Healthcare Facilities: Pharmaceutical Wastes and Subchapter P

Guidance on Hazardous Waste Requirements

WISCONSIN DEPT. OF NATURAL RESOURCES

Introduction

Wisconsin has adopted the federal hazardous waste pharmaceuticals regulations, commonly referred to as "Subchapter P" or the "Pharma Rules." This revised the hazardous waste regulations pertaining to the management of hazardous waste pharmaceuticals for healthcare facilities, pharmacies and reverse distributors. [Subchapter P of Chapter NR 666, Wis. Adm. Code]

The revised regulations:

- streamline the management of pharmaceuticals by healthcare facilities;
- simplify the requirements to increase compliance and environmental protections; and
- allow for reverse distribution of certain pharmaceuticals.

This document outlines the applicability, definitions and management requirements for healthcare facilities generating creditable and non-creditable pharmaceuticals. These requirements apply to small and large quantity generators (SQGs and LQGs) and in some cases, very small quantity generators (VSQGs).

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General Requirements

The following regulatory requirements – the sewering ban, empty container residues and OTC nicotine therapies- apply to all generators of hazardous wastes and HW pharmaceuticals and are independent of whether the facility is a healthcare facility, the facility's generator status or whether the facility is operating under Subchapter P.

Hazardous waste regulations are found in chapters NR 600-679 of the Wisconsin Administrative Code

Sewering ban: Pharmaceuticals entering the environment, through flushing or other means have been shown to have a negative effect on aquatic ecosystems and on fish and animal populations, and studies have documented the presence of various pharmaceutical active ingredients and metabolic by-products in surface waters and groundwater in the United States. These findings highlight the increasing importance of pharmaceutical use and management and led the U.S. Environmental Protection Agency (EPA) to finalize a prohibition on disposing of hazardous waste

pharmaceuticals down the drain by those entities subject to this rule, and a recommendation that healthcare facilities avoid sewering all pharmaceuticals.

All healthcare facilities, including VSQGs, are **prohibited** from discharging hazardous waste pharmaceuticals into a sewer system (i.e., disposing of them down a sink or toilet drain). This rule became effective nationwide as of Aug. 21, 2019. [s. NR 666.505, Wis. Adm. Code]

Empty container residues: Residues of P-listed pharmaceuticals are no longer hazardous waste when they remain in empty common medical containers and delivery devices such as stock, dispensing and unit dose containers, syringes and intravenous (IV) bags. See s. NR 666.507, Wis. Adm. Code for a complete definition or *Pharmaceutical Waste: Empty Containers* (WA-1256) for more details. [s. NR 661.0007(3), Wis. Adm. Code]

Over-the-counter nicotine replacement therapies are no longer P075 hazardous waste:
Nicotine patches, gums, and lozenges, when FDA approved for sale over-the-counter (OTC) as nicotine replacement therapies (NRT), have been removed from the P075 nicotine listing. [s. NR 661.0033 (5), Wis. Adm. Code] The amendment to the P075 nicotine listing applies to these specific OTC NRT wastes when generated at all facilities regardless of whether they are operating under Subchapter P and regardless of their generator category (i.e., VSQG, SQG or LQG).

Nicotine wastes:
All forms of unused, partially used or damaged nicotine-containing e-cigarettes and electronic nicotine delivery systems are considered HW pharma for disposal purposes. Unused product and residues from prescription therapies and electronic vaping fluids containing nicotine continue to be a P-listed hazardous waste.

Applicability

Two types of facilities are subject to the regulations in Subchapter P: healthcare facilities and reverse distributors (see definitions sections). All reverse distributors must manage their HW pharma under s. NR 666.510, Wis. Adm. Code. Pharmaceutical manufacturers and reverse logistics centers cannot operate under Subchapter P and must continue to manage their HW pharma as standard hazardous wastes under NR 662, Wis. Adm. Code. [s. NR 666.501(6), Wis. Adm. Code]

It is important to note that a healthcare facility or reverse distributor must manage its HW pharma in compliance with Subchapter P in order to have the benefit of not counting its HW pharma toward determining its overall generator category.

Reverse distributors have their own requirements under Subchapter P: Standards for the management of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals at reverse distributors. [s. NR 666.510, Wis. Adm. Code]

LQG and SQG healthcare facilities
Healthcare facilities that generate small or large quantity amounts of hazardous waste must now manage their HW pharma under Subchapter P requirements.

Generator status: count all hazardous wastes generated in each calendar month – pharmaceutical and non-pharmaceutical. If the amount in any month is greater than 2.2 pounds of acute hazardous waste or greater than 220 pounds of non-acute hazardous waste, the facility may be either a small or large quantity generator and must comply with the management requirements in Subchapter P.

These requirements allow for both HW pharma and non-HW pharma to be designated as either potentially creditable or non-creditable HW pharma. Potentially creditable HW pharma is sent to a reverse distributor to be evaluated for potential manufacturer's credit. Non-creditable pharma is sent directly to a licensed HW incinerator for disposal.

	VSQG	SQG	LQG
Monthly generation limit of non-acute hazardous waste	<220 pounds	220 pounds or more, but <2,205 pounds	No limit
Monthly generation limit of acute (P-listed) hazardous waste	<2.2 pounds	<2.2 pounds	No limit
Onsite accumulation limit	2,205 pounds	13,230 pounds	No limit

Subchapter P may reduce the healthcare facility's generator category, thus reducing the management requirements, by allowing HW pharmaceuticals to not count toward monthly generation totals.

1. Count all hazardous wastes generated, including pharmaceutical wastes (see table above).
2. If the facility is an SQG or LQG based on the total hazardous waste amounts generated or stored, including hazardous waste pharmaceuticals, the facility must operate under the Subchapter P pharmaceutical rules and notify the Wisconsin Department of Natural Resources (DNR). The facility may then be able to operate under a lower generator status based on the amounts of non-pharmaceutical hazardous wastes generated:
    - An LQG may be able to function as an SQG or VSQG for their non-pharmaceutical hazardous wastes.
    - An SQG may be able to function as a VSQG for their non-pharmaceutical hazardous wastes.

3. Once the facility notifies the DNR, including providing the new Subchapter P-based generator status, pharmaceutical wastes can then be managed under the Subchapter P requirements.

The non-pharma HW continues to be regulated under the HW generator regulations of ch. NR 662, Wis. Adm. Code.

VSQG "opting in" to Subchapter P
A healthcare facility that generates VSQG amounts (see table above) when counting both hazardous waste and HW pharmaceuticals may choose to opt in to the Subchapter P management requirements. See the Very Small Quantity Generator section of this document for options and requirements.

Definitions – Facility Types

Healthcare facility: Means any person that is lawfully authorized to do any of the following:

1. Provide preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, and counseling, service, assessment or procedure 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.

2. Distribute, sell, or dispense pharmaceuticals, including over−the-counter pharmaceuticals, dietary supplements, homeopathic drugs or prescription pharmaceuticals. Including wholesale distribution, third-party logistics that serve as forward distributors, 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 and veterinary hospitals.

This definition does not include pharmaceutical manufacturers, reverse distributors or reverse logistics centers. The full definition can be found in s. NR 666.500(3), Wis. Adm. Code.

Long-term care facility: Means a licensed entity that provides assistance with activities of daily living, including managing and administering pharmaceuticals to one or more individuals at the facility. This definition includes:

- hospice facilities
- nursing facilities
- skilled nursing facilities
- nursing and skilled nursing care portions of continuing care retirement communities.

Not included within the scope of this definition are group homes, independent living communities, assisted living facilities and the independent and assisted living portions of continuing care retirement communities. [s. NR 666.500(5), Wis. Adm. Code]

Although not regulated under Subchapter P, the EPA 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 the Drug Enforcement Administration regulations, to ensure their proper management, avoid flushing and minimize the potential for accidental poisonings, misuse or abuse.

Reverse distributor: means any person that receives and accumulates prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer credit. [s. NR 666.500(11), Wis. Adm. Code]

Any person, including distributors, third−party logistics providers, and pharmaceutical manufacturers, that process prescription pharmaceuticals for the facilitation or verification of manufacturer credit is considered a reverse distributor.

Reverse logistics means the reverse flow of non-prescription pharmaceuticals and other unsold retail items. Reverse logistics centers evaluate whether items can be sold on the secondary market, donated or recycled. Non-prescription pharmaceuticals and other unsold retail items for which there is a reasonable expectation of being legitimately used/reused (e.g., sold or donated) or reclaimed can be sent to a reverse logistics center without being considered waste at the healthcare facility.

Legitimately reclaimed, used or reused
When lawfully donated or redistributed for their intended purpose, pharmaceuticals, over the counter (OTC) pharmaceuticals, dietary supplements or homeopathic drugs are not solid wastes and therefore not hazardous waste pharmaceuticals. [s. NR 666.500(2), Wis. Adm. Code]

Definitions – Pharmaceuticals

Pharmaceuticals: The definition of pharmaceutical includes:

- any drug or dietary supplement for use by humans or other animals;
- any electronic nicotine delivery system, such as an electronic cigarette or vaping pen; or
- any liquid nicotine, or e−liquid, packaged for retail sale for use in electronic nicotine delivery systems, such pre−filled cartridges or vials.
- dietary supplements, as defined by the federal food, drug and cosmetic act; prescription drugs, as defined by 21 CFR 203.3 (y);
- over−the−counter 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. [s. NR 666.500(9), Wis. Adm. Code]

OTC pharmaceutical: any over-the-counter pharmaceutical that does not require a prescription.

Hazardous waste pharmaceutical:
Means a pharma that is a solid waste, as defined in s. NR 661.0002, and exhibits one or more characteristics identified in Subchapter C of ch. NR 661 or is listed in Subchapter D of ch. NR 661, Wis. Adm. Code.

Any pharma may be over-classified by the generator as a HW pharma and collected and managed as HW pharma under Subchapter P.

> Electronic nicotine delivery systems (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) are HW pharmaceuticals when disposed.

Non-creditable hazardous waste pharmaceutical: Means pharmaceuticals for which:

- there is no reasonable expectation of eligibility for manufacturer credit, or;
- there is no reasonable expectation of legitimate use, reuse, or reclamation.

Examples include investigational drugs, free samples of pharmaceuticals received by healthcare facilities, certain pharmaceutical residues remaining in containers, contaminated personal protective equipment, floor sweepings, and clean-up material from the spills of pharmaceuticals. [s. NR 666.500(6), Wis. Adm. Code]

Potentially creditable hazardous waste pharmaceuticals: [s. NR 666.500(10), Wis. Adm. Code]
Means prescription HW pharmaceuticals (all must apply):

1. for which there is a reasonable expectation of receiving manufacturer credit;
2. that is in original manufacturer packaging, except pharmaceuticals that were subject to a recall;
3. that is un-dispensed; and
4. that is unexpired or less than one year past its expiration date.

The term does not include evaluated hazardous waste pharmaceuticals or nonprescription pharmaceuticals including over-the-counter drugs, homeopathic drugs, and dietary supplements.

Evaluated hazardous waste pharmaceutical:
Means a prescription HW pharma 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. [s. NR 666.500(1), Wis. Adm. Code]

General Requirements

Notification: Healthcare facilities that are small quantity generators (SQGs) or large quantity generators (LQGs) must notify the DNR that they are operating under Subchapter P using EPA Form 8700-12 or on their hazardous waste annual report. This notification must occur on or before the healthcare facility's next annual report. [s. NR 662.502(1)(a), Wis. Adm. Code]

Two types of hazardous waste pharmaceuticals: Hazardous waste pharmaceuticals are now either considered "potentially creditable hazardous waste pharmaceuticals" or "non-creditable hazardous waste pharmaceuticals." [NR 666.500(6) and (10), Wis. Adm. Code]

Standards for management of non-creditable hazardous waste pharmaceuticals are detailed in s. NR 666.502, and potentially creditable in s. NR 666.503, Wis. Adm. Code.

Hazardous waste codes: All non-creditable hazardous waste pharmaceuticals must be identified on item 13 on the uniform hazardous waste manifest (EPA form 8700-22). Acceptable EPA HW codes include PHRM or PHARMS, depending on whether the manifest is paper or electronic. [s. NR 666.508(1)(b)2, Wis. Adm. Code]

Waste Counting: Once operating under Subchapter P, a healthcare facility does not count its hazardous waste pharmaceuticals when determining its monthly generator category. [s. NR 662.013(3)(i), Wis. Adm. Code]

Metal-bearing wastes: Metal-bearing wastes have specific management requirements. While combustion/incineration is the required treatment standard for most HW pharma, combustion is prohibited for several metal-bearing hazardous wastes. A healthcare facility must Identify which HW pharma contains metals that are prohibited from being incinerated and therefore must:

- accumulate those particular metal-bearing HW pharma in a separate container at the initial point of accumulation, and
- label them with the appropriate hazardous waste codes in to prevent them from being inadvertently combusted. [s. NR 666.502(4)(d), Wis. Adm. Code]

The use of lab packs at the initial point of accumulation or at a later point in the management of the hazardous waste pharmaceuticals does not change this requirement. These HW pharma are prohibited from being included in lab packs that will be incinerated under the alternative LDR treatment standard and must be accumulated separately.

Examples of hazardous waste pharmaceuticals listed in ch. NR 668 Appendix IV that are prohibited from being lab-packed and incinerated	
Hazardous Waste Code	**Hazardous Waste Chemical Name**
D009	Mercury (toxicity characteristic)
P012	Arsenic Trioxide
P076	Nitric Oxide
U151	Mercury

Non-creditable HW Pharma Management Requirements

Non-creditable HW pharma have no potential for credit and cannot be sent to a reverse distributor. Instead, the waste must be managed under s. NR 666.502 Wis. Adm. Code, sent to a hazardous waste Treatment, Storage or Disposal (TSD) facility licensed to manage these materials, transported by a licensed hazardous waste transporter, and shipped using a uniform hazardous waste manifest. When accumulating these wastes on-site the health care facility must do the following:

A healthcare facility may choose to manage its non-HW pharma as non−creditable HW pharma. [s. NR 666.502(3), Wis. Adm. Code]

Notification: Healthcare facilities that are SQGs or LQGs must notify the DNR (one-time) of their operation under Subchapter P using EPA Form 8700-12. [s. NR 666.502(1), Wis. Adm. Code]

Training: Ensure that all personnel that manage non−creditable HW pharma are thoroughly familiar with proper waste handling and emergency procedures relevant to their responsibilities. [s. NR 666.502(2), Wis. Adm. Code]

Containers and waste types: Place the non-creditable HW pharma in a container that is structurally sound, compatible with its contents, and that lacks evidence of leakage, spillage, or damage that could cause leakage under reasonably foreseeable conditions. [s. NR 666.502(4)(a), Wis. Adm. Code]

1. A healthcare facility that manages ignitable or reactive non−creditable HW pharma, or that mixes or commingles incompatible non−creditable HW pharma must manage the container so that it does not have the potential to do any of the following: [s. NR 666.502(4)(b), Wis. Adm. Code]
    a. Generate extreme heat or pressure, fire or explosion, or violent reaction.
    b. Produce uncontrolled toxic mists, fumes, dusts, or gases in sufficient quantities to threaten human health.
    c. Produce uncontrolled flammable fumes or gases in sufficient quantities to pose a risk of fire or explosion.
    d. Damage the structural integrity of the container of non−creditable HW pharma.
    e. Threaten human health or the environment through other like means.
2. Keep containers of non−creditable HW pharma closed and secured in a manner that prevents unauthorized access to their contents. [s. NR 666.502(4)(c), Wis. Adm. Code]
3. Metal-containing HW pharma are prohibited from being combusted due to the dilution prohibition of s. NR 668.03(3) Wis. Adm. Code. These wastes must be accumulated in separate containers and labeled with all applicable hazardous waste codes. [NR 666.502(4)(d), Wis. Adm. Code]

Labeling and marking: Clearly mark each container of non−creditable HW pharma with the phrase “Hazardous Waste Pharmaceuticals.” [s. NR 666.502(5), Wis. Adm. Code]

Accumulation and timeframes: A healthcare facility may accumulate non-creditable HW pharma on site for one year or less without a TSD license. [s. NR 666.502(6)(a), Wis. Adm. Code]

A healthcare facility must be able to demonstrate the length of time that the non-creditable HW pharma have been accumulating, starting from the date the pharmaceuticals first become a waste. [s. NR 666.502(6)(b), Wis. Adm. Code]

Land Disposal Restrictions: The non−creditable HW pharma are subject to the LDR requirements under ch. NR 668 Wis. Adm Code. The healthcare facility is not required to identify the hazardous waste codes on the LDR notification.

However, lab packs destined for incineration must be marked with hazardous waste codes if they contain any of the following hazardous wastes:

Hazardous waste codes
Arsenic (D004)
Barium (D005)
Cadmium (D006
Chromium (D007)
Lead D008)
Selenium (D010)
Silver (D011)

Subsection NR 668.42(3)(d), Wis. Adm Code, requires any incinerator residues from lab packs that contain any of these specific metals to undergo further treatment prior to land disposal. [ss. NR 666.502(7) and 666.508(1.)(a.)3.c., Wis. Adm. Code]

Rejected shipments: If a healthcare facility receives a rejected shipment from a TSD facility, then the healthcare facility must terminate the manifest. This involves providing the transporter with a copy of the signed manifest and sending a signed copy back to the rejecting TSD facility within 30 days. Rejected shipments from the TSD facility may be managed at the healthcare facility for up to an additional 90 days. [s. NR 666.502(8), Wis. Adm. Code]

Reporting: Non-creditable HW pharma managed under Subchapter P are not subject to annual reporting requirements. [s. NR 666.502(9)(a), Wis. Adm. Code]

A healthcare facility is subject to exception reporting if a final manifest is not received from the TSD facility within 60 days. Check for the final manifest in EPA's e-Manifest system prior to completing an exception report because the TSD facility may no longer be sending final paper copies to the generator. [s. NR 666.502(9)(b), Wis. Adm. Code]

Recordkeeping: A healthcare facility must keep copies of the following records for at least three years from the dates noted below.

- Waste determinations: from the date the waste was last sent to an on-site or off−site TSD facility.
- LDR notifications: from the date that the waste that is the subject of the documentation was last sent to an on−site or off−site TSD facility.
- Manifests: from the date the waste was accepted by the initial transporter.
- Exception reports: from the date of the report.

The periods of retention are automatically extended during any unresolved enforcement action regarding the regulated activity, or as requested by the DNR. All records must be readily available upon request by the DNR. [s. NR 666.502(10), Wis. Adm. Code]

Spills: A healthcare facility must immediately contain all spills of non-creditable HW pharma and manage the spill clean−up materials as non-creditable HW pharma in accordance with the requirements of Subchapter P. [s. NR 666.502(11), Wis. Adm. Code]

VSQG HW pharmaceutical consolidation: A healthcare facility may accept non-creditable HW pharma from an off-site VSQG healthcare facility when the receiving facility meets the following [s. NR 666.502(12), Wis. Adm. Code]:

- The healthcare facilities are under the control of the same person as defined in s. NR 660.10(90), Wis. Adm. Code.
- Operates under Subchapter P for the management of its non−creditable HW pharma.
- Manages the non-creditable HW pharma received from off site in compliance with s. NR 666.502, Wis. Adm. Code.
- Keeps records of the non−creditable HW pharma shipments it receives from off site for 3 years from the date that the shipment is received.

Shipping: A healthcare facility shipping HW pharma must follow the requirements outlined below.

- Department of Transportation requirements: DOT's packaging, labeling, marking, and placarding requirements when shipping non−creditable HW pharma. [s. NR 666.508(1), Wis. Adm. Code]
- Manifesting: A healthcare facility must comply with the manifesting requirements of Subchapter B of chapter NR 662, Wis. Adm. Code, when sending its non−creditable HW pharma off site. [s. NR 666.508(1)(b), Wis. Adm. Code]
- Exports: A healthcare facility that exports non−creditable HW pharma is subject to Subchapter H of chapter NR 662, Wis. Adm. Code. [s. NR 666.508(2), Wis. Adm. Code]

Potentially Creditable HW Pharma Requirements

Whether a potentially creditable HW pharma will ultimately receive manufacturer credit is determined solely by the manufacturer's return policy. As these return policies change regularly, a healthcare facility that sends potentially creditable HW pharma to a reverse distributor does not have to definitively know whether that particular pharmaceutical will receive manufacturer credit. However, the healthcare facility must have a reasonable expectation that it will.

Conversely, if a healthcare facility knows that a specific waste pharmaceutical will not receive manufacturer credit, that item would be considered a non-creditable HW pharma which cannot be sent to a reverse distributor.

Potentially creditable HW pharma are managed under s. NR 666.503, Wis. Adm. Code. While accumulating potentially creditable HW pharma on-site the health care facility must do the following:

Notification: Healthcare facilities that are SQGs or LQGs must notify the DNR (one-time) that they are operating under Subchapter P, using EPA Form 8700-12. [s. NR 666.501(4)(b), Wis. Adm. Code]

VSQG HW pharma consolidation: A healthcare facility may accept potentially creditable HW pharma from an offsite VSQG healthcare facility when the receiving facility meets the following: [s. NR 666.503(2), Wis. Adm. Code]

- The healthcare facilities are under the control of the same person as defined in s. NR 660.10(90), Wis. Adm. Code.
- Operates under Subchapter P for the management of its potentially creditable HW pharma.
- Manages the potentially creditable HW pharma received from off site in compliance with s. NR 666.503, Wis. Adm. Code.
- Keeps records of the potentially creditable HW pharma shipments it receives from off site for 3 years from the date that the shipment is received.

Prohibition: A healthcare facility may not send its hazardous wastes (other than potentially creditable HW pharma) to a reverse distributor. [s. NR 666.503(3), Wis. Adm. Code]

Reporting: Potentially creditable HW pharma managed under Subchapter P are not subject to annual reporting requirements. [s. NR 666.503(4), Wis. Adm. Code]

Recordkeeping: A healthcare facility sending potentially creditable HW pharma to a reverse distributor must keep copies of the following records for at least three years.

- Confirmation of delivery.
- Shipping papers prepared in accordance with 49 CFR part 172 subpart C, if applicable.

The periods of retention are automatically extended during any unresolved enforcement action regarding the regulated activity, or as requested by the DNR. All records must be readily available upon request by the DNR. [s. NR 666.503(5), Wis. Adm. Code]

Spills: A healthcare facility must immediately contain all spills of potentially creditable HW pharma and manage the spill clean−up materials as non-creditable HW pharma in accordance with the requirements of Subchapter P. [s. NR 666.503(6), Wis. Adm. Code]

Shipping: A healthcare facility shipping HW pharma must follow the requirements outlined below.

- Department of Transportation requirements: DOT's packaging, labeling, marking, and placarding requirements when shipping potentially creditable HW pharma that are classified as a DOT hazardous material (i.e., DOT Hazard Class 1–8). [s. NR 666.509(1), Wis. Adm. Code]
- Delivery Confirmation: If a healthcare facility does not receive delivery confirmation within 35 calendar days from the date that the shipment of potentially creditable HW pharma was sent, the healthcare facility must contact the carrier and the reverse distributor to report that the delivery confirmation was not received and to determine the status of the potentially creditable HW pharma. [s. NR 666.509(3). Wis. Adm. Code]
- Exports: A healthcare facility that exports potentially creditable HW pharma is subject to Subchapter H of chapter NR 662, Wis. Adm. Code. [s. NR 666.509(4), Wis. Adm. Code]

There are no accumulation time limits, container management standards, or container labeling requirements for potentially creditable HW pharma managed under s. NR 666.503, Wis. Adm. Code.

Non-prescription Pharmaceuticals

A healthcare facility may send a non-prescription HW pharma to a reverse distributor, provided the non-prescription pharmaceutical meets the following criteria:

- there is a reasonable expectation of receiving manufacturer credit;
- it is in original manufacture packaging (un-dispensed);
- it is unexpired or less than one-year past expiration; and
- it is managed as a potentially creditable HW pharma under Subchapter P.

When a non-prescription pharmaceutical is sent to a reverse logistics facility, it is not a solid waste if it there is a reasonable expectation it will be used/reused or reclaimed.

If a non-prescription pharmaceutical does not meet the requirements for reverse distribution or logistics, a waste determination must be conducted to determine if the waste is hazardous or non-hazardous. See *Waste Determination and Recordkeeping* (WA-1152) for more information on this process.

On the other hand, a prescription pharmaceutical sent to a reverse distributor is a product or "potentially creditable pharmaceutical" until it is evaluated and determined to be a solid waste and/or hazardous waste.

Controlled Substances

To eliminate any duplicative regulations, HW pharma that are also U.S. Drug Enforcement Administration (DEA) controlled substances listed in 21 CFR Part 1308 are not subject to RCRA regulations when all of the following conditions are met. [s. NR 666.506(1), Wis. Adm. Code]
The DEA-controlled hazardous waste pharmaceuticals must:

- not be sewered
- be managed in compliance with all DEA regulations for controlled substances
- be destroyed by a method that meets DEA's non-retrievable standard of destruction or combusted in one of the following types of permitted facilities:
  - a large or small municipal waste combustor;
  - a hospital, medical and infectious waste incinerator;
  - a commercial and industrial solid waste incinerator; or
  - a hazardous waste combustor.

On-site pharmaceuticals sequestration unit: Drug sequestration units are often marketed to healthcare facilities for the collection of leftover partially administered pharmaceuticals (what DEA refers to as "pharmaceutical wastage"). According to DEA's "Dear Practitioner" letter from Oct. 17, 2014, pharmaceutical wastage of DEA controlled substances does not have to be destroyed to the DEA's non-retrievable standard; therefore, pharmaceutical wastage of controlled substances may be placed in sequestration units.

The DNR and EPA recommend that healthcare facilities take a conservative approach by assuming the likely scenario that healthcare workers will use the sequestration units to collect a combination of pharmaceutical wastage, including:

- Regulated RCRA hazardous wastes
- Conditionally exempt RCRA hazardous wastes that are also DEA controlled substances.
- DEA controlled substances.

When the sequestration unit contains any of the above types of pharmaceutical wastage, the following applies:

- The sequestration unit may not be put in the trash.
- The unit would not be eligible for the conditional exemption in s. NR 666.506, Wis. Adm. Code.
- The unit would be subject to Subchapter P container standards during accumulation and prior to transportation.
- The unit must go to a hazardous waste combustor for treatment.

If a healthcare facility uses the sequestration unit only for collecting pharmaceutical wastage of DEA controlled substances that are not RCRA hazardous wastes, the unit may go in the trash. However, EPA and the DNR expect that this is an unlikely scenario. [Feb. 22, 2019; 84 FR 5816]

Very Small Quantity Generators

Healthcare facilities that generate VSQG amounts of hazardous waste when including HW pharma in their generation count are subject to the hazardous waste generator regulations for VSQGs in s. NR 662.014, Wis. Adm. Code, as well as three sections of Subchapter P:

- The prohibition of sewering HW pharma [s. NR 666.505, Wis. Adm. Code]

- The empty containers standards [s. NR 666.507, Wis. Adm. Code]
- The optional provisions for VSQGs [s. NR 666.504, Wis. Adm. Code]

A healthcare facility that is a VSQG when counting both the generated pharmaceutical hazardous waste and non-pharmaceutical hazardous waste can choose to "opt-in" to Subchapter P. The information below provides details on opting in, changes in generator status, and what happens when the VSQG generating pharmaceutical waste wants to access the episodic generation provision found in ch. NR 662, Wis. Adm. Code.

Opt-in: Healthcare facilities that are VSQGs when counting all of their hazardous waste, including pharmaceuticals, can choose to "opt-in" to Subchapter P and enjoy the streamlined management of hazardous and non-hazardous waste pharmaceuticals.

A healthcare facility that is a VSQG and chooses to be fully subject to Subchapter P must notify the DNR using the site identification form, EPA form 8700-12, that it is a healthcare facility. [s. NR 666.501(2), Wis. Adm. Code]

Opt-out: A healthcare facility that is operating under Subchapter P but is no longer required to operate under Subchapter P because its hazardous waste generation total **including pharmaceuticals** has dropped to VSQG amounts, can elect to withdraw from Subchapter P. The healthcare facility must notify the DNR using the site identification form, EPA form 8700-12, that it is no longer operating under Subchapter P before the healthcare facility starts operating under the VSQG requirements of s. NR 662.014 Wis. Adm. Code. [s. NR 662.501(1)(b), Wis. Adm. Code]

Episodic Generation: A VSQG facility can use the episodic generation provision of NR 662, Subchapter L for all of its hazardous waste. For example, if a VSQG healthcare facility is directed to dispose of recalled pharmaceuticals, it could use the episodic generator provisions of Subchapter L of chapter NR 662, Wis. Adm. Code, to avoid an increase in its hazardous waste generator category.

Note that if a healthcare facility that is a VSQG generates hazardous waste in excess of the allowable amounts as a VSQG, and it chooses not to use the episodic generator provisions in Subchapter L of ch. NR 662, Wis. Adm. Code, it would become subject to Subchapter P of Chapter NR 666, Wis. Adm. Code, for its hazardous waste pharmaceuticals. For details on episodic generation, go to *Episodic Generation of Hazardous Waste* (WA-1872). [Feb. 22, 2019; 84 FR 5935]

Best Management Practices

The DNR and EPA recommend the following best management practices (BMPs) for wastes that possess hazardous waste-like qualities yet are not regulated as hazardous waste:

1. **No sewering**: The DNR and EPA recommend no sewering of any non-hazardous waste pharmaceutical from any source or location.

2. Most pharmaceuticals are not regulated as RCRA hazardous wastes when discarded by healthcare facilities. These ''non-RCRA-hazardous'' pharmaceuticals can be divided into two categories: those that possess hazardous waste-like qualities and those that do not.

   Managing non-hazardous waste pharmaceuticals possessing hazardous waste-like qualities Hazardous waste incineration is recommended for pharmaceuticals that possess hazardous waste-like qualities. This recommendation would apply to pharmaceuticals with more than one active ingredient listed on the P- or U-lists, chemotherapeutic agents characterized as bulk wastes,130 pharmaceuticals which meet the hazardous drug criteria set by the National Institute for Occupational Safety and Health (NIOSH),131 pharmaceuticals with LD50s ≤ 50 mg/kg, pharmaceuticals that are carcinogenic or endocrine disrupting compounds, and vitamin/mineral preparations containing heavy metals.

Managing non-hazardous waste pharmaceuticals that do not possess hazardous waste-like qualities: Municipal solid waste incineration or medical waste incineration is recommended for any non-hazardous waste pharmaceuticals. [Feb. 22, 2019; 84 FR 5840]

3. **Develop voluntary pharmaceutical collection programs:** Assisted living facilities, group homes, independent living communities, and the independent and assisted living portions of continuing care retirement communities should develop voluntary pharmaceutical collection programs for both hazardous and non-hazardous waste pharmaceuticals as a best management practice, as allowed by DEA regulations, to ensure proper management, avoid flushing, and minimize the potential for accidental poisonings, misuse or abuse. [Feb. 22, 2019; 84 FR 5882]
4. **Spill mitigation**: To mitigate the potential for spills or leaks, healthcare facilities should place the original containers, and packaging containing liquids and aerosols pharmaceuticals, in separate individual containers (e.g., sealed storage bag) before placing them in the accumulation container. [Feb. 22, 2019; 84 FR 5887]
5. **Illicit diversion of potentially creditable hazardous waste pharmaceuticals:** Potentially creditable hazardous waste pharmaceuticals should be accumulated in a designated area that is labeled and kept locked or sealed according to best management practices for that facility as an additional deterrent to illicit diversion. [Feb. 22, 2019; 84 FR 5887]
6. **Advance notice prior to shipping:** Healthcare facilities shipping potentially creditable hazardous waste pharmaceuticals should provide advance notice to the recipients to the extent practicable to ensure the shipment will be accepted. [Feb. 22, 2019; 84 FR 5913]
7. **Recycle containers whenever possible:** In Wisconsin, most recyclable containers are prohibited from landfill disposal. For a complete list of recyclables banned from landfills see the DNR website at: https://dnr.wi.gov/topic/Recycling/Banned.html. Check with your local solid waste authority about collection of recyclable containers. [ch. 287.07, Wis. Stats.]

Resources and Contact Information

EPA Hazardous Waste Pharmaceuticals FAQ website: https://www.epa.gov/hwgenerators/frequent-questions-about-management-standards-hazardous-waste-pharmaceuticals-and

EPA 2019 memorandum (84 FR 58270) on Reverse Distribution and Reverse Logistics https://rcrapublic.epa.gov/files/14915.pdf.

The Feb. 22, 2019, federal register on the pharmaceutical rule: https://www.govinfo.gov/content/pkg/FR-2019-02-22/pdf/2019-01298.pdf.

Other DNR healthcare resources can be found by going to dnr.wi.gov and searching the titles of the following guidance documents:

- *Healthcare Facilities: Common Wastes* (WA-1259)
- *Pharmaceutical Waste: Regulated and Household Facilities* (WA-1214)
- *Pharmaceutical Waste: Empty Containers* (WA-1256)
- *Waste Determination and Recordkeeping* (WA-1152)

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 and enter “hazardous waste requirements” in the subject field and choose the appropriate county contact.

Mailing address: DNR Waste and Materials Management Program, PO Box 7921 Madison, WI 53707
Email: DNRWasteMaterials@Wisconsin.gov

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