



Management Standards for Hazardous Waste Pharmaceuticals Applicability and Waste Counting Guidance for Healthcare Facilities and Reverse Distributors

On February 22, 2019, the Environmental Protection Agency (EPA) promulgated the Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine Rule ([84 Federal Register \(FR\) 5816; February 22, 2019](#)). This rule was effective on the federal level on August 21, 2019.

Two parts of this federal rule were effective in North Carolina on August 21, 2019:

- 1) The sewer prohibition (described at [40 CFR 266.505](#)) which prohibits healthcare facilities and reverse distributors from sewer disposing hazardous waste pharmaceuticals.
- 2) The amendment to the P075 nicotine listing ([40 CFR 261.33](#)) which removed FDA regulated nicotine replacements therapies (specifically nicotine gums, patches and lozenges) from being a P075 hazardous waste. This part of the rule applies to any site and is not specific only to healthcare facilities and reverse distributors.

North Carolina adopted the rest of the federal provisions of [40 CFR 266 Subpart P](#) ("Subpart P") through incorporation by reference in [15A NCAC 13A .0111](#) without addition or amendment. The provisions (except for the two mentioned above) were effective in North Carolina on July 1, 2020. This document provides a three-step evaluation to determine whether your site is subject to the requirements of 40 CFR 266 Subpart P. Start at Step 1, below.

Step 1 - Site Applicability: This rule applies to "healthcare facilities" and "reverse distributors." (*See the below definitions for healthcare facility and reverse distributor*).

A. Is your site (or part of your site) a "**healthcare facility**"? If your facility (or part of your site) meets the below definition of a healthcare facility, then go to Step 2.

A **healthcare facility** means 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) Distributes, sell, or dispense pharmaceuticals, dietary supplements, homeopathic drugs, or prescription pharmaceuticals. (*See Step 2 for a definition of "pharmaceutical"*)

The definition of **healthcare facility** includes (but is not limited to):

- wholesale distributors,
- third-party logistics providers that serve as forward distributors,
- military medical logistics facilities,
- hospitals,
- psychiatric hospitals,
- ambulatory surgical centers,
- health clinics, physicians' offices,
- optical providers,
- dental providers,
- chiropractors,
- long-term care facilities,
- ambulance services,
- pharmacies,
- long term care pharmacies,
- mail-order pharmacies,
- retailers of pharmaceuticals,
- veterinary clinics/veterinary hospitals.

A healthcare facility may be part of a site ("co-located" at a site) so Subpart P provisions could apply to a portion of a site like a university or military base with a health clinic or a manufacturing or other type of site that has a healthcare component (e.g., nurse's office, clinic, a room with a first aid kit, area where employee blood monitoring is performed or vaccines are administered, etc.)

- B.** Is your facility a "**reverse distributor**"? If your facility meets the below definition of a reverse distributor and manages the applicable hazardous waste pharmaceuticals in Step 2, the requirements of 40 CFR 266 Subpart P apply to your facility regardless of the generation category of the facility. You do not need to proceed to Step 3.

A **reverse distributor** means any person that receives and accumulates prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals for the purposes of facilitating or verifying manufacturer credit.

Any person, including forward distributors, third-party logistics providers, and pharmaceutical manufacturers, that processes prescription pharmaceuticals for the facilitation or verification of manufacturer credit is considered a reverse distributor.

If your facility (or part of your site) is **not** a healthcare facility or reverse distributor, the requirements of 40 CFR 266 Subpart P do not apply to your facility.

If you are not sure whether the provisions of this rule apply to your facility, contact your [Hazardous Waste Section Inspector](#). The following website link provides a map showing the regions and contact information of the Hazardous Waste Section Inspectors of the at the following website link:

https://files.nc.gov/ncdeq/Waste+Management/DWM/HW/Compliance/Compliance_Map_by_Inspector.pdf

Step 2 - Waste Applicability: Subpart P applies to "hazardous waste pharmaceuticals" generated at healthcare facilities and handled at reverse distributors. Definitions for pharmaceuticals, hazardous waste pharmaceuticals and non-hazardous waste pharmaceuticals are as follows.

- A. Pharmaceutical** means any drug or dietary supplement for use by humans or other animals; any electronic nicotine delivery system (e.g., electronic cigarette or vaping pen); or any liquid nicotine (e-liquid) packaged for retail sale for use in electronic nicotine delivery systems (e.g., pre-filled cartridges or vials).

The definition of **pharmaceutical** includes (but is not limited to):

- dietary supplements, as defined by the [Federal Food, Drug and Cosmetic Act \(Section 201\(ff\)\)](#);
- prescription drugs, as defined by [21 CFR 203.3\(y\)](#);
- over-the-counter drugs;
- homeopathic drugs;
- compounded drugs;
- investigational new drugs;
- pharmaceuticals remaining in non-empty containers;
- personal protective equipment contaminated with pharmaceuticals; and
- clean-up material from spills of pharmaceuticals.

The definition of **pharmaceutical** does not include:

- dental amalgam or
- sharps.

If an over the counter product is required by the FDA to include "Drug Facts" on the label, it would be considered a pharmaceutical for the purposes of this rule. If an item meets the criteria to be considered a pharmaceutical under Subpart P but is not labeled with Drug Facts, it should still be managed as a pharmaceutical. ([84 FR 5842, February 22, 2019](#))

The Subpart P requirements do not apply to wastes generated from the manufacturing of pharmaceuticals but could apply to areas of a manufacturing facility that operate as healthcare facility (e.g., nurses office).

B. Hazardous waste pharmaceutical means a pharmaceutical (as described above) that is a solid waste, as defined in [40 CFR 261.2](#), and exhibits one or more characteristics identified in [40 CFR 261 Subpart C](#) or is listed in [40 CFR 261 Subpart D](#).

- Tips to, perhaps, avoid having to manage hazardous waste pharmaceuticals under Subpart P:
 - Track inventory of pharmaceuticals that are a hazardous waste when disposed and ensure any hazardous waste pharmaceuticals are legitimately used for intended purpose, so it does not have to be disposed.
 - Carefully evaluate any events that can cause a site or portion of the site to be considered a healthcare facility (e.g., administration of vaccines or employee blood monitoring).
- Hazardous waste pharmaceuticals generated or managed by entities other than healthcare facilities and reverse distributors (e.g., pharmaceutical manufacturers and reverse logistics centers) are not subject to Subpart P. Other generators (other than healthcare facilities and reverse distributors) are subject to 40 CFR 262 for the generation and accumulation of hazardous wastes, including hazardous waste pharmaceuticals.

C. Non-hazardous waste pharmaceutical means a pharmaceutical that is a solid waste, as defined in [40 CFR 261.2](#), and is not listed in [40 CFR 261 Subpart D](#), and does not exhibit a characteristic identified in [40 CFR 261 Subpart C](#).

- The following are not hazardous waste pharmaceuticals and not subject to 40 CFR parts 260 through 273 (including not being subject to Subpart P):
 - A pharmaceutical is not a solid waste, as defined in 40 CFR 261.2, and therefore not a hazardous waste pharmaceutical, if it is legitimately used/reused (e.g., lawfully donated for its intended purpose) or reclaimed.
 - An over-the-counter pharmaceutical, dietary supplement, or homeopathic drug is not a solid waste, as defined in 40 CFR 261.2, and therefore not a hazardous waste pharmaceutical, if it has a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for its intended purpose) or reclaimed.
 - The EPA Memo dated October 17, 2019 (<https://rcrapublic.epa.gov/files/14915.pdf>) clarifies reverse logistics applies to the entire retail sector, beyond pharmaceuticals/healthcare facilities and strongly emphasizes that items sent through reverse logistics (from a retail store to a reverse logistics facility) are not considered a waste (at the retail store) if they have some reasonable expectation of being legitimately used/reused or reclaimed.
- The following are not subject to 40 CFR parts 260 through 273, except as specified:
 - Household waste pharmaceutical means a pharmaceutical that is a solid waste, as defined in 40 CFR 261.2, but is excluded from being a hazardous waste under 40 CFR 261.4(b)(1) [*the household hazardous waste exclusion*]. Household waste pharmaceuticals, including those that have been collected by an authorized collector (as defined by the Drug Enforcement Administration), provided the authorized collector complies with the conditional exemption in 40 CFR 266.506(a)(2) and 266.506(b).

- Pharmaceuticals being managed in accordance with a recall strategy that has been approved by the Food and Drug Administration in accordance with 21 CFR part 7 Subpart C. Subpart P does apply to the management of the recalled hazardous waste pharmaceuticals after the Food and Drug Administration approves the destruction of the recalled items.
- Pharmaceuticals being managed in accordance with a recall corrective action plan that has been accepted by the Consumer Product Safety Commission in accordance with 16 CFR part 1115. Subpart P does apply to the management of the recalled hazardous waste pharmaceuticals after the Consumer Product Safety Commission approves the destruction of the recalled items.
- Pharmaceuticals stored according to a preservation order, or during an investigation or judicial proceeding until after the preservation order, investigation, or judicial proceeding has concluded and/or a decision is made to discard the pharmaceuticals.
- Investigational new drugs for which an investigational new drug application is in effect in accordance with the Food and Drug Administration's regulations in 21 CFR part 312. Subpart P does apply to the management of the investigational new drug after the decision is made to discard the investigational new drug or the Food and Drug Administration approves the destruction of the investigational new drug if the investigational new drug is a hazardous waste.

Step 3 - Waste Counting (waste counting has two steps (A and B) described below)

A. Hazardous Waste Category Applicability

For Healthcare Facilities:

- 1) Calculate the total hazardous waste generated at the entire site.

TOTAL Hazardous Waste for Site = Hazardous Waste Pharmaceuticals + Non-Pharmaceutical Hazardous Waste

- 2) Is the TOTAL hazardous waste amount for the entire healthcare facility greater than the threshold for a Very Small Quantity Generator (VSQG)? VSQG hazardous waste generator category threshold is as follows:
 - Greater than 220 lbs. (100 kg) in a calendar month for non-acute hazardous waste; and/or
 - Greater than 2.2 lbs. (1 kg) of acute hazardous waste in a calendar month; and/or
 - Greater than 100 kg (220 pounds) of residues from a clean-up of acute hazardous waste generated in a calendar month?
- 3) Does the facility have a total hazardous waste amount for the healthcare facility that is:
 - Greater than 2,200 lbs. (1000 kg) non-acute hazardous waste at any time; and/or
 - Greater than 2.2 lbs. (1 kg) acute hazardous waste at any time; and/or
 - Greater than 220 lbs. (100 kg) acute hazardous waste from a spill clean-up at any time?

If **YES** to #2 and/or #3, above, then healthcare facility must comply with 40 CFR 266 Subpart P requirements and notify the Hazardous Waste Section of this activity as a healthcare facility. Go to STEP 3B.

- See the *Management Standards for Hazardous Waste Pharmaceuticals Notification Requirement Guidance for Healthcare Facilities and Reverse Distributors* document on the Hazardous Waste Section website at this link for information on notification requirements:

<https://deq.nc.gov/about/divisions/waste-management/hw/technical-assistance-education-guidance/documents#hazardous-waste-pharmaceuticals>

If **NO** to both questions, then healthcare facility must comply with sewer prohibition but has the option to comply with very small quantity generator requirements (VSQG) in 40 CFR 262.14 or provisions of 40 CFR 266 Subpart P.

For Reverse Distributors:

If the site is a reverse distributor, the Subpart P requirements are applicable to all reverse distributors regardless of their generator category. The reverse distributor must comply with 40 CFR 266 Subpart P requirements and notify the Hazardous Waste Section of this activity as a reverse distributor. Do not go to STEP 3B.

- See the *Management Standards for Hazardous Waste Pharmaceuticals Notification Requirement Guidance for Healthcare Facilities and Reverse Distributors* document on the Hazardous Waste Section website at this link for information on notification requirements:
<https://deq.nc.gov/about/divisions/waste-management/hw/technical-assistance-education-guidance/documents#hazardous-waste-pharmaceuticals>

B. Counting Hazardous Waste for Healthcare Facilities after Notification of Subpart P Activity: Healthcare facilities that are large quantity generator (LQG) or small quantity generators (SQG) when calculating the **TOTAL** hazardous waste for the entire site (in Step 3A) must comply with Subpart P requirements. Once a LQG or SQG healthcare facility notifies as operating under Subpart P, the amount of hazardous waste pharmaceuticals does not need to be counted towards the generator category when managed under Subpart P (40 CFR 262.13(c)(9)).

- See the *Management Standards for Hazardous Waste Pharmaceuticals Notification Requirement Guidance for Healthcare Facilities* document on the Hazardous Waste Section website at this link for information on notification requirements: <https://deq.nc.gov/about/divisions/waste-management/hw/technical-assistance-education-guidance/documents#hazardous-waste-pharmaceuticals>
- When operating under Subpart P (including notification as a healthcare facility), the healthcare facility may subtract the amount of hazardous waste pharmaceuticals from the total amount of hazardous waste to determine generator category.
- Healthcare facilities previously operating as an SQG or an LQG prior to operating under Subpart P, may be able to reduce their hazardous waste generation category because hazardous waste generation is based only on non-pharmaceutical hazardous waste under Subpart P.
- When a healthcare facility is able to downgrade their category because they do not have to count the hazardous waste pharmaceuticals managed under Subpart P towards their generator category, they are still operating under Subpart P and must meet Subpart P requirements.
 - For example, when a SQG healthcare facility is able to downgrade to a VSQG healthcare facility because they no longer need to count the hazardous waste pharmaceuticals managed under Subpart P, they are still required to meet Subpart P requirements.
 - It is only the VSQG with the total hazardous waste (Hazardous Waste Pharmaceuticals + Non-Pharmaceutical Hazardous Waste) that has the option on whether to operate under the VSQG requirements of 40 CFR 262.14 or the Subpart P requirements.

Who do I contact if I have questions?

- Questions about **this document, hazardous waste, and management standards for hazardous waste pharmaceuticals**:
 - Contact your Hazardous Waste Section Inspector (contact information and region provided on the map at this link):
https://files.nc.gov/ncdeq/Waste%20Management/DWM/HW/Compliance/Compliance_Map_by_Inspector.pdf

- Questions about **management of non-hazardous waste pharmaceuticals and non-hazardous medical waste**:
 - Contact the NCDEQ, Solid Waste Section:
<https://deq.nc.gov/about/divisions/waste-management/medical-waste>