Hazardous Waste Pharmaceuticals and Amendment to the Nicotine Listing (P075) Final Rule

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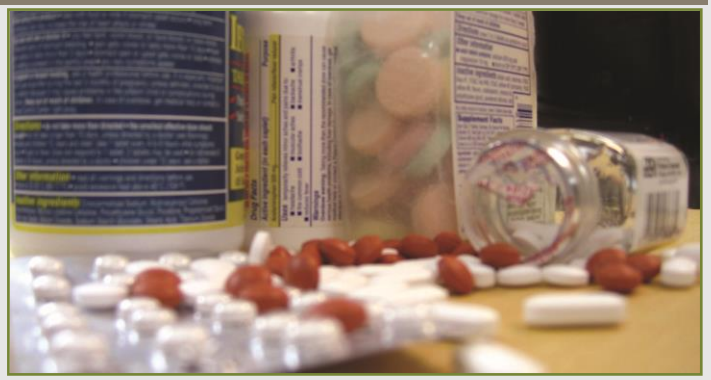
U.S. EPA's Final Rule to create new management standards for hazardous waste (HW) pharmaceuticals was published in the Federal Register Feb. 22, 2019 and will become effective in Iowa on Aug. 21, 2019. Healthcare facilities and reverse distributors must comply with the new Subpart P rule which is designed to improve and clarify regulation of HW pharmaceuticals.

SUBPART P

The new rule, Subpart P, defines and regulates two different entities: healthcare facilities and reverse distributors. The rule defines a ***Healthcare Facility*** as any person that is lawfully authorized to:

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; or
2. Distribute, sell, or dispense pharmaceuticals, including over-the-counter pharmaceuticals, dietary supplements, homeopathic drugs, or prescription pharmaceuticals.

Healthcare facilities are subject to two different sets of standards when managing HW pharmaceuticals, based on whether the pharmaceuticals are "potentially creditable" or "non-creditable."



POTENTIALLY CREDITABLE HW PHARMACEUTICALS are prescription HW pharmaceuticals that have a reasonable expectation of receiving manufacturer credit and is

1) In original manufacturer packaging,
2) Un-dispensed, and
3) Unexpired (or less than one year past its expiration date).

This rule allows healthcare facilities to send potentially creditable hazardous waste pharmaceuticals to reverse distributors, provided they meet the minimal requirements in §266.502(a), §266.503 and §266.509.

NON-CREDIBLE HW PHARMACEUTICALS are prescription HW pharmaceuticals that do not have a reasonable expectation to be eligible for manufacturer credit or a nonprescription HW pharmaceutical that does not have a reasonable expectation to be legitimately used/reused or reclaimed. These pharmaceuticals will typically be sent to a designated Treatment Storage Disposal (TSD) facility and must be managed by healthcare facilities in accordance with §266.502 and §266.508 requirements.

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REVERSE DISTRIBUTORS are entities that receive potentially creditable HW pharmaceuticals from healthcare facilities and evaluate them to determine if they are eligible for manufacturer credit. The new rule allows reverse distributors to accept these HW pharmaceuticals from offsite without a Resource Conservation and Recovery Act (RCRA) permit as long as they comply with the requirements in §266.510.

REVERSE LOGISTICS – nonprescription pharmaceuticals that are sent through reverse logistics are not wastes at the healthcare or retail facility *IF* they have a reasonable expectation of being lawfully used or reused for their intended purpose or reclaimed. Reverse Logistics Centers are designed to:

- Evaluate unsold retail items including nonprescription pharmaceuticals.
- Analyze secondary markets.
- Access the suitability of the unsold retail items for reuse in those secondary markets.

REVERSE DISTRIBUTION	REVERSE LOGISTICS
Prescription pharmaceuticals - Reverse Distributors (RD) are designed to: • Receive shipments of unused or expired prescription pharmaceuticals from healthcare facilities and, on behalf of manufacturers, facilitate the process of crediting healthcare facilities for these unused pharmaceuticals. • Prescription pharmaceuticals at RD are not reused nor resold and are discarded.	Non-Prescription pharmaceuticals • e.g., over –the-counter (OTC) and dietary supplements All other unsold retail items. Reverse Logistic centers are designed to: • Evaluate unsold retail items, including nonprescription pharmaceuticals. • Analyze secondary markets. • Assess the suitability of the unsold retail items for reuse in those secondary markets.
No redistribution occurs.	Redistribution sometimes occurs via: • Donation • Liquidation (secondary market)
Prescription pharmaceuticals sent to reverse distributors <u>are solid waste</u> at the healthcare facility.	Non-Prescription pharmaceuticals and other unsold retail items sent to reverse logistics *are not solid waste if* there is a reasonable expectation of legitimate use/reuse or reclamation.
In Part 266 Subpart P, which is effective in Iowa August 2019.	Newly codified in part 266 Subpart P, effective in Iowa August 2019.

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SEWERING PROHIBITION 266.505

The final rule prohibits the sewering (e.g., by pouring them into a sink, toilet or floor drain) of HW pharmaceuticals by all healthcare facilities and reverse distributors, including those that qualify as Very Small Quantity Generators (VSQGs). This does not apply to non-hazardous waste pharmaceutical or households, but the Environmental Protection Agency (EPA) strongly recommends against sewering any pharmaceuticals by any entity.

EMPTY CONTAINER STANDARDS

§261.7 / § 266.507

	RCRA EMPTY	
	Non-acute HW pharms	Acute HW pharms*
Stock/Dispensing bottles (1 liter or 10,000 pills and unit-dose containers)	Remove contents	Remove contents
Syringes	Fully depress plunger	Fully depress plunger
IV Bags	Fully administer contents or 261.7(b)(1)	Fully administer contents
Other Containers	261.7(b)(1) or (2)	Cannot be RCRA empty

EMPTY CONTAINER PROVISION

The final rule amends the definition of Resource Conservation and Recovery Acts (RCRA) empty container in relation to HW pharmaceuticals and further requires for managing containers with remaining residues. Stock, dispensing and unit-dose containers (not exceeding 1 liter or 10,000 pills) will be considered RCRA-empty if the pharmaceuticals have been removed using standard practices employed to remove materials from that type of container. Syringes will be regarded as empty if the contents have been removed by fully depressing the plunger of the syringes. IV bags will be considered empty provided the pharmaceuticals in the IV bag have been fully administered to the patient. The details vary depending on the specific type of container and can be read in detail at §266.507.

**Triple rinsing of containers with acute hazardous waste pharmaceuticals is no longer allowed.*

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NICOTINE P075 REVISION

The P075 listing for nicotine is being amended such that Food and Drug Administration approved over-the-counter (OTC) nicotine replacement therapies will no longer be included under the P075 listing for HW. Thus nicotine patches, gums and lozenges can be discarded as non-hazardous waste.

Other unused formulations of nicotine will still be considered P075 when discarded including:

- E-liquids/e-juices in e-cigarettes cartridges or vials.
- Legacy pesticides containing Nicotine.
- Nicotine used in research and manufacturing.

SUMMARY MATRIX OF PART 266 SUBPART P		
	Standards for Healthcare Facilities	**Standards for Reverse Distributors**
	POTENTIALLY CREDITABLE	**POTENTIALLY CREDITABLE**
On-site accumulation	• No standards • No time limit	Evaluate within 30 days
Shipping to a reverse distributor	• Confirmation of delivery • Common carrier	• Confirmation of delivery • Common carrier
	NON-CREDITABLE	**EVALUATED**
On-site accumulation	• UW-like standards • 1 year maximum	• LQG-like standards • 180 days after evaluation
Shipping to a Treatment Storage Disposal Facility (TSDF)	• Manifest (PHARMS) • HW transporter	• Manifest (waste codes) • HW transporter

This fact sheet contains key highlights of the final rule. For a more detailed summary of the rule, please visit: **www.epa.gov/hwgenerators/final-rule-management-standards-hazardous-waste-pharmaceuticals-and-amendment-p075**