drugs present in the facility typically are for long term residents. There would be limited use of epinephrine, nicotine patches and chemotherapy agents. Warfarin is likely to be the most common medication in use that is a hazardous waste.
- Non-controlled substances, including warfarin, can be returned to the pharmacy for reuse. If that is done, nursing homes would not have to dispose of them as hazardous pharmaceutical waste. It is therefore assumed that many nursing homes would generate a small quantity of pharmaceutical hazardous waste.
- Medications in nursing homes, such as Coumadin (Warfarin) and other non-controlled substances, are often returned to the pharmacy for reuse. With the exception of controlled substances, the pharmacy code allows this (Ch. Phar 7.04, Wis. Adm. Code).

Community-based residential facilities (CBRFs)

- Serve 5 or more residents.

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- Services are above the level of room and board, and may include full medication management, infectious waste, and household waste. There is no designation on a CBRF license about the extent of medication services offered.
- Non-controlled substances, including warfarin, can be returned to the pharmacy for reuse if certain criteria are met. If that is done, CBRFs would not have to dispose of them as hazardous pharmaceutical waste. Therefore, it is assumed that many CBRFs would generate very little pharmaceutical hazardous waste.
- Medications in CBRFs, such as Coumadin (Warfarin) and other non-controlled substances, can be returned to the pharmacy for reuse if certain criteria are met. With the exception of controlled substances, the pharmacy code allows this (Ch. Phar 7.04, Wis. Adm. Code).

Residential care apartment complexes (RCACs)

- Serve 5 or more tenants.
- Wide range of types of services offered.
- Services may include central storage and administration of medicines.
- Unused medicines are sent home with apartment residents or their families; if the facility chooses to take responsibility for the medications or otherwise centrally manages medications on behalf of residents, the facility becomes the generator and the medication waste is no longer considered household waste.
- Controlled substances and any medications in residential care apartment complexes cannot be returned to a pharmacy for reuse.

Adult family homes (AFHs)

- Serve 4 or fewer residents, and are similar in size to many households.
- Prescription medications may be controlled by the facility.
- Controlled substances and any medications in adult family homes cannot be returned to a pharmacy for reuse.

Hospice care

- Hospice care providers often provide services in patients' homes. Some hospice care providers come into nursing homes and CBRFs to treat patients and manage end-of-life care.
- Inpatient hospice facilities are either a freestanding structure or a separate part of a structure that provides other services. These inpatient facilities are typically small, with 10-20 beds.
- In a patient's home, hospice care medication is usually under the control of the patient or family.
- For hospice care provided in facilities like nursing homes and CBRFs, the medication is under the control of the facility.
- Hospice care provided in an inpatient setting would be under control of the hospice.
- Most inpatient hospice care settings are assumed to generate very small amounts of pharmaceutical hazardous waste.
- Controlled substances and any medications in hospices cannot be returned to a pharmacy for reuse.

All unused medications represent a waste stream that is problematic for applying hazardous waste management requirements, which include the requirement to evaluate and characterize waste. This is

particularly true for controlled substances, which in the past, were often flushed or placed in the garbage to prevent diversion.

The DNR and the Wisconsin Department of Administration are working to inform facilities considered to be businesses that there are specific requirements for managing hazardous waste in order to reduce confusion between hazardous(chemical) waste and infectious (biohazardous) waste and to promote compliance with applicable regulatory requirements.

Related guidance

- **How to safely dispose of household pharmaceutical waste** This DNR webpage offers guidance for households at: <http://dnr.wi.gov/topic/HealthWaste/HouseholdPharm.html>
- **Collecting household pharmaceutical waste** This DNR webpage offers guidance for collection events or on-going collection sites. <http://dnr.wi.gov/topic/healthwaste/CollectPharm.html>
- **How to Collect Unwanted Household Pharmaceuticals** ([publication WA1024](#)) This document summarizes the regulatory aspects of collecting household pharmaceuticals. <http://dnr.wi.gov/files/PDF/pubs/wa/wa1024.pdf>
- **Hazardous Waste and Solid Waste Requirements Pertaining to Collected Household Pharmaceuticals** ([publication WA1052](#), also known as the “enforcement discretion” document) This document describes how the DNR will and will not exercise discretion in enforcing hazardous waste and solid waste regulations for those who collect and manage household pharmaceuticals. <http://dnr.wi.gov/files/PDF/pubs/wa/wa1052.pdf>

This publication is available in alternative format upon request. For more information, e-mail DNRWasteMaterials@wisconsin.gov

Disclaimer: This document is intended solely as guidance and does not contain any mandatory requirements except where requirements found in statute or administrative rule are referenced. Any regulatory decisions made by the Department of Natural Resources in any matter addressed by this guidance will be made by applying the governing statutes and administrative rules to the relevant facts.

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WISCONSIN DEPARTMENT OF NATURAL RESOURCES NOTICE OF FINAL GUIDANCE & CERTIFICATION

Pursuant to ch. 227, Wis. Stats., the Wisconsin Department of Natural Resources has finalized and hereby certifies the following guidance document.

DOCUMENT ID

WA-19-1214-C

DOCUMENT TITLE

Pharmaceutical Waste at Non-hospital Healthcare Facilities

PROGRAM/BUREAU

Waste and Materials Management

STATUTORY AUTHORITY OR LEGAL CITATION

Ch. 291, Wis. Stats., NR 660-679, Wis. Adm. Code

DATE SENT TO LEGISLATIVE REFERENCE BUREAU (FOR PUBLIC COMMENTS)

December 2, 2019

DATE FINALIZED

December 26, 2019

DNR CERTIFICATION

I have reviewed this guidance document or proposed guidance document and I certify that it complies with sections 227.10 and 227.11 of the Wisconsin Statutes. I further certify that the guidance document or proposed guidance document contains no standard, requirement, or threshold that is not explicitly required or explicitly permitted by a statute or a rule that has been lawfully promulgated. I further certify that the guidance document or proposed guidance document contains no standard, requirement, or threshold that is more restrictive than a standard, requirement, or threshold contained in the Wisconsin Statutes.

A handwritten signature in black ink, appearing to read 'Joseph P. Van Rossum'.

December 26, 2019

Signature

Date