NORTH CAROLINA DEPARTMENT OF ENVIRONMENTAL QUALITY
DIVISION OF WASTE MANAGEMENT
HAZARDOUS WASTE SECTION

Comparison of Baseline Hazardous Waste Generator Requirements and the Pharmaceutical Management Requirements of 40 CFR 266 Subpart P

This table provides a side by side comparison of the baseline hazardous waste generator requirements and the requirements for healthcare facilities and reverse distributors operating under 40 CFR 266 subpart P for hazardous waste pharmaceuticals. 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 generators or 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

	Baseline Hazardous Waste Generator Requirements			Key Difference Under the HW Pharmaceutical Management Requirements of 40 CFR 266 Subpart P	
	VSQGs	**SQGs**	**LQGs**	**For Healthcare Facilities**	**For Reverse Distributors**
Generation Rate					
- Quantity of non-acute HW generated in a calendar month	< 220 lbs. (100 kg)	> 220 lbs. (100 kg) but < 2,200 lbs. (1000 kg)	≥ 2,200 lbs. (1000 kg)	- Subpart P (with exception of sewer prohibition) applies to SQG and LQG healthcare facilities. *See Applicability & Waste Counting Guidance*. - VSQGs must comply with sewer prohibition and may opt into Subpart P or comply with 40 CFR 262.14. - Once applicability of Subpart P is determined, and a facility opts in, then there are no generation rate thresholds.	There are no generation rate thresholds. All reverse distributors must comply with the same requirements.
- Quantity of acute HW generated in a calendar month	< 2.2 lbs. (1 kg)	< 2.2 lbs. (1 kg)	≥ 2.2 lbs. (1 kg)		
- Quantity of residues from a clean-up of acute HW generated in a calendar month	< 220 lbs. (100 kg)	< 220 lbs. (100 kg)	≥ 220 lbs. (100 kg)		
Accumulation Volume Limit	- 2,200 lbs. (1000 kg) non-acute HW at any time - ≤ 2.2 lbs. (1 kg) acute HW at any time - ≤ 220 lbs. (100 kg) acute HW from a clean-up at any time	13,200 lbs. (6000 kg) non-acute HW at any time	None	- There is no accumulation volume limit for healthcare facilities in Subpart P. - Once a healthcare facility opts into Subpart P, HW pharmaceuticals no longer count towards generator category.	There is no accumulation volume limit for reverse distributors.

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Accumulation Time Limit	None	180 days; 270 days if HW is transported 200 miles or more to an off-site TSD facility	90 days	- For non-creditable HW pharmaceuticals the accumulation time limit increases for both SQGs and LQGs to one year.
				- One year maximum accumulation time must be demonstrated by:
				  - Marking/labeling the container with the date the non-creditable HW pharmaceutical became a waste;
				  - Maintaining an inventory system that identifies the date the non-creditable HW pharmaceutical became a waste;
				  - 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.
					- For LQG reverse distributors, the accumulation time limit increases to 180 days.
					- For current SQG reverse distributors that ship greater than 200 miles, the accumulation time limit decrease from 270 to 180 days.

Notification Requirements	None	Notify NCDEQ HWS (electronically using RCRAInfo) and obtain EPA ID Number		Under subpart P, facilities must submit a one-time notification to NCDEQ HWS (electronically using RCRAInfo) as a "healthcare facility" or "reverse distributor." - SQG Healthcare facilities must notify within 60 days of effective date of subpart or being subject to Subpart P - LQGs may notify during the next biennial report submission. - Must also notify when withdrawing from Subpart P.	
Labeling/Marking Requirements	None	All containers (satellite and central accumulation) must be marked/labeled with: - The words "Hazardous Waste," - An indication of the hazards of the contents of the container Central accumulation containers – must be marked with an accumulation start date.		- Non-creditable HW pharmaceuticals must be marked/labeled "Hazardous Waste Pharmaceuticals" - No requirement to mark/label with an indication of the hazards of the contents of the container. - No marking/labeling required for potentially creditable HW pharmaceuticals shipped to a reverse distributor.	Evaluated pharmaceuticals must be labeled "Hazardous Waste Pharmaceuticals"
Inspection Requirements	None	- Weekly inspections of central accumulation area(s) Inspections must be documented		No required inspections for areas where HW pharmaceuticals are accumulated	No change relative to baseline for LQGs and SQGs. VSQGs must now comply with the same standards as LQGs and SQGs.

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Container Management Requirements	None	- Containers must be in good condition and compatible with wastes accumulated. - Containers must be closed during accumulation except when adding or removing waste.		Non-creditable HW pharmaceuticals must be: - Placed in container that is structurally sound, compatible with its contents, and lacks evidence of leakage, spillage, or damage. - Closed and secured in a manner that prevents unauthorized access to its contents. - Follow specific management requirements for ignitable, reactive and commingled incompatible waste.	No change relative to baseline for LQGs and SQGs. VSQGs must now comply with the same standards as LQGs and SQGs.
Employee Training	None	Generator must ensure that all employees are thoroughly familiar with proper waste handling and emergency procedures relevant to their responsibilities during normal facility operations and emergencies.	Training program required for all employees with HW management duties. Training program must be documented, and records kept for each employees. Annual refresher training is required.	- Training is required to ensure all personnel managing non-creditable HW pharmaceuticals are thoroughly familiar with proper waste handling and emergency procedures relevant to their responsibilities during normal facilities operations and emergencies.	All reverse distributors must provide LQG-level training to employees regardless of their current hazardous waste generator category.
Hazardous Waste Determinations	Waste Determination in accordance with 40 CFR 262.11(a) through (d).	Waste Determination in accordance with 40 CFR 262.11(a) through (g).		For <u>non-creditable HW pharmaceuticals</u>, must determine whether that pharmaceutical is a HW pharmaceutical. - May choose to manage its non-HW pharmaceuticals as non-creditable HW pharmaceuticals. For <u>potentially creditable HW pharmaceuticals</u>, must determine whether that potentially creditable pharmaceutical is a HW pharmaceutical. - May choose to manage its potentially creditable non-HW pharmaceuticals as potentially creditable HW pharmaceuticals.	Reverse distributor must evaluate potentially creditable pharmaceutical to verify manufacturer credit within 30 calendar days of the waste arriving at the facility.

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Transportation	Must meet applicable DOT hazardous material regulations)	- Containers must be labeled with specific hazardous waste language and in compliance with DOT hazardous materials requirements - Hazardous waste may only be transported by a registered hazardous waste transporter - The generator must placard the transportation vehicle with the appropriate DOT placard.		Healthcare facility must comply with DOT hazardous material regulations for potentially creditable hazardous waste pharmaceuticals that are shipped to a reverse distributor.	Reverse distributors must comply with DOT hazardous materials regulations for hazardous waste pharmaceuticals that are shipped to another reverse distributor.
Manifests	None	Hazardous waste manifest must be prepared for each off-site shipment of hazardous waste. Containers and manifests must include RCRA HW waste codes.		- Manifests are required for shipments of non-creditable HW pharmaceuticals. - Must keep copies of completed manifests for shipments of non-creditable HW pharmaceuticals for 3 years. - Healthcare facilities that do not receive a completed copy of the manifest back in 60 days for non-creditable HW pharmaceuticals, must file/maintain exception report similar to SQG.	- No manifest required for shipments between reverse distributors, but reverse distributors must provide a delivery confirmation for each received shipment. - Manifests are required for evaluated pharmaceuticals shipped off-site as hazardous waste.
Land Disposal Restrictions	None	Must comply with the land disposal restrictions of 40 CFR 268.		- Non-creditable HW pharmaceuticals are subject to land disposal restrictions of 40 CFR 268. - The healthcare facility must comply with 40 CFR 268.7(a) except it is not required to identify the HW codes on the LDR notifications.	- Evaluated pharmaceuticals are subject to land disposal restrictions of 40 CFR 268. - A reverse distributor accepting potentially creditable HW pharmaceuticals from off site must comply with the land disposal restrictions in accordance with 40 CFR 268.7(a) requirements.

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Recordkeeping (General Summary, not all inclusive)	None	The following must be maintained for three years: - Records of weekly inspections of central accumulation area(s) - Records of waste determinations - Signed, completed HW Manifests - Exception reports	The following must be maintained for three years: -Records of weekly inspections of central accumulation area(s) -Records of waste determinations -Signed, completed HW Manifests -Exception reports -Biennial Reports -RCRA Training	- For healthcare facilities operating as a LQG, non-creditable and/or potentially creditable HW pharmaceuticals are not subject to reporting requirements on the biennial report. - Must keep copies of records of any test results, waste analyses, or other waste determinations for 3 years. - For shipments of potentially creditable HW pharmaceuticals to a reverse distributor, the following must be maintained for 3 years: - Confirmation of delivery; - DOT shipping papers in accordance with 49 CFR part 172 subpart C;	Evaluated HW pharmaceuticals going for disposal must be included on biennial report.
Preparedness and Prevention and Emergency Response	None	- Facilities must be maintained and operated to prevent fire, explosion, or release of hazardous waste. Appropriate equipment and procedures must be in place. Arrangements must be made with local authorities. - Facility must have a designated emergency coordinator. - Emergency information must be posted at the facility (SQG) or submitted to the local emergency authorities (LQG). - Facility must immediately contain all spills and manage clean-up material by applicable HW requirements.		For spills of non-creditable and/or potentially creditable HW pharmaceuticals, facility must immediately contain all spills and manage the spill clean-up materials as non-creditable HW pharmaceuticals.	Requirements are similar to the Baseline HW Generator Requirements
Long-term Care Facilities	Long-term care facilities were previously exempt from RCRA requirements under the household hazardous waste exclusion for their patient generated hazardous waste.			Long-term care facilities must meet all rule requirements unless they are a VSQG.	Not Applicable
Sewer Disposal	Sewer disposal was previously allowed if facilities notified their local publicly owned treatments works (POTW). Sewer disposal of hazardous waste pharmaceuticals by a healthcare facility or reverse distribuor is prohibited (as of August 21, 2019).			Sewer disposal of hazardous waste pharmaceuticals is prohibited (as of August 21, 2019). EPA administers and enforces this until NC adopts this provision.	

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DEA Exemption	N/A	N/A	N/A	Hazardous waste pharmaceuticals that are also DEA controlled substances (chloral/chloral hydrate, fentanyl sublingual spray, phenobarbital, testosterone gel/solutions, and valium injectable/gel) are exempt from 40 CFR 262 through 273 when:
				- Managed in compliance with the sewer prohibition of 40 CFR 266.505;
				- Collected, stored, transported, and disposed of in compliance with all applicable DEA regulations for controlled substances;
				- 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:
				  - A permitted large municipal waste combustor, subject to 40 CFR 62 subpart FFF or applicable state plan for existing large municipal waste combustors, or 40 CFR 60 subparts Eb for new large municipal waste combustors; or
				  - A permitted small municipal waste combustor, subject to 40 CFR 62 subpart JJJ or applicable state plan for existing small municipal waste combustors, or 40 CFR 60 subparts AAAA for new small municipal waste combustors; or
				  - A permitted hospital, medical and infectious waste incinerator, subject to 40 CFR 62 subpart HHH or applicable state plan for existing hospital, medical and infectious waste incinerators, or 40 CFR 60 subpart Ec for new hospital, medical and infectious waste incinerators.
				  - A permitted commercial and industrial solid waste incinerator, subject to 40 CFR part 62 subpart III or applicable state plan for existing commercial and industrial solid waste incinerators, or 40 CFR 60 subpart CCCC for new commercial and industrial solid waste incinerators.	

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Accepting HW from Off-site (Basic Summary)	N/A – a VSQG may not accept HW from off-site, but a VSQG may send HW to a LQG that is under the control of the same person as the VSQG provided the containers are marked/labeled with the words "Hazardous Waste" and an indication of the hazards of the contents of the container.	N/A	A LQG may accept HW from a VSQG provided that: - Under the control of the same person as the VSQG; - LQG notifies (electronically using the EPA 8700-12 form) at least 30 days prior to receiving the first shipment from the VSQG - Maintains records of shipments received from the VSQG - Manages the HW received under the LQG requirements.	A healthcare facility may accept non-creditable and potentially creditable HW pharmaceuticals from off-site healthcare facilities that are VSQGs as long as the receiving facility is: - Under the control of the same person as the VSQG; - Operating under Subpart P for the management of non-creditable and/or potentially creditable HW pharmaceuticals; - Manages non-creditable and/or potentially creditable HW pharmaceuticals received from off-site in compliance with subpart P; - Keeps records of the non-creditable and/or potentially creditable HW pharmaceutical shipments it receives from off-site for 3 years.	N/A
Residues of Hazardous Waste in Empty Containers	Residues of HW in Empty Containers (40 CFR 261.7) (a)(1) Any hazardous waste remaining in either: an empty container; or an inner liner removed from an empty container, as defined in paragraph (b) of this section, is not subject to regulation under parts 261 through 268, 270, or 124 this chapter or to the notification requirements of section 3010 of RCRA. (2)Any hazardous waste in either a container that is not empty or an inner liner removed from a container that is not empty, as defined in paragraph (b) of this section, is subject to regulation under parts 261 through 268, 270 and 124 of this chapter and to the notification requirements of section 3010 of RCRA. (b)(1) A container or an inner liner removed from a container that has held any hazardous waste, except a waste that is a compressed gas or that is identified as an acute hazardous waste listed in §§261.31 or 261.33(e) of this chapter is empty if:			Residues of HW Pharmaceuticals in Empty Containers (40 CFR 266.507) ✓ A stock bottle, ✓ Dispensing bottle, ✓ Vial, or Ampule (not to exceed 1 liter or 10,000 pills); or ✓ A unit-dose container (e.g., a unit-dose packet, cup, wrapper, blister pack, or delivery device) **Is considered empty and the residues are not regulated as HW** *When:* The pharmaceuticals have been removed from the stock bottle, dispensing bottle, vial, ampule, or the unit-dose container using the practices commonly employed to remove materials from that type of container. ✓A syringe **Is considered empty and the residues are not regulated as HW**	

	Residues of HW in Empty Containers (continued) (i) All wastes have been removed that can be removed using the practices commonly employed to remove materials from that type of container, e.g., pouring, pumping, and aspirating, and (ii) No more than 2.5 centimeters (one inch) of residue remain on the bottom of the container or inner liner, or (iii)(A) No more than 3 percent by weight of the total capacity of the container remains in the container or inner liner if the container is less than or equal to 119 gallons in size; or (B) No more than 0.3 percent by weight of the total capacity of the container remains in the container or inner liner if the container is greater than 119 gallons in size. (2) A container that has held a hazardous waste that is a compressed gas is empty when the pressure in the container approaches atmospheric. (3) A container or an inner liner removed from a container that has held an acute hazardous waste listed in §§261.31 or 261.33(e) is empty if: (i) The container or inner liner has been triple rinsed using a solvent capable of removing the commercial chemical product or manufacturing chemical intermediate; (ii) The container or inner liner has been cleaned by another method that has been shown in the scientific literature, or by tests conducted by the generator, to achieve equivalent removal; or (iii) In the case of a container, the inner liner that prevented contact of the commercial chemical product or manufacturing chemical intermediate with the container, has been removed. Once the 40 CFR 266 Subpart P provisions are effective in North Carolina (anticipated July 1, 2020), a VSQG Healthcare Facility (when counting total hazardous waste at the facility) may utilize the Residues of HW Pharmaceuticals in Empty Containers described at 40 CFR 266.507 (described in the right column).	<u>*When:*</u> the contents have been removed by fully depressing the plunger of the syringe *Residues of HW Pharmaceuticals in Empty Containers (continued)* If a syringe is <u>not empty:</u> • The syringe must be placed with its remaining HW pharmaceuticals into a container That is managed & disposed of as a non-creditable HW pharmaceutical Meets any applicable requirements for sharps containers & medical waste ✓ Intravenous (IV) bags **<u>Are considered empty and the residues are not regulated as HW</u>** <u>*When*</u>: the pharmaceuticals in the IV bag have been fully administered to a patient If an IV bag is <u>not empty</u>: • The IV bag must be placed with its remaining HW pharmaceuticals into a container that is managed and disposed of as a non-creditable HW pharmaceutical Unless the IV bag held non-acute hazardous waste pharmaceuticals and is empty as defined in 40 CFR 261.7(b)(1). ✓ Other containers, including delivery devices HW pharmaceuticals remaining in **<u>all other types of unused, partially administered, or fully administered containers</u>** must be managed as non-creditable HW pharmaceuticals • Unless the container held non-acute HW pharmaceuticals & is empty as defined in 40 CFR 261.7(b)(1) or (2). • This includes, but is not limited to, residues in inhalers, aerosol cans, nebulizers, tubes of ointments, gels, or creams.