TIP No. 37-090-0221

NEW MANAGEMENT STANDARDS FOR HAZARDOUS WASTE PHARMACEUTICALS

Introduction

In February 2019, the U.S. Environmental Protection Agency (EPA) issued a new rule that finalized new standards for the management of pharmaceutical hazardous wastes (HW). It was designed to help relieve healthcare workers from the cumbersome Resource Conservation and Recovery Act (RCRA) regulations, which were initially promulgated for manufacturing industries. The rule excludes HW pharmaceuticals from regulation under the more stringent RCRA HW management standards, and creates new sector-specific regulations. These new regulations are codified in Title 40, Code of Federal Regulation (40 CFR) Part 266, Subpart P.

This rule is complicated as it establishes comprehensive provisions for managing pharmaceutical HW at healthcare facilities, reverse distributors, and reverse logistics facilities. Note that while States are required to adopt the rule, the effective dates will vary by State. The traditional RCRA regulations will continue to be in effect until a State formally adopts the new provisions. Contact your garrison representative for information regarding the status of the rule in your State. https://www.govinfo.gov/content/pkg/FR-2019-02-22/pdf/2019-01298.pdf.

This document is divided into ten sections to address the most significant aspects of the rule. These include:

- New Regulatory Terms.
- Sewering Prohibition.
- Amendment to the Acute HW Listing for Nicotine and Salts (HW No. P075).
- Reverse Logistics and Reverse Distribution.
- New Conditional Exemptions.
- Standards for Healthcare Facilities that Manage Non-creditable HW Pharmaceuticals.
- Standards for Healthcare Facilities that Manage Potentially Creditable HW. Pharmaceuticals.
- Standards for Managing Residues in Containers that Held Acute and Non-Acute HW Pharmaceuticals.
- Standards for Managing Potentially Creditable HW Pharmaceuticals at Reverse Distributors.
- Very Small Quantity Generators (VSQG).

New Regulatory Terms

Evaluated HW pharmaceutical: A prescription HW pharmaceutical that has been evaluated by a reverse distributor and will not be sent to another reverse distributor for further evaluation or verification of manufacturer credit.

Hazardous waste pharmaceutical: A pharmaceutical that is both a solid waste per 40 CFR 261.2 and exhibits a characteristic or is listed per Part 261, Subpart C or D, respectively. If a pharmaceutical is legitimately used/reused or reclaimed, it is not a solid waste and, therefore,

not a HW. If an over-the-counter (OTC) pharmaceutical, dietary supplement, or homeopathic drug has a reasonable expectation of being legitimately used/reused or reclaimed, it is not a solid waste and, therefore, not a HW pharmaceutical.

Healthcare facility: Any person that is lawfully authorized to—

- Provide preventive, 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; or
- Distribute, sell, or dispense pharmaceuticals, including OTC pharmaceuticals, dietary supplements, homeopathic drugs, or prescription pharmaceuticals.

This definition includes, but is not limited to—

- Wholesale distributors;
- Third-party logistics providers 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.

Household waste pharmaceutical: A pharmaceutical that is a solid waste per 40 CFR 261.2, but is excluded from being a HW under 40 CFR 261.4(b)(1).

Long-term care facility: 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, but is not limited to—

- Hospice facilities;
- Nursing facilities;
- Skilled nursing facilities; and
- 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
- Independent and assisted living portions of continuing care retirement communities.

Non-creditable HW pharmaceutical: A prescription HW pharmaceutical that does not have a reasonable expectation to be eligible for manufacturer credit or a non-prescription HW pharmaceutical that does not have a reasonable expectation to 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.

Non-hazardous waste pharmaceutical: A pharmaceutical that is a solid waste, as defined in 40 CFR 261.2, but neither exhibit a characteristic nor is listed in 40 CFR 261, Subparts C and D, respectively.

Non-pharmaceutical hazardous waste: A solid and HW that does not meet the definition of pharmaceutical.

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 nonempty containers;
- Personal protective equipment contaminated with pharmaceuticals; and
- Clean-up material from spills of pharmaceuticals.

This definition does not include dental amalgam or sharps.

Potentially Creditable HW Pharmaceutical: A prescription HW pharmaceutical that has a reasonable expectation to receive manufacturer credit and is—

- In original manufacturer packaging (except pharmaceuticals that were subject to a recall);
- Undispensed; and
- Unexpired or less than 1 year past expiration date.

The term does not include evaluated HW pharmaceuticals, nonprescription pharmaceuticals including, but not limited to—

- OTC drugs;
- Homeopathic drugs; and
- Dietary supplements.

Reverse Distributor: Any person that receives and accumulates prescription pharmaceuticals that are potentially creditable HW 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.

Sewering Prohibition
One of the more stringent changes finalized in the rule is the ban on "sewering" HW pharmaceuticals. Prior to this rule, discharging HW pharmaceuticals to a sewer/wastewater system was permissible under certain conditions (e.g., domestic sewage exemption, headworks exemption). The new language in the rule removes those exemptions by prohibiting all healthcare facilities and reverse distributors from discharging HW pharmaceuticals to Publically Owned Treatment Works. Healthcare facilities that are VSQGs are generally not subject to Subpart P, but this sewering ban applies to those generators as well.

The rule does not specifically prohibit the discharge of HW pharmaceuticals to Federally Owned Treatment Works. Healthcare facilities on installations with that type of treatment system should coordinate with garrison representatives for specific guidance prior to discharging any HW.

This prohibition was promulgated under the authority of the Hazardous and Solid Waste Amendments (HSWA) and therefore automatically went into effect at all facilities in the United States on the effective date of the rule (August 21, 2019). All other parts of the pharmaceutical rule were promulgated under non-HSWA authority and must be approved in each State/territory that has its own RCRA-authorized program before they become effective.

Amendment to the Acute HW Listing for Nicotine and Salts (HW No. P075)
Previously, the P075 HW listing was applicable to all discarded commercial chemical products containing nicotine as the sole active ingredient. Unused dermal patches containing nicotine, nicotine gum, and nicotine lozenges were classified as P075 HW when discarded. In recent

years, retail industries and manufacturers petitioned EPA to undertake a rulemaking to remove low-concentration nicotine products from the P075 listing. The petitioners contended their low-concentration nicotine products did not meet RCRA's requirements for acute HW when discarded. After conducting a review of available toxicity data and consulting with the Food and Drug Administration (FDA), the EPA agreed the nicotine-containing products did not meet the acute listing criteria.

The new rule amends the acute HW listing for P075 in 40 CFR 261.33(e) by exempting FDA-approved OTC nicotine replacement therapies (NRTs). Specifically, the P075 listing for nicotine now includes a parenthetical phrase stating that the listing does **not** include patches, gums, and lozenges that are FDA-approved OTC NRTs. Therefore, patches, gums, and lozenges (along with their empty containers) are considered non-hazardous wastes (rather than acute HW) when discarded and can be managed as solid waste.

The new rule does not exempt e-cigarettes, e-liquids, or cartridges from the P075 HW listing. EPA indicated the FDA considers these items to be tobacco products rather than drugs because the nicotine levels are unregulated. Additionally, the exemption does not apply to prescription NRTs as they contain nicotine at higher concentrations and in a more readily available form (i.e., in liquid and mist) than the OTC NRTs. All of these non-exempted products are still eligible to be managed as HW pharmaceuticals under Subpart P of 40 CFR 266 when discarded.

Note: This amendment to the nicotine listing was classified as being less stringent than the existing RCRA regulations. Therefore, states with authorized HW programs are not required to adopt this provision.

Reverse Logistics and Reverse Distribution
The final rule distinguishes between OTC and prescription drugs when determining which products are classified as solid wastes. This was accomplished by creating separate rules for reverse logistics and reverse distribution.

Reverse logistics is described in the preamble of the final rule as the practice of returning OTC pharmaceuticals (or other unsold retail products) to logistic centers established by manufacturers, distributors, or national retailers to assess the ultimate distribution of returned products. Products moving through this system are not solid wastes at the healthcare or retail facility if they have a reasonable expectation of being legitimately used/reused or reclaimed. If items are not in good condition or are leaking, these items must be managed as wastes at the healthcare/retail facility according to any applicable HW regulations.

Reverse distribution generally describes the system through which prescription pharmaceuticals are transferred from the healthcare facility to a distributor/vendor for potential manufacturer credit. Under the old RCRA rules, prescription pharmaceuticals processed in this manner were not considered solid wastes until the reverse distributor discarded them. However, the new rule states that such prescription pharmaceuticals are solid wastes at the healthcare facility and must be evaluated for hazardous classification at that time. EPA indicated this change was made after stakeholders informed the agency that unused prescription pharmaceuticals are normally discarded rather than reused/reclaimed.

New Conditional Exemptions

The 40 CFR 266.503 includes two conditional exemptions for certain HW pharmaceuticals. The first provides a conditional exemption from RCRA regulations for HW pharmaceuticals that are also Drug Enforcement Agency (DEA) controlled substances listed in 21 CFR Part 1308. This is designed to reduce overlapping regulations and to facilitate proper disposal as it is challenging to locate treatment facilities permitted to receive these dual regulated wastes. EPA identified chloral hydrate, fentanyl, phenobarbital, testosterone gels, valium, paregoric, paraldehyde, and opium tincture as examples of such dual regulated drugs in the preamble to the final rule. The second conditional exemption allows HW pharmaceuticals collected from the public by retail pharmacies and law enforcement in DEA-authorized collection receptacles to qualify for the household HW exclusion.

To qualify for either of these conditional exemptions, the HW pharmaceuticals must be—

- Managed in compliance with the sewer prohibition of 40 CFR 266.505; and
- Collected/stored/transported/disposed of in compliance with all applicable DEA regulations; and
- Destroyed by a method that DEA has publicly deemed in writing to meet their non-retrievable standard of destruction, or combusted at one of the following units:
  - Permitted large or small municipal waste combustor.
  - Medical and infectious waste incinerator.
  - Commercial and industrial waste incinerator.
  - Hazardous waste combustor.

Dual wastes and HW pharmaceuticals collected by retail pharmacies/law enforcement that are not managed according to these criteria are subject to all applicable provisions in Subpart P of 40 CFR 266.

Standards for Healthcare Facilities that Manage Non-Creditable HW Pharmaceuticals

HW Determination	Must determine if a discarded pharmaceutical is listed in 40 CFR Part 261 Subpart D and/or if it exhibits one or more of the four characteristics of HW. If the discarded pharmaceutical is classified as a non-creditable HW pharmaceutical, then it must be managed under the new 40 CFR 266 Subpart P instead of 40 CFR 262.
Notification of Activity	Healthcare facilities that generate non-creditable HW pharmaceuticals must notify the EPA Regional Administrator using EPA Form 8700-12 that they are operating under the new Subpart P. Large Quantity Generator (LQG) healthcare facilities with existing EPA identification numbers that are subject to this Subpart must perform the notification as part of its next Biennial Report.

	Small Quantity Generator (SQG) healthcare facilities subject to this Subpart must perform the notification within 60 days of the effective date of the rule in their State. Personnel must keep a copy of its notification on file for as long as the healthcare facility is subject to Subpart P. Very Small Quantity Generators (VSQG) are not required to operate under Subpart P and, therefore, are not subject to the notification requirement.
Training for Personnel	All personnel that manage non-creditable HW pharmaceuticals must be trained to be thoroughly familiar with the proper handling and emergency procedures relevant to their responsibilities during normal operations and emergencies. The information can be disseminated verbally, via printed materials, or other means.
Standards for Containers	Containers used to accumulate non-creditable HW pharmaceuticals must be structurally sound, compatible with its contents, and show no evidence of leakage, spillage, or damage that could cause leakage under reasonably foreseeable conditions. Containers must be closed and secured to prevent unauthorized access A healthcare facility that manages ignitable or reactive non-creditable HW pharmaceuticals, or that mixes or commingles incompatible non-creditable HW pharmaceuticals, must manage the container so it does not have the potential to— • Generate extreme heat or pressure, fire or explosion; • Produce uncontrolled toxic mists, fumes, dusts, or gases in sufficient quantities to threaten human health; • Produce uncontrolled flammable fumes or gases in sufficient quantities to pose a risk of fire or explosions; • Damage the structural integrity of the container of non-creditable HW pharmaceuticals.
Labeling Containers	Containers for accumulating non-creditable HW pharmaceuticals must be labeled with the phrase “Hazardous Waste Pharmaceuticals.” Non-creditable HW pharmaceuticals prohibited from being combusted because of the RCRA dilution prohibition (such as arsenic trioxide) must be accumulated in separate containers and labeled with all applicable HW numbers (i.e., HW codes).

Maximum Accumulation time	Non-creditable HW pharmaceuticals can be accumulated at the healthcare facility for up to 1 year without having a permit. The length of time that the non-creditable HW pharmaceuticals have been accumulating must be demonstrated by one of the following methods: • Marking or labeling the container of non-creditable HW pharmaceuticals with the date they became a waste; • Maintaining an inventory system that identifies the date the non-creditable HW pharmaceuticals being accumulated first became a waste; or • Placing the non-creditable HW pharmaceuticals in a specific area and identifying the earliest date, that any of the non-creditable HW pharmaceuticals in the area, became a waste. Accumulation time limits only apply to a healthcare facility's non-creditable HW pharmaceuticals and do not apply to any other type of non-pharmaceutical HW generated on-site.
Shipping from Healthcare Facilities to Treatment, Storage, and Disposal Facilities	Shipments of non-creditable HW pharmaceuticals are subject to the manifest requirements of 40 CFR 262 Subpart B, except that HW numbers are not required to be listed on the manifest. Instead, the word "PHARMS" must be listed in block 13 of the manifest. Shipments of non-creditable HW pharmaceuticals are also subject to existing DOT pre-transport requirements for packaging, labeling, and marking.
Recordkeeping/ Reporting	Healthcare facility must keep a signed copy of each HW manifest as a record for 3 years from the date that the non-creditable HW pharmaceutical was accepted by the initial HW transporter. Healthcare facilities must submit an exception report to the EPA Regional Administrator if a signed copy of the manifest is not received from the designated facility within 60 days of the date the waste was received by the transporter. Healthcare facilities that are required to submit a Biennial Report are not required to include their non-creditable HW pharmaceuticals in the report.
Accepting Non-Creditable HW Pharmaceuticals from off-site VSQG	A healthcare facility may accept non-creditable HW pharmaceuticals from an off-site VSQG healthcare facility (such as off-post clinic or medical home) provided that the receiving facility—

	• Is under control of the same person as the VSQG; • Operates under Subpart P for the management of its non-creditable HW pharmaceuticals; • Manages all HW pharmaceuticals, according to Subpart P, once they arrive at the receiving healthcare facility; and • Keeps records of the non-creditable HW pharmaceutical shipments it receives from off-site for 3 years.
Importation	A person that imports a non-creditable HW pharmaceutical is subject to 40 CFR Part 262 Subpart H. A healthcare facility may not accept imported non-creditable or evaluated HW pharmaceuticals unless they have a permit to accept hazardous waste from off-site.

Standards for Healthcare Facilities that Manage Potentially Creditable HW Pharmaceuticals

HW Determination	Healthcare facilities must make an HW determination according to 40 CFR 266.503(a) on each potentially creditable waste pharmaceutical, which would subject the HW to regulation under Subpart P.
Training	Personnel handling potentially creditable HW pharmaceuticals are not specifically required to receive training. However, it is advisable to train all pharmacy personnel on the new requirements since they have the potential to handle non-creditable HW pharmaceuticals.
Accumulation Time, Container Management and Labeling for Healthcare Facilities Managing Potentially Creditable HW Pharmaceuticals	There are no specific standards in 40 CFR 266.503 that limit the length of time healthcare facilities may accumulate containers of potentially creditable HW pharmaceuticals. However, the accumulation time is regulated indirectly by the definition of “potentially creditable HW pharmaceuticals” in 40 CFR 266.500 that requires that a prescription HW pharmaceutical be unexpired or less than 1 year past the expiration date. There are no container management standards, but EPA recommends that liquids and aerosols should be in sealed plastic bags or containers during accumulation to reduce the risk of spills and releases. There are no specific labeling standards for containers accumulating potentially creditable HW pharmaceuticals.

Accepting Potentially Creditable HW Pharmaceuticals from Off-site VSQG Healthcare Facility	Healthcare facility may accept potentially creditable HW pharmaceuticals from an off-site VSQG healthcare facility provided that the receiving facility— • Is under control of the same person as the VSQG; • Operates under Subpart P for the management of its potentially creditable HW pharmaceuticals; • Manages all HW pharmaceuticals according to Subpart P once they arrive at the receiving healthcare facility; and • Keeps records of the potentially creditable HW pharmaceutical shipments it receives from off-site facilities for 3 years.
Shipping from Healthcare Facilities to Reverse Distributor	Healthcare facilities are prohibited from sending HW, other than potentially creditable HW pharmaceuticals, to a reverse distributor. Shipments of potentially creditable HW pharmaceuticals are not subject to the manifest requirements of 40 CFR 262 Subpart B. Healthcare facilities must retain delivery confirmation and any applicable shipping papers for 3 years from the date of shipment. Healthcare facilities must contact the carrier and the intended recipient if delivery confirmation is not received within 35 calendar days from the date of shipment.
Importation	A person that imports potentially creditable HW pharmaceuticals into the United States is subject to paragraphs (a) through (c) of 40 CFR 266.509 in lieu of 40 CFR 262 Subpart H. After the potentially creditable HW pharmaceuticals enter the United States, they are subject to all applicable requirements of Subpart P.

Standards for Managing Potentially Creditable HW Pharmaceuticals at Reverse Distributors

Notification	Must provide a one-time notification to EPA of its HW pharmaceutical activities using EPA Form 8700–12 within 60 days of effective date of rule.
Recordkeeping	Must keep an inventory of the potentially creditable HW pharmaceuticals and evaluated HW pharmaceuticals that are on site. Must inventory each potentially creditable HW pharmaceutical within 30 calendar days of arriving at the reverse distributor.

	Must maintain a copy of the delivery confirmation and the shipping papers for each shipment of potentially creditable HW pharmaceuticals that it receives for at least 3 years.
Maximum Accumulation Time	180-day accumulation limit for HW pharmaceuticals at each reverse distributor. No specific method required to document the accumulation time.
Facility Standards	Must meet a performance-based security requirement to prevent unknowing entry and minimize the possibility for the unauthorized entry into the portion of the facility where potentially creditable HW pharmaceuticals and evaluated HW pharmaceuticals are kept. Must meet LQG standards for developing a contingency plan, emergency procedures, and facility closure. A reverse distributor must inspect its on-site accumulation area at least once every seven days, looking at containers for leaks and for deterioration caused by corrosion or other factors, as well as for signs of diversion.
Container Labeling/Marking	No container marking or labeling requirements.

Standards for Managing Residues in Containers that Held Acute and Non-Acute HW Pharmaceuticals

Container	New Standard
Bottle, ampule, or vial (not exceeding 1 liter or 10,000 pills) or Unit dose container (packet, wrapper, blister pack, cup, or delivery device)	Considered empty and the residues are not regulated as HW when the pharmaceuticals have been removed from the container using the practices commonly employed to remove materials from that type of container. A container that cannot meet the condition listed above is not considered empty. In this scenario, the container and residue must be managed as HW pharmaceuticals. This exemption applies to containers that held either acute or non-acute HW. Note: This regulatory change is significant because it is no longer required to triple rinse containers that held acute HW, nor will be it necessary to measure the remaining contents of containers that held non-acute HW, for the containers to be considered empty.

Container	New Standard
Syringe	A syringe that held a HW is considered empty and the residues are not regulated as HW, provided one of the following conditions is met: • The plunger of the syringe is fully depressed when administering the contents to a patient; • The plunger of the syringe is fully depressed when injecting the contents into another delivery device such as an IV bag; or • The plunger of the syringe is fully depressed when injecting the contents into a HW container. A discarded syringe that cannot meet any of the conditions listed above is not considered empty. In this scenario, the syringe and residue must be managed as HW pharmaceuticals. This provision applies to containers that previously held either acute or non-acute HW.
IV Bags	Considered empty and residues not regulated as HW provided the pharmaceuticals have been fully administered to a patient (acute and non-acute HW pharmaceuticals), OR if the IV bag meets the empty container standard of 40 CFR 261.7 (non-acute pharmaceuticals only). An IV bag that cannot meet either of the conditions listed above is not considered empty. In this scenario, the IV bag and residue must be managed as HW pharmaceuticals.
Other Containers (inhalers, aerosols, nebulizers, tubes of ointments, gels, or creams)	Containers that held an acute HW pharmaceutical cannot be classified as empty. The container and residue must be managed as HW pharmaceuticals. Containers that once held a non-acute HW pharmaceutical are considered empty and the residues are not regulated as HW if they meet the RCRA empty container standard of 40 CFR 261.7. A container that cannot meet this standard is not considered empty. The container and residue must be managed as HW pharmaceuticals.

Very Small Quantity Generators
All healthcare facilities that are VSQGs are subject to the sewer prohibition.

A healthcare facility that is a VSQG when counting all of its HW, including both its HW pharmaceuticals and its non-pharmaceutical HW, remains subject to 40 CFR 262.14 for the management of its non-pharmaceutical HW. These facilities have the option of managing its HW pharmaceuticals in one of the three following ways:

- Managing HW pharmaceuticals solely in compliance with 40 CFR 262.14.

- Managing HW pharmaceuticals in compliance with 40 CFR 262.14, along with the optional Subpart P provisions in 40 CFR 266.504.
- Managing HW pharmaceuticals in compliance with all of 40 CFR 266 Subpart P.

Healthcare facilities that become VSQGs as a result of not being required to count their HW pharmaceuticals towards their generator status are informally referred to as Subpart P VSQGs. These facilities are VSQGs with respect to the management of their non-pharmaceutical HW only and must manage their HW pharmaceuticals under full compliance with Subpart P.