



What You Need to Know: DEQ's Pharmaceutical Rule

The Pharmaceutical Rule changes the method of regulating hazardous waste pharmaceuticals and the sites that generate these wastes. This rule streamlines management standards for hazardous waste pharmaceuticals and prohibits flushing or putting pharmaceutical waste down a drain, also called sewerage. This fact sheet focuses on the rule's application to healthcare facilities. It does not address reverse distributor management standards for potentially creditable or evaluated hazardous waste pharmaceuticals managed at those facilities.



Who is affected?

Healthcare facilities and reverse distributors that generate and manage hazardous waste pharmaceuticals are subject to this rule, which is both sector- and waste-specific. It will help to reference the flowchart on the last page of this document.

Small quantity generators and large quantity generators that are healthcare facilities must comply with 40 Code of Federal Regulations 266 Subpart P for their hazardous waste pharmaceuticals. Any healthcare facility generating more than very small quantity generator amounts for all their hazardous wastes must notify DEQ as a healthcare facility operating under the new rule. Notification involves submitting a DEQ Site Identification Form via Your DEQ Online and must be made within 60 days of being subject to the pharmaceutical rule.

All healthcare facilities are subject to the sewerage prohibition, no matter their hazardous waste generator size, including VSQGs. VSQGs are not subject to the full management standards of the pharmaceutical rule unless they opt in, but may follow the optional provisions in 40 CFR 266.504. VSQGs should also use the Empty Container Residue Standards in 40 CFR 266.507. (Reference the Resource Conservation and Recovery Act Empty Container table, page 6).

Although not required, a VSQG may choose to opt into the full rule. To opt in, a VSQG must notify DEQ and follow all the healthcare facility management standards for their hazardous waste pharmaceuticals. Please note: After opting in, a VSQG can no longer use the optional provisions of the rule.

Pharmaceutical manufacturers, production facilities and other generators of hazardous waste pharmaceuticals are not subject to this rule.

In summary, the following entities must notify DEQ using a Hazardous Waste Site Identification Form:

- Reverse distributors.
- Healthcare facilities that generate small or large quantities of combined pharmaceutical and non-pharmaceutical hazardous waste.
- Healthcare facilities, generating very small quantities of combined pharmaceutical and non-pharmaceutical hazardous waste, that choose to opt in.

What is a pharmaceutical?

The definition of a pharmaceutical includes drugs for human or animal use, including prescription and over-the-counter pharmaceuticals, dietary supplements, homeopathic drugs, compounded drugs, investigational new drugs, as well as nicotine e-liquids packaged for retail sale and electronic nicotine delivery systems. Not included in this definition are medical wastes, infectious wastes, laboratory solvents and dental amalgam or sharps.

Why was the change made?

The Pharmaceutical Rule establishes cost savings by streamlining standards for handling hazardous waste pharmaceuticals to better fit the healthcare sector's operations while continuing to protect human health and the environment. This rule can make our drinking and surface water safer by reducing the number of hazardous waste pharmaceuticals entering our waterways under the sewerage prohibition.

The rule:

- Revises and tailors the hazardous waste regulations to improve the management of hazardous waste pharmaceuticals for the healthcare sector,
- Removes duplicative regulations for Drug Enforcement Administration controlled substances, and
- Encourages better management and disposal of non-hazardous waste pharmaceuticals.

Key Benefits



More flexible management –

A healthcare facility that has notified DEQ and is complying with this rule is no longer required to count or report hazardous waste pharmaceuticals to DEQ.

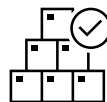


Less paperwork – No waste codes required when shipping pharmaceutical waste with a manifest; instead, use generic code PHRM or PHARMS.



Longer accumulation times –

Healthcare facilities can accumulate non-creditable (defined below) hazardous waste pharmaceuticals for up to one year.



Manufacturer credit – Healthcare facilities can send potentially creditable hazardous waste pharmaceuticals to a reverse distributor for credit.

What changed?

Along with new management standards for facilities managing waste pharmaceuticals, the rule defines three different types of wastes: potentially creditable, non-creditable and evaluated hazardous waste pharmaceuticals. Healthcare facilities manage potentially creditable and non-creditable. The management standards vary depending on the type of waste and type of facility. Potentially creditable hazardous waste pharmaceuticals have less burdensome management requirements than non-creditable. Below are a few of the requirements for healthcare facilities.

	Potentially creditable	Non-creditable
Definition	<p>Prescription hazardous waste pharmaceuticals that have a reasonable expectation of receiving a manufacturer credit and are:</p> <ul style="list-style-type: none"> • In the original manufacturer packaging, except for pharmaceuticals subject to a recall. • Undispensed. • Unexpired or less than one year past the expiration date. 	<p>Prescription hazardous waste pharmaceuticals that do not have a reasonable expectation of being eligible for manufacturer credit or non-prescription hazardous waste pharmaceuticals that do not have a reasonable expectation of being legitimately used, reused or reclaimed.</p>
Accumulation time limits	<p>Potentially creditable hazardous waste pharmaceuticals have no accumulation time limit but must be less than one year expired.</p>	<p>One year or less without a permit by:</p> <ul style="list-style-type: none"> • Marking the container with the date the non-creditable hazardous waste pharmaceuticals became a waste. • Maintaining an inventory system that identifies the date non-creditable pharmaceuticals became a waste. • Placing the waste pharmaceuticals in a specific area that identifies the date they became a waste.
Container requirements	<p>In original manufacturer packaging and undispensed.</p>	<p>Structurally sound, compatible with its contents, lacks evidence of leakage, spillage, or damage that could cause leakage under reasonably foreseeable conditions.</p> <p>Keep containers closed and secured in a manner that prevents unauthorized access to the contents.</p> <p>Label or clearly mark each container with the phrase "hazardous waste pharmaceuticals."</p>
Notification	<p>Notify as a healthcare facility using DEQ's Hazardous Waste Site Identification Form on Your DEQ Online if you generate small or large quantities of combined pharmaceutical and non-pharmaceutical hazardous waste.</p>	<p>Notify as a healthcare facility on DEQ's Hazardous Waste Site Identification Form if you generate small or large quantities of combined pharmaceutical and non-pharmaceutical hazardous wastes.</p>
Employee Training	<p>None</p>	<p>Must train all employees who manage non-creditable hazardous waste pharmaceuticals on proper waste handling and emergency procedures relevant to their responsibilities during normal operations and emergencies.</p>

	Potentially creditable	Non-creditable
Shipping	<p>Healthcare facilities must ship only potentially creditable hazardous waste pharmaceuticals to a reverse distributor.</p> <p>Healthcare facilities may not send any other hazardous waste that is not a pharmaceutical or any non-creditable hazardous waste pharmaceuticals to a reverse distributor.</p> <p>A healthcare facility does not have to use a hazardous waste manifest when shipping potentially creditable hazardous waste off site to a reverse distributor. Shipments may be made using a common carrier that complies with U.S. DOT requirements.</p> <p>All shipments must be accounted for to ensure receipt by the reverse distributor. If your healthcare facility has not received delivery confirmation from the reverse distributor within 35 days, you must contact the carrier or transporter to determine shipment status.</p>	<p>Healthcare facilities must use a permitted hazardous waste transporter to ship all non-creditable hazardous waste pharmaceuticals to a treatment, storage or disposal facility for disposal. Reverse distributors are not allowed to accept this waste.</p> <p>Shipments of non-creditable hazardous waste pharmaceuticals must use a uniform hazardous waste manifest when shipping to a treatment storage and disposal facility. Use waste code PHRM or PHARMS.</p>
Record Keeping	<p>Healthcare facilities must maintain copies of shipping papers for three years from the date of the shipment.</p> <p>All records must be readily available upon request by an inspector.</p>	<p>Healthcare facilities must keep a copy of manifests signed by the receiving facility for three years from the date the waste was accepted.</p> <p>Healthcare facilities must keep records of any test results, waste analyses or other determinations made to support its hazardous waste determinations for at least three years from the date the waste was last sent to treatment, storage or disposal. However, a healthcare facility managing its non-hazardous waste pharmaceuticals as non-creditable hazardous waste pharmaceuticals is not required to keep this documentation.</p> <p>All records must be readily available upon request by an inspector.</p>
Annual Reporting	<p>None for healthcare facilities. However, if your site still operates as a large or small quantity generator due to other non-pharmaceutical hazardous waste streams, DEQ requires an annual report for those wastes.</p>	<p>None for healthcare facilities. However, if your site still operates as a large or small quantity generator due to other non-pharmaceutical hazardous waste streams, DEQ requires an annual report for those wastes.</p>

Resource and Conservation Recovery Act Empty or RCRA Empty

Historically, acute P-listed hazardous waste pharmaceutical containers were only considered RCRA empty if they were both emptied of product and triple-rinsed. The Pharmaceutical Rule changed the management of empty containers for acute and non-acute hazardous waste pharmaceuticals, so triple rinsing is not required. However, some acute hazardous waste pharmaceuticals containers must be managed as non-creditable hazardous waste pharmaceuticals.

Empty container residue management standards:

- If the hazardous waste pharmaceutical container meets the RCRA empty container standard, the container and the residues are not hazardous waste.
- If the container cannot meet the RCRA empty container standards, the container and its contents must be managed as non-creditable hazardous waste pharmaceuticals.
- The table below outlines these standards.

Type of Container	RCRA Empty Non-Acute	RCRA Empty Acute
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 meets 40 CFR 261.7(b)(1).	Fully administer contents. If not empty, then manage as non-creditable hazardous waste pharmaceuticals.
Other containers, including but not limited to inhalers, aerosols, neutralizers and tubes or ointments, gels or creams	Meets 40 CFR 261.7(b)(1) or (2).	Cannot be RCRA empty. Manage with non-creditable hazardous waste pharmaceuticals.

Where to find more information?

Complete federal regulations can be found at 40 CFR Part 266 Subpart P. Reference Oregon Administrative Rule 340-102-0500 for Oregon's changes to the federal regulations. The rest of this federal rule is incorporated by reference at OAR 340-100-0002.

Have questions?

DEQ has made it easy to get your questions answered. To learn more and request free, non-regulatory technical assistance, please visit www.oregon.gov/deq/Hazards-and-Cleanup.

To submit forms, visit Your DEQ Online at yourdeqonline.oregon.gov.

Alternative formats

DEQ can provide documents in an alternate format or in a language other than English upon request. Call DEQ at 800-452-4011 or email deqinfo@deq.state.or.us.

Overview of the Pharmaceutical Rule

