Comparison of Very Small Quantity Generator (VSQG) Hazardous Waste Generator Requirements and the Pharmaceutical Management Requirements of 40 CFR 266 Subpart P for Healthcare Facilities

This table provides a side-by-side comparison of the baseline hazardous waste generator requirements and the requirements for healthcare facilities 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 is useful for a VSQG healthcare facility to see the management requirements that would apply depending on whether they opt into Subpart P or not. 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 Very Small Quantity Generator (VSQG) Hazardous Waste Generator Requirements	**Key Difference Under the HW Pharmaceutical Management Requirements of 40 CFR 266 Subpart P**
Generation Rate		
- Quantity of non-acute HW generated in a calendar month	< 220 lbs. (100 kg)	- Subpart P (with exception of sewer prohibition which applies to HW categories) 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.
- Quantity of acute HW generated in a calendar month	< 2.2 lbs. (1 kg)	
- Quantity of residues from a clean-up of acute HW generated in a calendar month	< 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	- 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.

Accumulation Time Limit	None	- No time limit for accumulation of potentially creditable hazardous waste pharmaceuticals.
		- For non-creditable pharmaceuticals: 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.

	Baseline VSQG Hazardous Waste Generator Requirements	Key Difference Under the HW Pharmaceutical Management Requirements of 40 CFR 266 Subpart P
Notification Requirements	None	Under subpart P, facilities must submit a one-time notification to NCDEQ HWS (electronically using RCRAInfo) as a "healthcare facility" - 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. - VSQGs that opts into using Subpart P must notify within 60 days of effective date of subpart or being subject to Subpart P and must have an EPA ID number (or request one during notification). - Must also notify when withdrawing from Subpart P.
Labeling/Marking Requirements	None	- 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.
Inspection Requirements	None	No required inspections for areas where HW pharmaceuticals are accumulated
Container Management Requirements	None	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.
Employee Training	None	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.
Hazardous Waste Determinations	Waste Determination in accordance with 40 CFR 262.11(a) through (d).	For non-creditable HW pharmaceuticals, must determine whether that pharmaceutical is a HW pharmaceutical. - May choose to manage its non-HW pharmaceuticals as non-creditable HW pharmaceuticals. For potentially creditable HW pharmaceuticals, 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.
Transportation	Must comply with DOT hazardous material regulations.	Healthcare facility must comply with DOT hazardous material regulations for potentially creditable hazardous waste pharmaceuticals that are shipped to a reverse distributor.
Manifests	None	- 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.

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Land Disposal Restrictions	None	- 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.
Recordkeeping (General Summary, not all inclusive)	None	- 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;
Preparedness and Prevention and Emergency Response	None	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.
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.
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 distributor 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.
DEA Exemption	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

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DEA Exemption *(continued)*		*DEA Exemption continued:* - 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.
Accepting HW from Off-site (Basic Summary)	When the 40 CFR 266 Subpart P provisions are effective in North Carolina on July 1, 2020, a VSQG healthcare facility may not accept hazardous waste from off-site, but can send non-creditable and potentially creditable HW pharmaceuticals to an off-site healthcare facility meeting the following requirements: - [Healthcare consolidation provision – see the right column]The receiving facility meets the conditions of 40 CFR 266.502(l) or 266.503(b), as applicable; or - [Hazardous Waste Generator Consolidation provision] The VSQG meets the conditions of 40 CFR 262.14(A)(5)(viii) and the LQG meets the conditions of 40 CFR 262.17(f). (See Consolidation Provision)	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.
Disposition of Hazardous Waste Pharmaceuticals	- A VSQG healthcare facility (when counting total hazardous waste) may send its potentially creditable hazardous waste pharmaceuticals to a reverse distributor. - All other hazardous waste must be disposed of in accordance with 40 CFR 262.14.	- Potentially creditable hazardous waste pharmaceuticals must be sent to a reverse distributor. - Non-creditable hazardous waste pharmaceuticals must be shipped to a hazardous waste treatment, storage, and disposal facility.

	Baseline VSQG Hazardous Waste Generator Requirements	Key Difference Under the HW Pharmaceutical Management Requirements of 40 CFR 266 Subpart P
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: (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.	In addition to the Residues of HW in Empty Containers (40 CFR 261.7) (in the left column), 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** *When:* the contents have been removed by fully depressing the plunger of the syringe If a syringe is not empty: • 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 **Are considered empty and the residues are not regulated as HW** *When*: the pharmaceuticals in the IV bag have been fully administered to a patient If an IV bag is not empty: • 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 **all other types of unused, partially administered, or fully administered containers** 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.

	Baseline VSQG Hazardous Waste Generator Requirements	Key Difference Under the HW Pharmaceutical Management Requirements of 40 CFR 266 Subpart P
Residues of Hazardous Waste in Empty Containers *(continued)*	*Residues of HW in Empty Containers (continued)* (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 on 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).**	