



## Hazardous Waste Pharmaceutical Management Requirements (40 CFR 266 Subpart P) For Non-Creditable and Potentially Creditable Hazardous Waste Pharmaceuticals at Healthcare Facilities

This table provides a side by side comparison of requirements for healthcare facilities generating and managing hazardous waste pharmaceuticals (non-creditable and potentially creditable) under 40 CFR 266 subpart P. Except for the sewer prohibition (which was effective August 21, 2019) the requirements of 40 CFR 266 subpart P were effective in North Carolina on July 1, 2020. This table does not include all hazardous waste requirements for hazardous waste pharmaceuticals. This document is for guidance only and does not contain all of the North Carolina Hazardous Waste Management Rules. Many of the requirements described are paraphrased. For complete rules refer to 15A NCAC 13A for specific state requirements and federal regulations incorporated by reference in the state rules. State law is found at N.C.G.S. 130A-290 through 130A-310.12. The following Hazardous Waste Section website provides links to state hazardous waste rules and law: <https://deq.nc.gov/about/divisions/waste-management/hw/rules>

	<b>Non-Creditable Hazardous Waste (HW) Pharmaceutical</b>	<b>Potentially Creditable Hazardous Waste (HW) Pharmaceutical</b>
<b>Definition</b>	<p>A prescription HW pharmaceutical that does not have a reasonable expectation to be eligible for manufacturer credit or a nonprescription hazardous waste pharmaceutical that does not have a reasonable expectation to be legitimately used/reused or reclaimed.</p> <ul style="list-style-type: none"> <li>- 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 the spills of pharmaceuticals.</li> </ul>	<p>A prescription HW pharmaceutical that has a reasonable expectation to receive manufacturer credit and is—</p> <ul style="list-style-type: none"> <li>- In original manufacturer packaging (except pharmaceuticals that were subject to a recall);</li> <li>- Undispensed; and</li> <li>- Unexpired or less than one year past expiration date.</li> </ul> <p>The term does not include:</p> <ul style="list-style-type: none"> <li>- Evaluated HW pharmaceuticals or</li> <li>- Nonprescription pharmaceuticals including, but not limited to, over-the-counter drugs, homeopathic drugs, and dietary supplements.</li> </ul>
<b>Is Sewer Disposal Allowed?</b>	<ul style="list-style-type: none"> <li>- No. Sewer disposal is not allowed.</li> <li>- VSQG healthcare facilities are also prohibited from sewerage HW Pharmaceuticals</li> </ul>	
<b>Notification Requirements</b>	<ul style="list-style-type: none"> <li>- If a facility already has an EPA ID number, notify (electronically using RCRAInfo) as a healthcare facility operating under 40 CFR 266 subpart P.</li> <li>- If facility does not already have an EPA ID number, notify the NC Hazardous Waste Section (electronically using RCRAInfo), obtain EPA ID number, and notify as a healthcare facility operating under 40 CFR 266 subpart P.</li> <li>- Healthcare facility must notify of withdrawal from operating under 40 CFR subpart P</li> </ul>	
<b>Counting Hazardous Waste Pharmaceuticals Toward Generator Category</b>	<p>HW pharmaceuticals managed under 40 CFR 266 subpart P are not counted toward healthcare's hazardous waste generator category</p>	
<b>Accumulation Volume Limits</b>	None	

	<b>Non-Creditable Hazardous Waste (HW) Pharmaceutical</b>	<b>Potentially Creditable Hazardous Waste (HW) Pharmaceutical</b>
<b>Accumulation Time Limits</b>	<p>One year. Must be able to demonstrate by:</p> <ul style="list-style-type: none"> <li>- Marking/labeling the container with the date;</li> <li>- Maintaining an inventory system that identifies the date;</li> <li>- Placing the non-creditable hazardous waste pharmaceuticals in a specific area and identifying the earliest date that any of the non-creditable hazardous waste pharmaceuticals in the area became a waste.</li> </ul>	No time limit
<b>Container Management Requirements</b>	<ul style="list-style-type: none"> <li>- Containers must be in good condition and compatible with wastes stored.</li> <li>- Must secure containers to prevent unauthorized access to contents.</li> </ul>	None
<b>Inspection Requirements</b>	None	
<b>Employee Training</b>	<ul style="list-style-type: none"> <li>- Ensure all employees that manage HW pharmaceuticals are thoroughly familiar with proper waste handling and emergency procedures relevant to their responsibilities during normal facility operations and emergencies.</li> <li>- Documentation of training is not required.</li> </ul>	
<b>Preparedness and Prevention and Emergency Response</b>	<ul style="list-style-type: none"> <li>- Determine whether residues from releases are hazardous waste. If they are, manage the residues and any other materials resulting from a release (e.g., cleanup equipment, contaminated soils, etc.) under the regulations for non-creditable HW pharmaceuticals.</li> </ul>	
<b>Pre-Transport and Transportation Requirements</b>	<ul style="list-style-type: none"> <li>- Containers must be labeled as "Hazardous Waste Pharmaceuticals"</li> <li>- HW Pharmaceuticals may only be transported by a registered HW transporter</li> <li>- Must ship in compliance with DOT regulations</li> </ul>	<ul style="list-style-type: none"> <li>- Containers are not required to have a label</li> <li>- Can use common carriers such as UPS</li> <li>- Must ship in compliance with DOT regulations.</li> </ul>
<b>Manifests</b>	<ul style="list-style-type: none"> <li>- HW manifests must be prepared for each offsite shipment of HW pharmaceuticals</li> <li>- HW codes DO NOT need to be on the manifest</li> </ul>	<ul style="list-style-type: none"> <li>- No manifest required</li> <li>- Must ship with a return receipt notification</li> <li>- Waste codes do not need to be on shipping papers.</li> </ul>
<b>Reporting &amp; Recordkeeping</b>	<ul style="list-style-type: none"> <li>- Keep copies of manifest for 3 years</li> <li>- HW pharmaceuticals not required to be on the healthcare facility's biennial report (if required to complete a biennial report)</li> </ul>	<ul style="list-style-type: none"> <li>- Must keep return receipt and shipping papers for all shipments shipped for at least 3 years</li> <li>- HW pharmaceuticals not required to be on healthcare facility's biennial report (if required to complete a biennial report)</li> </ul>
<b>Whether Pharmaceuticals must go to a HW Treatment, Storage, and Disposal Facility (TSDF)</b>	Yes	<ul style="list-style-type: none"> <li>- It can go to a reverse distributor that is a HW TSDF, but it is not required</li> </ul>

	<b>Non-Creditable Hazardous Waste (HW) Pharmaceutical</b>	<b>Potentially Creditable Hazardous Waste (HW) Pharmaceutical</b>
<b>Whether HW Pharmaceuticals may go to a Reverse Distributor</b>	No	Yes
<b>Management of Residues in Pharmaceutical Containers</b>	<ul style="list-style-type: none"> <li>- <i>(Simply stated)</i> For blister packs, dispensing bottles, cups, patch wrappers, syringes, and IV bags, removing the P-listed HW pharmaceutical is the same as triple rinsing and the residues in the container are not HW.</li> <li>- All other types of containers with HW pharmaceuticals managed as HW.</li> </ul>	
<b>Long Term Care Facilities</b>	Nursing care facilities and continuing care retirement communities must operate as healthcare facility under 40 CFR 266 subpart P, unless they generate less than or equal to 220 lbs. (100 kg) of non-acute HW per month and less than or equal to 2.2 lbs. (1 kg) of acute HW per month.	