



Management Standards for Hazardous Waste Pharmaceuticals Notification Requirement Guidance for Healthcare Facilities and Reverse Distributors

This document provides information on the notification requirement for healthcare facilities generating hazardous waste pharmaceuticals and reverse distributors handling hazardous waste pharmaceuticals.

North Carolina adopted the federal provisions of [40 CFR 266 Subpart P](#) ("Subpart P") through incorporation by reference in [15A NCAC 13A .0111](#) without addition or amendment. These Subpart P provisions were effective in North Carolina on July 1, 2020, except for the sewer prohibition ([40 CFR 266.505](#)) which was effective nationwide August 21, 2019. The notification requirement is for healthcare facilities and reverse distributors to notify of performing hazardous waste pharmaceutical activities at their site.

What sites must notify as operating under Subpart P?

See the [Management Standards for Hazardous Waste Pharmaceuticals Applicability and Waste Counting Guidance for Healthcare Facilities and Reverse Distributors](#) document on the Hazardous Waste Section website at the following link for more information: <https://deq.nc.gov/about/divisions/waste-management/hw/technical-assistance-education-guidance/documents#hazardous-waste-pharmaceuticals>

Below is a very brief summary of the applicability of the regulation and when a site must notify of hazardous waste pharmaceutical activity.

- The Management Standards for Hazardous Waste Pharmaceuticals provisions apply to healthcare facilities and reverse distributors that manage hazardous waste pharmaceuticals.
- Any healthcare facility that operates as a small quantity generator (SQG) or large quantity generator (LQG) of hazardous waste when counting TOTAL hazardous waste for the site (TOTAL hazardous waste = hazardous waste pharmaceuticals + non-pharmaceutical hazardous waste for *the entire site*) **must notify** (i.e., it is mandatory) as operating under this Subpart P and must notify when the site withdraws from operating under Subpart P.
- A healthcare facility that is a very small quantity generator (VSQG) when counting the TOTAL hazardous waste for the site (TOTAL hazardous waste = hazardous waste pharmaceuticals + non-pharmaceutical hazardous waste *for the entire site*) **has the option of notifying** and operating under Subpart P or continue to operate under the requirements applicable to very small quantity generators ([40 CFR 262.14](#)).
- A healthcare facility that is co-located within a larger facility that is not a healthcare facility (e.g., a clinic at a military base, school, or manufacturer), must notify that it is operating as a healthcare facility under 40 CFR Part 266, Subpart P, unless the entire site is a VSQG. Co-located healthcare facilities share the same EPA identification number as the larger facility within which it is located. Accordingly, hazardous waste pharmaceutical activity at the healthcare facility will be included on the notification of the larger facility.
- A reverse distributor must comply with the provisions of this rule and **must notify** (i.e., it is mandatory) as operating under the rule (regardless of the hazardous waste generator category of the site).

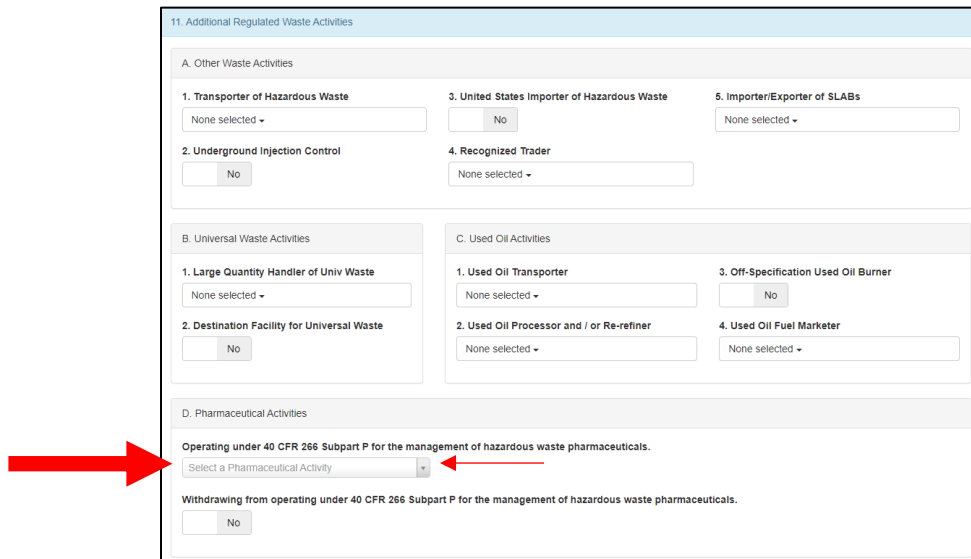
When must a healthcare facility or reverse distributor notify?

- For healthcare facilities:
 - A LQG healthcare facility must notify but may do so as part of its next Biennial Report.
 - A SQG healthcare facility must notify within 60 days of the effective date of Subpart P or within 60 days of becoming subject to the Subpart P provisions.

- A VSQG that opts into using the Subpart P provisions must notify within 60 days of the effective date or within 60 days of becoming subject to this rule. A VSQG must have an EPA ID number (or obtain one when they opt into using subpart P). It is optional for a VSQG to use subpart P provisions, but if the site uses the provisions, they must opt in.
- For reverse distributors:
 - Regardless of generator category, a reverse distributor must notify within 60 days of the effective date of Subpart P or within 60 days of becoming subject to Subpart P.

How does a site notify as operating under Subpart P?

- Notification of operating under the Subpart P provisions (a.k.a. operating under the Management Standards for Hazardous Waste Pharmaceuticals or “Pharmaceutical Activities” in RCRAInfo), is done by the site electronically in EPA's RCRAInfo database.
 - Link to the RCRAInfo database: <https://rcrainfo.epa.gov/rcrainfoprod/action/secured/login>
 - Anyone not already registered in the RCRAInfo database (or CDX), must first register in RCRAInfo, and create their own RCRAInfo account before making any site information updates (such as notifying of Pharmaceutical Activities). A tutorial (complete with step-by-step instructions and screen shots) that may be helpful with registration and using RCRAInfo can be found at this link: <https://files.nc.gov/ncdeq/Waste%20Management/DWM/HW/8700-guidelines/Electronic-Filing-of-EPA-Notifications.pdf>
 - If you are already registered in RCRAInfo, just sign into RCRAInfo. If you have a CDX account, sign in to the RCRAInfo website (<https://rcrainfo.epa.gov/rcrainfoprod/action/secured/login>) using your CDX credentials.
 - EPA provides instructions on completing the notification form at this link: https://rcrapublic.epa.gov/rcrainfoweb/documents/rcra_subtitleC_forms_and_instructions.pdf
 - Even though the notification is submitted electronically in EPA's database, the North Carolina Hazardous Waste Section reviews and accepts the RCRAInfo submittals and registration requests.
 - For questions about RCRAInfo please contact: Andrew Minter by phone: 919-707-8265 or by email: Andrew.Minter@ncdenr.gov
- To notify as operating under Subpart P, in RCRAInfo, myRCRAid module, electronic Site Identification form, Section 11.D “Pharmaceutical Activity” must be marked as either “Healthcare Facility” or “Reverse Distributor” by clicking on the drop-down arrow and selecting one of the options. See the below screen shot.



Click on the drop-down arrow and select either Healthcare Facility or Reverse Distributor (whichever applies to your site (or a portion of your site)).

D. Pharmaceutical Activities

Operating under 40 CFR 266 Subpart P for the management of hazardous waste pharmaceuticals.

Healthcare Facility x

Reverse Distributor

D. Pharmaceutical Activities

Operating under 40 CFR 266 Subpart P for the management of hazardous waste pharmaceuticals.

Healthcare Facility x

Withdrawing from operating under 40 CFR 266 Subpart P for the management of hazardous waste pharmaceuticals.

No

- Once a healthcare facility has notified as operating under Subpart P (by marking Section 11.D on the RCRAInfo Site Identification form as "Healthcare Facility") they may recalculate the site's hazardous waste generator category (and not include the amount of hazardous waste pharmaceuticals in the calculation). Go to Section 10.A.1 "Generator of Hazardous Waste" of the form and make any necessary updates to the hazardous waste generator category, now that the healthcare facility has notified under Subpart P. If you need more information on the hazardous waste generator categories, see the Generator Category Guidance on the Hazardous Waste Section website at this link: <https://files.nc.gov/ncdeq/Waste%20Management/DWM/HW/Guidance%20Document%20table%20documents/2018/Generator%20Category%20Guidance.pdf>

10. Type of Federal Regulated Waste Activity

A. Hazardous Waste Activities

1. Generator of Hazardous Waste (Federal) *

1 - Large Quantity Generator x

Generator of Hazardous Waste (State) *

F - Same as Federal x

2. Short Term Generator

No

3. Treater, Storer, or Disposer of Haz Waste

No

4. Receives Hazardous Waste from Off-site

No

5. Recycler of Hazardous Waste

Select Recycler Activity

6. Exempt Boiler and / or Industrial Furnace

None selected

Updates to the hazardous waste generator category can be made by clicking on the drop-down arrow and selecting the applicable hazardous waste generator category.

10. Type of Federal Regulated Waste Activity

A. Hazardous Waste Activities

1. Generator of Hazardous Waste (Federal) *

1 - Large Quantity Generator x

1 - Large Quantity Generator

2 - Small Quantity Generator

3 - Very Small Quantity Generator

N - Not a Generator

3. Treater, Storer, or Disposer of Haz Waste

No

4. Receives Hazardous Waste from Off-site

No

5. Recycler of Hazardous Waste

Select Recycler Activity

6. Exempt Boiler and / or Industrial Furnace

None selected

- Review the other information on the RCRAInfo Site Identification form and make any necessary updates to the site information.
 - Please ensure that Section 8 of the form "Site Contacts" has accurate information including an email address.

8. Site Contact Person

First Name * John	Middle Initial 	Last Name * Smith
Title Environmental Director	Email John.Smith@hospital.com	
Phone Number * 919-707-8200	Extension 	Fax

- Please always make a comment in Section 18 of the form briefly indicating the changes that were made on the form from the last submission and note that the facility is notifying under the Subpart P provisions.

18. Comments

Public Comments

How do I withdraw from Subpart P (Pharmaceutical Activities)?

A healthcare facility that operated under Subpart P but is no longer subject to the subpart because it is a very small quantity generator for all of its hazardous waste, including hazardous waste pharmaceuticals, may withdraw from managing its hazardous waste pharmaceuticals under 40 CFR Part 266, Subpart P. This may include a healthcare facility that 1) had been required to operate under Subpart P but no longer is because it generates VSQG amounts of hazardous waste, or 2) is a VSQG but chose to operate under Subpart P. A healthcare facility must notify the Hazardous Waste Section that it is withdrawing from this subpart before it begins operating under the conditional exemption of 40 CFR 262.14. Reverse distributors may NOT withdraw from this rule.

To withdraw from Subpart P, go to Section 11.D of the notification form.

D. Pharmaceutical Activities

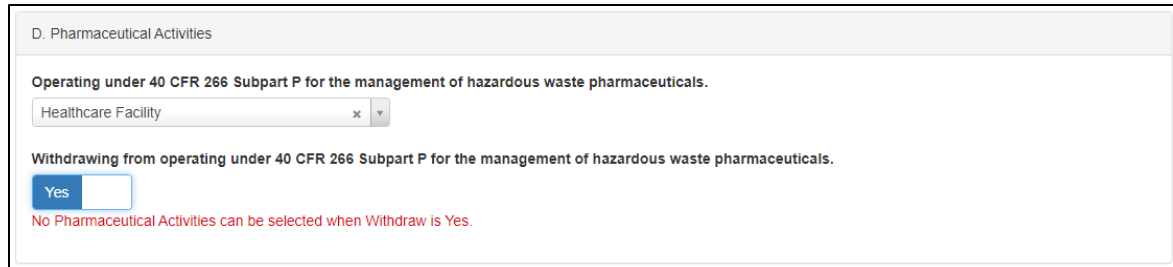
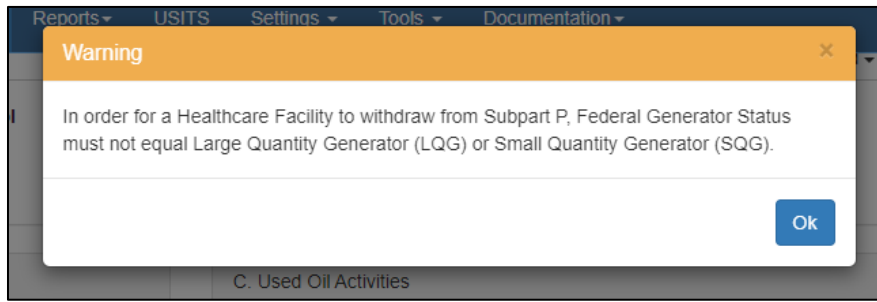
Operating under 40 CFR 266 Subpart P for the management of hazardous waste pharmaceuticals.

Healthcare Facility

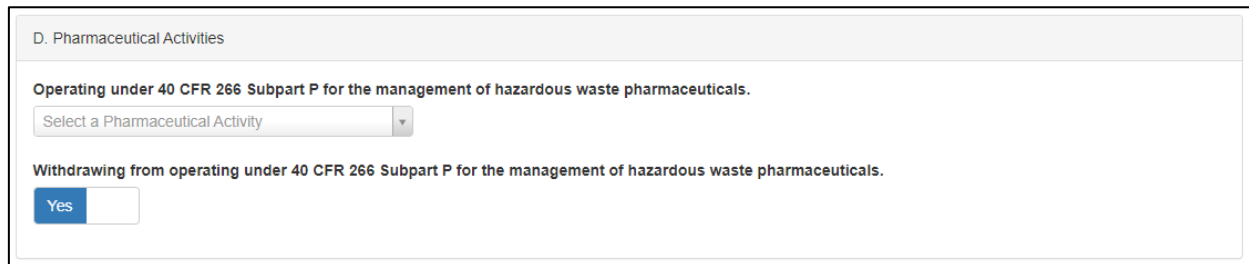
Withdrawing from operating under 40 CFR 266 Subpart P for the management of hazardous waste pharmaceuticals.

No

If you only switch the withdraw option in 11.D to “No,” you will receive the following message:

A screenshot of a web form titled "D. Pharmaceutical Activities". It contains the following elements: a section header "Operating under 40 CFR 266 Subpart P for the management of hazardous waste pharmaceuticals." followed by a dropdown menu currently showing "Healthcare Facility" with an "x" icon to its right; a second section header "Withdrawing from operating under 40 CFR 266 Subpart P for the management of hazardous waste pharmaceuticals." followed by a "Yes" button; and a red error message below the button: "No Pharmaceutical Activities can be selected when Withdraw is Yes."

To withdrawal from Subpart P, you must remove the selected “Healthcare Facility” from the first part of 11.D by clicking the “x” to the right of the words “Healthcare Facility.” Once this field shows as “Select a Pharmaceutical Activity,” then toggle the Yes/No button for “Withdrawing from operating under 40 CFR Subpart P for management of hazardous waste pharmaceuticals” to “Yes.”

A screenshot of the same web form as above, but after the change. The dropdown menu now shows "Select a Pharmaceutical Activity". The "Yes" button is still present, and the red error message is no longer visible.

What regulation requires a healthcare facility and a reverse distributor to notify?

- For SQG and LQG healthcare facilities: [40 CFR 266.502\(a\)](#), adopted by reference at [15A NCAC 13A .0111\(g\)](#).
- For Reverse Distributors: [40 CFR 266.510\(a\)\(1\)](#), adopted by reference at [15A NCAC 13A .0111\(g\)](#)

Where can I find more information about hazardous waste requirements?

- North Carolina hazardous waste guidance documents can be found at this link: <https://deq.nc.gov/about/divisions/waste-management/hw/technical-assistance-education-guidance/documents>
- Link to North Carolina hazardous waste laws and rules: <https://deq.nc.gov/about/divisions/waste-management/hw/rules>

Who can I contact if I have site specific hazardous waste questions?

For site specific question, contact your local 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