

Healthcare Facilities: Definitions

Guidance on Hazardous Waste Requirements



Introduction

Wisconsin has adopted pharmaceutical hazardous waste regulations, commonly referred to as Subchapter P of the federal Resource Conservation and Recovery Act, for healthcare facilities and others that generate and manage pharmaceutical wastes. The goal of the regulations is to streamline requirements while continuing to protect human health and the environment. The regulations are found in ch. NR 666, Wis. Adm. Code.

Hazardous waste regulations are found in chapters [NR 600-679](#) of the Wisconsin Administrative Code

Pharmaceutical wastes can be separated into two categories:

- Creditable HW pharmaceuticals (HW Pharma)
- Non-creditable HW pharmaceuticals

These regulations also allow for all pharmaceuticals to be managed as HW Pharma to promote easy collection, management and destruction of this waste stream.

This document outlines the definition of healthcare facilities and when Subchapter P regulations apply, which in turn determines how the hazardous waste pharmaceutical are regulated.

All healthcare facilities, regardless of hazardous waste generator status, are **prohibited** from discharging hazardous waste pharmaceuticals into a sewer system (i.e., disposing of them down a sink or toilet drain). [s. NR 666.505, Wis. Adm. Code]

This prohibition became effective nationwide on Aug. 21, 2019. In addition, the U.S. Environmental Protection Agency and the DNR recommend that facilities avoid sewerage **any** pharmaceuticals to further protect our waterways and the environment.

Household waste is any material, including, garbage, trash, and sanitary and septic tank waste derived from households including single and multiple residences. Refer to s. 661.0004(2), Wis. Adm. Code, for the full definition. Household generated waste is not subject to Subchapter P regulations unless collected for management. Households are encouraged to not sewer their pharmaceutical wastes.

Refer to DNR guidance *Collecting Unwanted Household Pharmaceuticals* (WA-1024) for information on pharmaceutical collection and take-back programs. Go to dnr.wi.gov and search "WA-1024."

Healthcare Facility Definitions

Subchapter P regulations define healthcare facilities and specify when these healthcare facilities are subject to regulation. [s. NR 666.500, Wis. Adm. Code]

Healthcare facility: A healthcare facility is any person that is lawfully authorized to:

1. provide preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care and counseling, service, assessment or procedures with respect to the physical or mental condition, or functional status, of a human or animal or that affects the structure or function of the human or animal body; or
2. distribute, sell, or dispense pharmaceuticals, including OTC pharmaceuticals, dietary supplements, homeopathic drugs, or prescription pharmaceuticals.

Retail stores selling over-the-counter (OTC) pharmaceuticals could include grocery, home improvement, and convenience stores

This definition includes, but is not limited to:

- military medical logistics facilities
- hospitals
- psychiatric hospitals
- ambulatory surgical centers
- health clinics
- physicians' offices
- optical and dental providers
- chiropractors
- long-term care facilities
- ambulance services
- pharmacies
- long-term care pharmacies
- mail-order pharmacies
- retailers of pharmaceuticals
- veterinary clinics
- veterinary hospitals
- wholesale distributors
- third-party logistics providers that serve as forward distributors

This definition excludes pharmaceutical manufacturers, reverse distributors, or reverse logistics centers.

Long-term care facility: a licensed entity that provides assistance with the activities of daily living, including managing and administering pharmaceuticals, to one or more individuals at the facility. This definition includes, but is not limited to, hospice, nursing, and skilled nursing facilities, and the nursing and skilled nursing care portions of continuing care retirement communities.

Residential-Based Living Facilities

Facilities that don't fall under the full hazardous waste regulatory requirements include residential-based living facilities where pharmaceuticals are managed by the residents and not as a centralized function of the facility.

These could be:

- group homes;
- independent living communities;
- assisted living facilities;
- independent and assisted living portions of continuing care retirement communities,
- in-home hospice care;
- adult family homes; and
- residential care apartment complexes that do not purchase, store, distribute or otherwise centrally manage medications on behalf of tenants.

Although they are not regulated under Subchapter P, the U.S. Environmental Protection Agency recommends that assisted living facilities, group homes, independent living communities, and the independent and assisted living portions of continuing care retirement communities develop voluntary

pharmaceutical collection programs for both hazardous and nonhazardous waste pharmaceuticals, as allowed by federal Drug Enforcement Administration regulations. The collection programs ensure proper management, avoid flushing of pharmaceuticals, and minimize the potential for accidental poisonings, misuse or abuse.

Pharmaceutical waste generated at these facilities is considered “household waste” and is exempt from regulation and can be disposed of in the trash, unless separated for collection at a drug take back day or pharmaceutical drop box. Once household hazardous waste is separated and collected at a household hazardous waste collection facility or event, it is no longer exempt from regulation in Wisconsin. Go to the DNR’s webpage on household hazardous waste for more information. Go to dnr.wi.gov and search “household hazardous waste.”

Pharmaceutical Definitions

Evaluated hazardous waste pharmaceutical: a prescription hazardous waste pharmaceutical that has been evaluated by a reverse distributor in accordance with s. NR 666.510(1)(c), Wis. Adm. Code, and will not be sent to another reverse distributor for further evaluation or verification of manufacture credit. These items are waste and are destined for disposal. [s. NR 666.500(1), Wis. Adm. Code]

Hazardous Waste Pharmaceutical (HW pharma): a pharmaceutical that is a solid waste, as defined in s. NR 661.0002, Wis. Adm. Code, and exhibits one or more characteristics identified in subch. C of ch. NR 661, Wis. Adm. Code, or is listed in subch. D of ch. NR 661, Wis. Adm. Code. A pharmaceutical is not a solid waste, as defined in s. NR 661.0002, Wis. Adm. Code, and therefore not a hazardous waste pharmaceutical, if it is legitimately used, reused (e.g., lawfully donated for its intended purpose), or reclaimed. An over-the-counter pharmaceutical, dietary supplement, or homeopathic drug is not a solid waste, as defined in s. NR 661.0002, Wis. Adm. Code, and therefore not a hazardous waste pharmaceutical, if there is a reasonable expectation that it will be legitimately used, reused (e.g., lawfully redistributed for its intended purpose), or reclaimed. [s. NR 666.500(2), Wis. Adm. Code]

Non-creditable hazardous waste pharmaceutical: a prescription HW pharma for which there is no reasonable expectation that it will be eligible for manufacturer credit, or a nonprescription HW pharma for which there is no reasonable expectation that it will be legitimately used/reused or reclaimed. This includes but is not limited to, investigational drugs, free samples of pharmaceuticals received by healthcare facilities, residues of pharmaceuticals remaining in empty containers, contaminated personal protective equipment, floor sweepings, and clean-up material from spills of pharmaceuticals. These items are waste and are destined for disposal. [NR 666.500(6), Wis. Adm. Code]

OTC (over-the-counter) or Nonprescription: any drug that does not require a prescription.

Pharmaceutical: any drug or dietary supplement for use by humans or other animals; any electronic nicotine delivery system (e.g., electronic cigarette or vaping pen); or any liquid nicotine (e-liquid) packaged for retail sale for use in electronic nicotine delivery systems (e.g., pre-filled cartridges or vials). This definition includes, but is not limited to:

- dietary supplements, as defined by the Federal Food, Drug and Cosmetic Act;
- prescription drugs, as defined by 21 CFR 203.3(y);
- OTC drugs; homeopathic drugs;
- compounded drugs;
- investigational new drugs;
- pharmaceuticals remaining in non-empty containers;
- personal protective equipment contaminated with pharmaceuticals; and
- clean-up material from spills of pharmaceuticals.

This definition does not include dental amalgam or sharps. [NR 666.500(9), Wis. Adm. Code]

Potentially creditable hazardous waste pharmaceuticals: a prescription HW pharma for which there is a reasonable expectation that it will receive manufacturer credit and is:

- 1) in original manufacturer packaging (except pharmaceuticals that were subject to a recall),
- 2) un-dispensed, and
- 3) unexpired or less than one-year past its expiration date.

The term does not include evaluated HW pharma or nonprescription pharmaceuticals including, but not limited to, OTC drugs, homeopathic drugs and dietary supplements. [s. NR 666.500(10), Wis. Adm. Code]

Reverse distributor: any person that receives and accumulates prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer credit. Any person, including forward distributors, third-party logistics providers, and pharmaceutical manufacturers, that processes prescription pharmaceuticals for the facilitation or verification of manufacturer credit is considered a reverse distributor. [s. NR 666.500(11), Wis. Adm. Code]

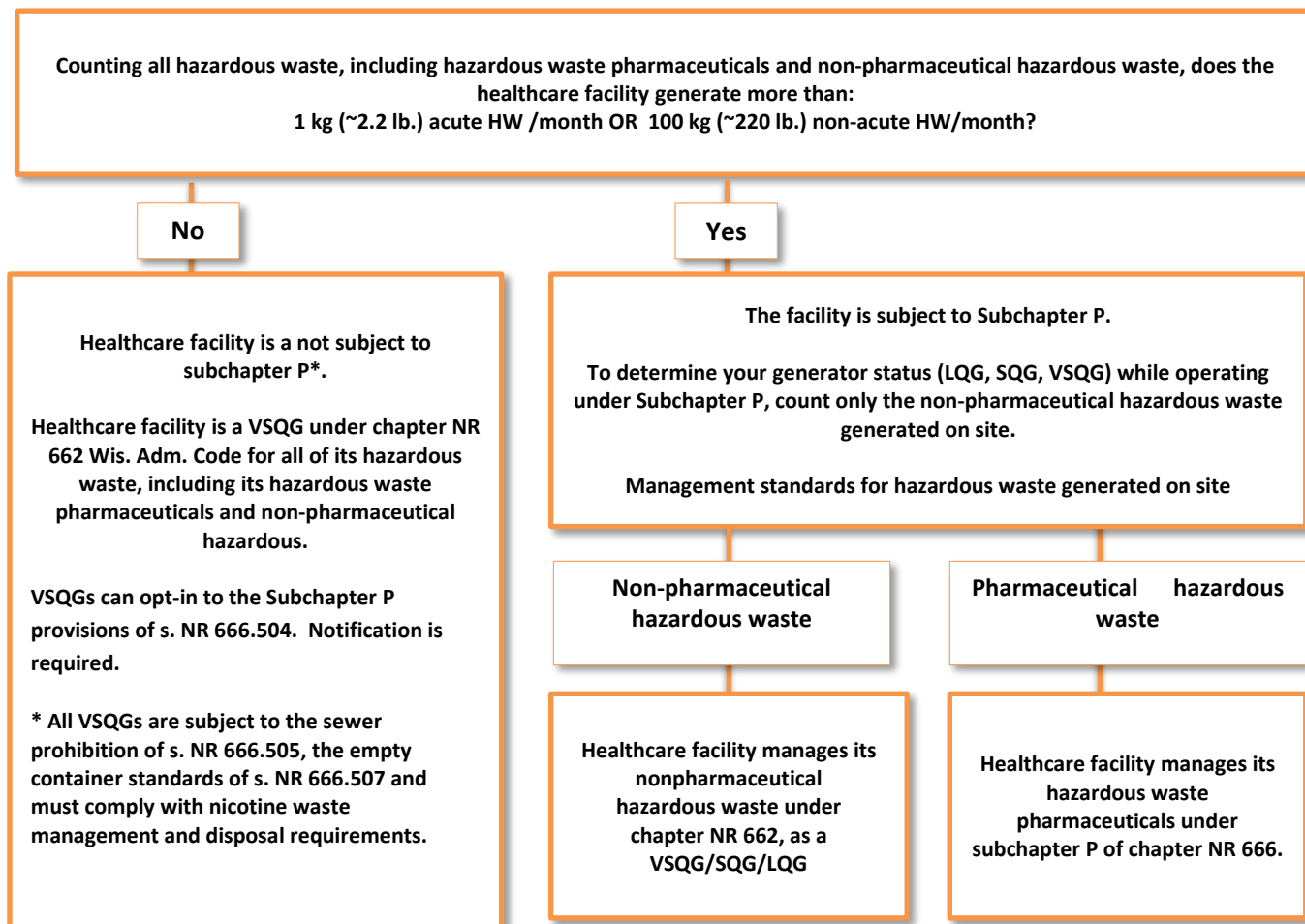
Reverse logistics: is a system by which unused pharmaceuticals for which there is a reasonable expectation that they will be used are sent from a retail location to a central distribution center or another retail location for sale or donation.

Key Requirements

This section outlines several requirements that are part of the pharmaceutical rules. Healthcare facilities with an overall generator status of a small or large quantity hazardous waste generator when counting their total monthly generation of all hazardous waste generated, including hazardous waste pharmaceuticals, must notify the DNR and comply with the requirements in NR 666, Wis. Adm. Code. [ss. NR 666.500 through NR 666.510, Wis. Adm. Code]

Once a facility's overall generator status is determined when counting all generated hazardous wastes, a healthcare facility operating under Subchapter P requirements can calculate their "Subchapter P generator status" by no longer counting the HW pharma wastes toward this evaluation. This may result in a decrease in a facility's overall operational generator status but does not change the requirement to manage wastes in accordance with the HW pharma regulations. [s. NR 662.013(3)(i), Wis. Adm. Code]

The figure below outlines how to determine whether a healthcare facility is subject to Subchapter P requirements.



Operating under Subchapter P requirements

When required to operate under Subchapter P, or when opting-in to operating under Subchapter P:

- Hazardous waste pharmaceuticals are now either considered “potentially creditable HW pharmaceuticals” or “non-creditable HW pharmaceuticals.” Standards for management of non-creditable HW pharmaceuticals are detailed in NR 666.502, and for potentially creditable HW pharmaceuticals in NR 666.503, Wis. Adm. Code.
- The facility must notify the DNR and comply with the requirements in NR 666, Wis. Adm. Code. Information on notification is found on the DNR’s website. Go to dnr.wi.gov and search “notification of hazardous waste activities. [ss. NR 666.500 through NR 666.510, Wis. Adm. Code]

Empty Containers

The definition of RCRA empty containers for common medical containers and delivery devices has been further clarified for **all facilities that generate hazardous waste**. See ss.NR 661.0007(3) and 666.507, Wis. Adm. Code.

Nicotine replacement therapies

Federal Drug Administration-approved OTC nicotine replacement therapies are no longer P-listed hazardous wastes. Unused product and residues from prescription therapies and electronic vaping fluids containing nicotine continue to be a P-listed hazardous waste. [s. NR 661.0033, Wis. Adm. Code]

Container labeling

Containers for HW pharmaceuticals must now be labeled “Hazardous Waste Pharmaceuticals.” [NR 666.502(5), Wis. Adm. Code]

For further detailed guidance on these topics please go to dnr.wi.gov and search for:

- *Healthcare Facilities: Common Wastes* (WA1259)
- *Pharmaceutical Waste: Managed under Subchapter P* (WA1902)
- *Pharmaceutical Waste: Empty Containers* (WA-1256)

Resources and Contact information

For more information, including [publications, inspection forms, and administrative codes and statutes](#), go to dnr.wi.gov and search “hazardous waste resources.” Use the *Additional Resources* menu to navigate to specific topics. For staff contact information, go to the [staff directory](#), enter “hazardous waste requirements” in the subject field and choose the appropriate county contact.

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Mailing address: DNR Waste & Materials Management Program, PO Box 7921 Madison, WI 53707

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***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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