Pharmaceutical Waste Management Guide

Division of Waste and Hazardous Substances, Compliance and Permitting Section

The Pharmaceutical Rule

Pharmaceuticals, whether over-the-counter (OTC) or prescription, have always been regulated in accordance with Delaware's *Regulations Governing Hazardous Waste* (DRGHW). As of January 2021, the method of regulating hazardous waste pharmaceuticals and the sites who generate them has changed. These regulatory requirements are commonly referred to as the "Pharmaceutical Rule."

The Pharmaceutical Rule is intended to assist sites that generate hazardous waste pharmaceuticals with:

- making accurate hazardous waste determinations at the point of generation,
- streamlining the management of hazardous waste pharmaceuticals to ensure proper off-site, final management,
- avoiding dual requirements for hazardous waste pharmaceuticals that are also regulated by the Drug Enforcement Agency (DEA) and Food and Drug Administration (FDA), and
- eliminating the disposal of hazardous waste pharmaceuticals down the drain (also known as "sewering").

Another significant element of the Pharmaceutical Rule is the clarification as to the types of nicotine-containing products that are required to be managed as P075 listed hazardous wastes when disposed. With the adoption of the Pharmaceutical Rule, FDA-approved OTC nicotine replacement therapies (i.e., patches, gum, lozenges) are no longer regulated as P075 hazardous waste when disposed, while nicotine e-juices and e-cigarettes remain subject to the P075 listing. Please see the Nicotine Waste Management and Vape Shop & E-Cigarette Retailer Hazardous Waste Management fact sheets for more information on this specific waste stream.

Who Is Subject to the Pharmaceutical Rule?

Healthcare facilities and reverse distributors that generate and manage hazardous waste pharmaceuticals are subject to the rule. Pharmaceutical manufacturers, production facilities and other generators of hazardous waste pharmaceuticals are not subject to the pharmaceutical rule.

The rule is officially codified within DRGHW Section 266, Subpart P – Hazardous Waste Pharmaceuticals. Subpart P contains several definitions (§266.500), the most critical of which as they pertain to your site's operations are: "healthcare facility," "reverse distributor" and "pharmaceutical."

Please be aware that Subpart P regulations are sector specific (healthcare facility or reverse distributor) and waste specific (pharmaceuticals). Both criteria must be met for Subpart P to be applicable for pharmaceutical waste management.

For example, if a site does not meet the definition of a healthcare facility but generates pharmaceuticals that are hazardous waste when disposed - Subpart P does not apply. In this example, all hazardous waste pharmaceuticals must be managed in accordance with applicable hazardous waste regulations found in DRGHW Part 262.

Definition of a Healthcare Facility (§266.500)

When thinking of a healthcare facility, one thinks of hospitals, nursing homes, doctor's offices and other facilities commonly associated with medical treatments. However, "healthcare facility" as it is defined in DRGHW has a wider scope.

"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) Distribute, sell, or dispense pharmaceuticals, including over-the-counter pharmaceuticals, dietary supplements, homeopathic drugs, or prescription pharmaceuticals.

Healthcare facilities include, but are not limited to:

- Hospitals
- Psychiatric hospitals
- Health clinics
- Long-term care facilities
- Outpatient surgery centers
- Physician, Dental, and Optical offices
- Ambulance Services
- Veterinary clinics and hospitals
- Pharmacies - including mail-order
- Vape Shops
- Retailers of pharmaceuticals

Healthcare facilities does not include pharmaceutical manufacturers, reverses distributors, or reverse logistic centers.

Definition of a Reverse Distributor (§266.500)

Reverse distributors are the other business sector required to manage pharmaceutical waste in accordance with Subpart P. Reverse distribution is not the same as reverse logistics. Reverse distributors manage prescription pharmaceuticals, while reverse logistic operators manage non-prescription pharmaceuticals and other retail items.

A "Reverse Distributor" is:

- Any person that receives and accumulates prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer credit.
- Examples include forward distributors, third-party logistic providers, and pharmaceutical manufacturers, that process prescription pharmaceuticals for the facilitation of or verification of manufacturer credit.

If your site meets the definition of a reverse distributor, please see the Reverse Distribution & Reverse Logistics fact sheet for more guidance.

Definition of a Pharmaceutical (§266.500)

"Pharmaceutical" as defined in DRGHW includes, but is not limited to:

- Dietary Supplements
- Prescription drugs
- OTC drugs
- Homeopathic drugs
- Compounded drugs
- Investigational drugs
- Pharmaceuticals remaining in non-empty containers
- Personal protection equipment (PPE) contaminated with pharmaceuticals
- Clean-up waste from spills of pharmaceuticals
- Electronic nicotine delivery systems (ENDS), such as, e-cigarettes and vape pens
- Nicotine e-liquid/e-juice packaged for retail sale for use in ENDS, such as, pre-filled cartridges and vials.

"Pharmaceutical" does not include dental amalgam, sharps, or infectious waste. Sharps and other infectious waste are considered solid wastes and must be managed in accordance with Delaware's *Regulations Governing Solid Waste* (DRGSW) as applicable. For information on infectious waste management and a full version of DRGSW, visit: dnrec.alpha.delaware.gov/waste-hazardous/management/infectious

Making a Hazardous Waste Determination on Waste Pharmaceuticals

The aforementioned definition of "pharmaceutical" defines the item with respect to it being a product. To determine how (if at all) Subpart P is applicable to your business, a pharmaceutical must be evaluated when it becomes a waste.

When any pharmaceutical is disposed of or discarded, a hazardous waste determination is required. Making a hazardous waste determination on a waste pharmaceutical is the same as making a hazardous waste determination on any waste stream. The following questions can assist you in making a hazardous waste determination. Additional guidance is also found within the Basic Business Guide for Hazardous Waste Management and Hazardous Waste Management: Waste Determinations fact sheets.

1. **Is the waste excluded or exempt from being a hazardous waste?***
   Commonly excluded and/or exempted pharmaceutical wastes are:
   - household waste pharmaceuticals, and
   - OTC pharmaceuticals, dietary supplements, or homeopathic drugs that are legitimately used, reused or reclaimed.

2. **Is the waste a listed hazardous waste?***
   For pharmaceutical wastes, the P- and U- listed wastes are important to consider when making a hazardous waste determination. While a site may generate other listed hazardous waste, the following is a list of P- and U- listed hazardous waste pharmaceuticals. Italicized chemicals are chemotherapy agents.

   There are eight P-listed chemicals that are also pharmaceuticals. These are:

   -*Arsenic Trioxide* (P012)
   -Epinephrine base (P042)
   -Nicotine (P075)
   -Nitroglycerin (P081)
   -Phentermine (P046)
   -Physostigmine (P204)
   -Physostigmine salicylate (P188)
   -Warfarin >0.3% (P001)

   There are 21 U-listed chemicals that are also pharmaceuticals. These are:

   -Chloral hydrate (U034)
   -*Chlorambucil* (U035)
   -*Cyclophosphamide* (U058)
   -*Daunomycin* (U059)
   -Dichlorodifluoromethane (U075)
   -*Diethylstilbestrol* (U089)
   -Hexachlorophene (U132)
   -Lindane (U0129)
   -*Melphalan* (U151)
   -Mercury (U151)
   -*Mitomycin C* (U010)
   -Paraldehyde (U182)
   -Phenol (U188)
   -Reserpine (U200)
   -Resorcinol (U201)
   -Saccharin (U202)
   -Selenium sulfide (U205)
   -*Streptozotocin* (U206)
   -Trichloromonofluoromethane (U121)
   -*Uracil mustard* (U237)
   -Warfarin >0.3% (U248)

3. **Does the waste exhibit a hazardous characteristic?***

- ***Ignitable*** (D001) wastes have a flash point below 140°F or is an ignitable compressed gas.
    - Example: An aqueous drug formulation containing 24% or more of alcohol by volume may exhibit this characteristic
- ***Corrosive*** (D002) wastes are liquids with a pH ≤2 or ≥12.5.
    - Example: Compounded medication waste generated in a pharmacy
- ***Reactive*** (D003) wastes chemically react with substances, such as water, producing toxic fumes and/or are capable of detonation.
    - Example: Nitroglycerin
- ***Toxicity*** (D004 thru D043) These wastes will leach a toxic contaminant under acidic conditions, should the leached contaminant exceed the regulatory level, the waste pharmaceutical is a hazardous waste. Toxicity is determined by the Toxicity Characteristic Leaching Procedure (TCLP).
    - Example: A formulation containing lindane used to treat lice or scabies could be D013 when disposed

***NOTE:** Full details for exclusions, exemptions, listed and characteristic wastes, are found in DRGHW, Part 261.

If a waste pharmaceutical is determined to be a hazardous waste, Subpart P may be applicable to your healthcare facility's operations.

To assist with the requirement to make hazardous waste determinations, a site may elect to manage all pharmaceutical waste as hazardous waste pharmaceuticals to avoid making hazardous waste determinations on each individual waste pharmaceutical. This provision is encouraged as it eliminates the necessity to evaluate potentially hundreds or thousands of pharmaceuticals individually. If this option is selected, all waste meeting the definition of a pharmaceutical must be managed as hazardous, there is no option to pick and choose which waste pharmaceuticals will be managed as non-hazardous or hazardous – all pharmaceuticals would be managed as a hazardous waste pharmaceutical.

The final step to determine if your healthcare facility is required to comply with Subpart P is to determine generator category.

Determining Your Generator Category

Generator category is based on the amount of hazardous waste generated per calendar month. You will be either a very small quantity generator (VSQG), a small quantity generator (SQG), or a large quantity generator (LQG) of hazardous waste. Do not include the amount of excluded and/or exempt waste, non-hazardous waste, used oil, or universal waste when determining your generator category.

Add the amount non-pharmaceutical hazardous waste plus pharmaceutical hazardous waste to determine the total amount of hazardous waste generated by your site. You should keep these waste streams separate because if Subpart P is applicable to your site, hazardous waste pharmaceuticals are required to be managed separately than all other hazardous waste generated at your healthcare facility. Once the total amount of all hazardous waste has been determined, use the chart below to identify your site's generator category.

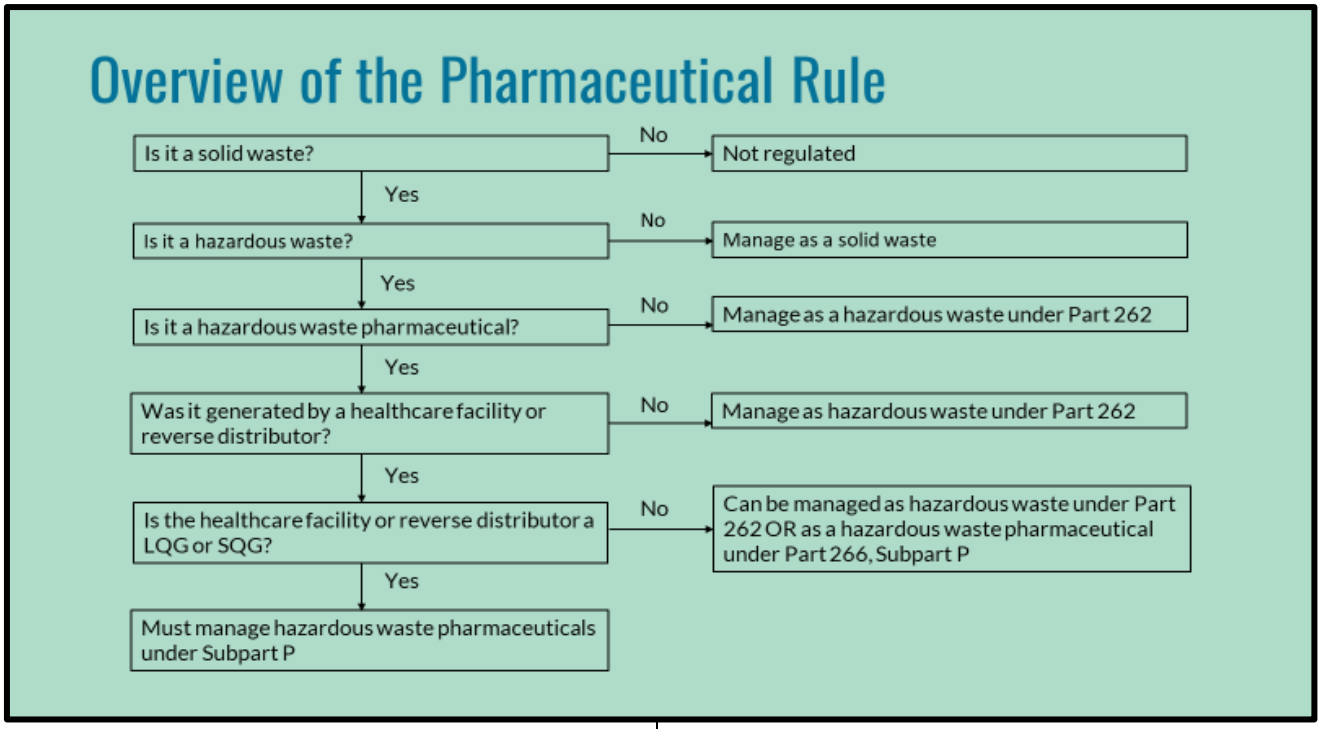
A common waste stream for healthcare facilities to consider when determining generator category is acute hazardous waste pharmaceutical residue remaining within containers. The pharmaceutical rule has new standards for the management of containers which allow those containers which held acute hazardous waste pharmaceuticals to be emptied through normal means and not be regulated as hazardous waste should certain conditions be met. Thus, this new rule may greatly impact a site's generator category. Below is one example of how the new management standards influence generator category, for further guidance and more examples please refer to the Empty Container Residues section of this guide.

- Example: Prior to the rule, pharmacies dispensing warfarin (P001) were either counting only the weight of the pill residue within the container towards their generator category or they were counting the weight of the warfarin container plus residue to determine generator category. Depending on how a pharmacy was counting, a pharmacy would be either a VSQG or a LQG because warfarin is a P-listed acute hazardous waste. Under the new requirements, the container would be considered "empty" and the residues and container would not be regulated as hazardous waste and not counted towards generator category.

Category:	Monthly Generation Rate:
VSQG	≤ 100 kg (220 lbs) ≤ 1 kg (2.2 lbs) acute hazardous waste
SQG	> 100 kg – < 1,000 kg (220 lbs – 2,200 lbs) ≤ 1 kg (2.2 lbs) acute hazardous waste
LQG	≥ 1,000 kg (2,200 lbs) > 1 kg (2.2 lbs) acute hazardous waste

Applicability of Subpart P

Now that your healthcare facility's generator category has been determined: **If your healthcare facility operates as a SQG or LQG of hazardous waste – the site is required to manage hazardous waste pharmaceuticals in accordance with Subpart P.** If your healthcare facility operates as a VSQG, hazardous waste pharmaceuticals must be managed in accordance with Part 262 or Part 266, Subpart P.



Notification Requirements

SQG and LQG healthcare facilities are required to comply with Subpart P and must notify with the CAPS for each site that is operating under Subpart P. VSQGs that elect to manage waste pharmaceuticals fully in accordance with Subpart P are also required to notify.

The hazardous waste generator status on the notification form is determined by the amount of only non-pharmaceutical hazardous waste generated within a month. So, while your healthcare facility may be a SQG or LQG when counting all hazardous waste for the applicability of Subpart P, it may not be a SQG or LQG after counting just non-pharmaceutical hazardous waste. Therefore, a healthcare facility must recalculate its generator category for only non-pharmaceutical hazardous waste to determine its true generator status. The follow are examples of how to apply the notification requirement:

- A pharmacy generated 3 lbs of acute hazardous waste pharmaceuticals and 85 lbs of non-pharmaceutical hazardous waste in a month, totaling 88 lbs of hazardous waste. Because of the amount of acute hazardous waste generated, the pharmacy is a LQG with respect to determining applicability for Subpart P. However, because the amount non-pharmaceutical hazardous waste is only 85 lbs, the pharmacy will notify as operating under Subpart P (if electing to fully opt in) and indicate the site is a VSQG on the notification form.

- A hospital generated 70 lbs of non-acute hazardous waste pharmaceuticals and 400 lbs of non-pharmaceutical hazardous spent solvents in a month, totaling 470 lbs of hazardous waste. The hospital is a SQG and is required to manage pharmaceuticals under Subpart P. Also, since the total of non-pharmaceutical hazardous waste is 470 lbs, the site is still a SQG for non-pharmaceutical hazardous waste and should select that status on the notification form.

Notification procedures are as follows:

- If this is your site's first time notifying **or** your site has an EPA identification number, but is not required to submit an Annual Report -- notification must be completed by March 21, 2021 or within 60 days of these regulations becoming applicable to your site's operations
- If your site has an EPA identification number and submits an Annual Report, notification of Subpart P activity can be made as part of the Annual Report submission.

Notification (and re-notification) are accomplished in one of two ways, either by submitting the form electronically through EPA's RCRAInfo application site or mailing/e-mailing a completed Site Identification Form (EPA Form 8700-12) to the CAPS. For more information on notifying, go the CAPS website at dnrec.alpha.delaware.gov/waste-hazardous/hazardous-waste-reporting

Very Small Quantity Generator (VSQG) Healthcare Facilities

If your healthcare facility operates as a VSQG for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste, you must manage hazardous waste pharmaceuticals in one of three ways:

- In accordance with §262.14 – which are the routine (non-pharmaceutical) hazardous waste management requirements.
  or
- Opt fully into using Subpart P and comply with all Subpart P regulations. If your healthcare facility opts into Subpart P, you may not utilize the optional provisions within §266.504. As a reminder, you must notify with the CAPS.
  or
- In accordance with §262.14 and utilize the optional provisions within §266.504. The optional provision allows for:
  - Sending potentially creditable hazardous waste pharmaceuticals to a reverse distributor (§266.504(a)). See the Shipping Off-Site to a Reverse Distributor section of this packet for guidance.
  - Sending hazardous waste pharmaceuticals off-site to another facility (§266.504(b)), provided that:
    - The receiving site is a healthcare facility operating under Subpart P and meeting the applicable criteria of §266.502(l) and §266.503(b).
      or
    - The VSQG is operating under §262.14(a)(6)(viii) and the receiving site is a non-healthcare facility operating as a LQG under Part 262 and meets the conditions for off-site consolidation as stated in §262.17(f). One of the conditions for this provision is that both the VSQG and the LQG must be controlled by the same person/entity.

Types of Hazardous Waste Pharmaceuticals

Subpart P breaks hazardous waste pharmaceuticals into three types: "potentially creditable hazardous waste pharmaceutical", "non-creditable hazardous waste pharmaceutical" and "evaluated hazardous waste pharmaceutical." The first two types of hazardous waste pharmaceuticals are managed by healthcare facilities, while evaluated hazardous waste pharmaceuticals are only managed by reverse distributors. The remainder of this fact sheet will address the management of potentially creditable and non-creditable hazardous waste pharmaceuticals. For information on the management of evaluated hazardous waste pharmaceuticals, please see refer to the Reverse Distribution & Reverse Logistics fact sheet.

A **"potentially creditable hazardous waste pharmaceutical"** is a prescription hazardous waste pharmaceutical that has a reasonable expectation to receive manufacturer credit and is:

(1) In original manufacturer packaging (except for pharmaceuticals that were subject to a recall);
(2) Undispensed; and
(3) Unexpired or less than one year past expiration date.

Non-prescription pharmaceuticals are not included in this definition. OTC drugs, homeopathic drugs, and dietary supplements are examples of non-prescription pharmaceuticals.

A **"non-creditable hazardous waste pharmaceutical"** is a:

- prescription hazardous waste pharmaceutical that does not have a reasonable expectation to be eligible for manufacturer credit, or
- A nonprescription hazardous waste pharmaceutical that does not have the reasonable expectation to be legitimately used, reused or reclaimed.

Examples include, but are not limited to, investigational drugs, free pharmaceutical samples, contaminated PPE, floor sweepings, pharmaceutical spill clean-up materials, and residues of pharmaceuticals remaining in containers.

When managing hazardous waste pharmaceuticals under Subpart P, requirements are not dependent on the healthcare facility's generator's category. Instead, management requirements change based on whether the hazardous waste pharmaceutical is potentially creditable or non-creditable.

Be aware that generator category remains a factor for all non-pharmaceutical hazardous wastes as those wastes must be managed in accordance with Part 262. When assessing the management requirements of Part 262, a healthcare facility will utilized the requirements based on their recalculated generator category for only non-pharmaceutical hazardous waste since waste pharmaceuticals managed under Subpart P do not count toward the site's generator category once the applicability of Subpart P has been determined.

Put another way, a healthcare facility managing hazardous waste pharmaceuticals under Subpart P does not have a generator category for hazardous waste pharmaceuticals, but it will be a VSQG, SQG, or LQG for non-pharmaceutical hazardous waste.

Managing Potentially Creditable Hazardous Waste Pharmaceuticals (§266.503)

Potentially creditable hazardous waste pharmaceuticals have less burdensome management requirements under Subpart P than non-creditable hazardous waste pharmaceuticals. However, to be able to be managed as such, the hazardous waste pharmaceuticals must meet the four criteria previously listed.

As a reminder, your healthcare facility may choose to manage potentially creditable non-hazardous waste pharmaceuticals as potentially creditable hazardous waste pharmaceuticals under Subpart P. This provision

eliminates the need to make hazardous waste determinations on each, separate pharmaceutical that meets the creditable criteria.

Accumulation Container Requirements

There are no accumulation container requirements for potentially creditable hazardous waste pharmaceuticals as there are for other hazardous waste accumulation containers. For example, there is no labeling requirement and no requirement to keep the container closed. However, a good management practice is to treat potentially creditable hazardous waste pharmaceuticals as a commodity since they must continue to meet the four criteria to be allowed to be managed under this provision.

Accumulation Limits

There is no limit to the amount of potentially creditable hazardous waste pharmaceuticals that may be accumulated by a healthcare facility.

There is no accumulation time limit by which potentially creditable hazardous waste pharmaceuticals need to be shipped off-site to a reverse distributor. However, since one of the criteria to meet the potentially creditable hazardous waste pharmaceutical is to be "unexpired or less than one year past expiration date", it is recommended that shipments be completed within a time frame that avoids your healthcare facility from being out of compliance with this requirement.

Shipping Off-Site to Reverse Distributor

Healthcare facilities must ship all potentially creditable hazardous waste pharmaceuticals to a reverse distributor. As previously mentioned, VSQGs may ship directly to a reverse distributor or consolidate shipments at another healthcare facility prior to shipping to a reverse distributor. Healthcare facilities are prohibited from sending any non-pharmaceutical hazardous waste (e.g., spent solvents, expired chemicals, etc.) or non-creditable pharmaceutical hazardous waste to the reverse distributor.

When shipping potentially creditable hazardous waste pharmaceuticals off-site to a reverse distributor, a hazardous waste manifest is not required. There is also no requirement to utilize a permitted hazardous waste transporter. Instead, healthcare facilities are allowed to utilize a shipping paper (e.g., bill of lading) and a common carrier (e.g., UPS, USPS, FedEx). Additionally, as always, the shipment must also be compliance with DOT requirements.

All shipments must be accounted for to ensure receipt by the reverse distributor. If within 35 calendar days of the shipment your healthcare facility has not received confirmation of delivery from the reverse distributor, you must contact the carrier/transporter and reverse distributor to determine the status of the shipment.

Reporting & Recordkeeping

There is no annual reporting requirement for hazardous waste pharmaceuticals managed under Subpart P. However, if your site still operates as a LQG due to other non-pharmaceutical hazardous waste streams, an annual report is required for those wastes.

A copy of the shipping paper utilized for each shipment to the reverse distributor must be maintained for three years from the date of the shipment. The document must confirm the delivery was made to the reverse distributor. The shipping documents may be maintained physically or electronically and must be readily available upon request.

Documentation used to make hazardous waste determinations (e.g., test results, waste analysis, SDS) on potentially creditable hazardous waste pharmaceuticals is not required to be maintained.

Managing Non-Prescription Potentially Creditable Pharmaceuticals

Your healthcare facility may generate waste pharmaceuticals that meet all the criteria of a potentially creditable hazardous waste pharmaceutical except the pharmaceutical isn't a prescription (e.g., OTC medications, dietary supplements, electronic cigarette). As long as there is a reasonable expectation of legitimate use, reuse (e.g., lawful donation or redistribution for its intended purpose) or reclamation of the non-prescription pharmaceutical waste, these are not considered a solid waste. However, instead of utilizing a reverse distributor (since they may only accept prescription pharmaceuticals), your facility would utilize a reverse logistics center.

Managing Non-Creditable Hazardous Waste Pharmaceuticals (§266.502)

Managing non-creditable hazardous waste pharmaceuticals is similar to managing other hazardous waste generated by your healthcare facility. For example, there are container standards, labeling requirements, accumulation time limits and manifesting requirements.

Additionally, your healthcare facility may choose to manage non-creditable non-hazardous waste pharmaceuticals as non-creditable hazardous waste pharmaceuticals under Subpart P. This provision eliminates the need to make hazardous waste determinations on each, separate waste pharmaceutical that is non-creditable. This makes compliance easier on healthcare facilities since all of the generated non-creditable waste pharmaceuticals may be managed as hazardous waste.

Accumulation Container Requirements

Containers used for the accumulation of non-creditable hazardous waste pharmaceuticals must be in good

condition (e.g., not cracked or leaking) and compatible with the waste contained within. If a hazardous waste pharmaceutical is ignitable/reactive or incompatible wastes are commingled within the same container, precautions must be taken to ensure the container remains intact and there are no releases or fires.

Should your healthcare facility generate a non-creditable hazardous waste pharmaceutical that is prohibited from being combusted (e.g., mercury arsenic trioxide), it must be accumulated within a separate container which is labeled with all applicable waste codes. If there is more than one combustion prohibited hazardous waste pharmaceutical generated, they can be commingled within the same container provided there are no incompatibility issues. A list of hazardous waste pharmaceuticals that cannot be combusted is found in Part 266, Appendix XI.

All containers must remain closed and controlled in a manner to prevent unauthorized access to the contents.

All containers must be clearly labeled, "Hazardous Waste Pharmaceuticals." Waste codes are not required for most non-creditable hazardous waste pharmaceuticals. Waste codes are only required for non-creditable hazardous waste pharmaceuticals that are prohibited from being combusted. The following is an example of an accumulation container label:

Accumulation Limits

There is no limit to the amount of non-creditable hazardous waste pharmaceuticals that may be accumulated by a healthcare facility.

Non-creditable hazardous waste pharmaceuticals may be accumulated for up to one year without a permit or interim status. You must be able to demonstrate the length of time the waste has been accumulated. This can be done by:

- Marking the accumulation container with the accumulation start date,
- Maintaining an inventory system that identifies the date when a non-creditable hazardous waste pharmaceutical first become a waste, or
- Placing the non-creditable hazardous waste pharmaceuticals into a designated area and identifying the earliest date that any of the non-creditable hazardous waste became a waste.

Shipping Off-Site for Final Management

All non-creditable hazardous waste pharmaceuticals must be shipped to a Treatment, Storage or Disposal facility (TSDF) for final management utilizing a permitted hazardous waste transporter. These wastes cannot be shipped to a reverse distributor.

A hazardous waste manifest and a Land Disposal Restriction (LDR) form must be utilized for all non-creditable hazardous waste pharmaceutical shipments from your healthcare facility. When completing the manifest, specific hazardous waste codes are only required for the non-creditable hazardous waste pharmaceuticals that cannot be combusted. For all other non-creditable hazardous waste pharmaceutical line items, you should write "PHARMS" or "PHRM" in the space designated for waste codes. As a note, the U.S. Environmental Protection Agency (EPA) has stated they prefer "PHRM" to be used on manifests since it a four-character code that works best with the uniform manifesting system.

Should your healthcare facility have a shipment of non-creditable hazardous waste pharmaceuticals rejected by the TSDF, please see §266.502(h) and/or §266.502(i)(2)(ii) for management requirements.

Employee Training

Healthcare facilities must train all employees that manage non-creditable hazardous waste pharmaceuticals. This training is not an annual requirement, but a one-time requirement. Employees must be trained to ensure they are thoroughly familiar with proper waste handling and emergency procedures that are relevant to their responsibilities during normal operations and emergencies.

For example, should a nurse need to dispose of an IV bag that is not completely empty, the nurse would need to be trained in the proper management of non-creditable hazardous waste pharmaceuticals.

You may find it easier and a best management practice to train employees on the overall management of pharmaceutical waste rather than only focusing on non-creditable hazardous waste pharmaceuticals, but this is not required.

Reporting & Recordkeeping

There is no annual reporting requirement for hazardous waste pharmaceuticals managed under Subpart P. However, if your site still operates as a LQG due other non-pharmaceutical hazardous waste streams, an annual report is required for those wastes.

A copy of the manifest utilized for each shipment must be maintained for three years from the date of the shipment. Manifests may be maintained physically or electronically and must be readily available upon request.

- If a TSDF signed manifest copy has not been provided to your healthcare facility within 60 days of a shipment being accepted by initial transporter, "exception reporting" requirements must be initiated (§266.502(i)(2)(i)). Exception reporting documentation must also be maintained for three years from the date the report was created.

Documentation used to make hazardous waste determinations on non-creditable hazardous waste pharmaceuticals must be maintained for three years since the waste was last sent off-site to a TSDF. However, should your site elect to manage all non-creditable pharmaceutical waste as hazardous, hazardous waste determinations are not required. As such, there is also no corresponding record keeping requirement.

Training records (e.g., class log with employee signatures, computer training that indicates employee completed the training) must be maintained for three years from the date the employee was trained.

All required documentation may be maintained physically or electronically and must be readily available upon request.

Spills of Hazardous Waste Pharmaceuticals

Spills happen, and when they do, the spill must be contained immediately. Both spills of potentially creditable hazardous waste pharmaceuticals and non-creditable hazardous waste pharmaceuticals must be managed as non-creditable hazardous waste pharmaceuticals.

Long-term Care Facilities

A long-term care facility is a specific subset of healthcare facilities that is defined in §266.500 as a licensed entity that provides assistance with activities of daily living, including managing and administering pharmaceuticals to one or more individuals at the facility. This definition includes, but is not limited to:

- Hospice facilities
- Nursing facilities
- Skilled nursing facilities
- Nursing and skilled nursing care portions of continuing care retirement communities.

Not included within the scope of this definition are:

- Group homes
- Independent living communities,
- Assisted living facilities, and
- Independent and assisted living portions of continuing care retirement communities.

Long-term care facilities are required to determine their generator category just like any other healthcare facility, but those with 20 beds or fewer are presumed to be VSQGs (§266.504(d)). A long-term healthcare facility with more than 20 beds may still meet the VSQG criteria, but the site must be able to demonstrate its generator category as a VSQG.

If your long-term care facility is a VSQG and maintains a registered U.S. Drug Enforcement Agency (DEA) approved on-site drug collection container, per §266.504(c), your facility is allowed to dispose of waste pharmaceuticals (both hazardous and non-hazardous) within the DEA-authorized containers. These DEA containers are the same ones that are approved to collect controlled substances. In order to use this provision for waste pharmaceutical management, your site must be managing the containers and their contents in accordance with DEA controlled substance regulations. This includes the collection, storage, transportation, destruction and disposal of the waste pharmaceuticals and controlled substances. Failure to do so will result in your site being required to manage hazardous waste pharmaceuticals in accordance with all applicable hazardous waste regulatory requirements for VSQGs.

Please note, you may not put personal protective equipment (e.g., gloves, glasses, gowns, etc.) or spent spill clean-up materials into the DEA collection containers. Those wastes must be managed separately according to the hazardous waste determination made on those wastes by your site.

Controlled Substances Exemption (§266.506)

As previously mentioned, the DEA regulates the management of drugs and pharmaceuticals they have deemed to be "controlled substances." Controlled substances are drugs, substances, and certain manufacturing chemicals that are categorized by the DEA based on their acceptable medical use, risk of being abused, and their dependency (addiction) potential. The DEA refers to their categorization as "schedules" and there are five schedules of drugs (e.g., Schedule III, Schedule IV). Schedule I drugs that have currently no accepted medical use and a high potential for abuse, while Schedule V drugs have lower potentials for abuse and limited quantities of narcotics. For example, heroin is a Schedule I drug, while oxycodone is a Schedule II drug. Controlled substances can also be hazardous waste pharmaceuticals, which leads to a regulatory overlap when the pharmaceutical is destined for disposal. In order to relieve the burden on generators, DRGHW provides an exemption for hazardous waste generators to manage their hazardous waste pharmaceuticals that are also controlled substances in accordance with DEA regulations. This exemption is valid as long as all requirements of §266.506 are met.

There are eight hazardous waste pharmaceuticals that are also controlled substances, and they are:

- Chloral/Chloral hydrate
- Fentanyl sublingual spray
- Phenobarbital
- Testosterone gel or solutions
- Valium injectables or gel
- Paraldehyde (not commonly used)
- Paregoric (not commonly used)
- Opium tinctures (not commonly used)

If the hazardous waste pharmaceutical you are disposing of is not one of these eight, it cannot be managed as a DEA controlled substance. It is required to be managed as a hazardous waste pharmaceutical. Only VSQG long-term care facilities are allowed to manage all their hazardous waste pharmaceuticals as DEA controlled substances provided the site meets the previously stated conditions within the Long-Term Care Facilities section of this guide.

Healthcare facilities, especially hospitals, should be cautious about the management of "sequestration units" because of the types of waste that healthcare workers dispose of within the unit. While the units are intended for the collection of partially administered DEA controlled substances ("wastage"), healthcare workers frequently utilize sequestration units to dispose of all pharmaceuticals – including those that may be hazardous waste. The CAPS recommends evaluating the use of sequestration units and developing a plan to ensure the units meet DRGHW requirements (i.e., container labeling, final disposal at a TSDF). For example, sequestration units are intended to collect pharmaceutical wastage which would be permissible to throw away as non-hazardous waste with prior written approval from the landfill. However, if the unit was used to accumulate hazardous waste pharmaceuticals, throwing it into the trash would result in a major violation of DRGHW.

Sewering Ban (§266.505)

All healthcare facilities – including VSQGs who elect to manage their waste in accordance with §262.14 instead of Subpart P – are subject to the sewering ban. The ban states that all healthcare facilities are prohibited from discharging hazardous waste pharmaceuticals to a sewer system that passes through a publicly-owned treatment works (POTW). In other words, healthcare facilities are not allowed to dispose of hazardous waste pharmaceuticals by pouring them down the drain or flushing them down the toilet.

Healthcare facilities remain subject to the national pretreatment standard prohibitions stated in 40 CFR 403.5(b)(1). Please note that while not explicitly stated in DRGHW's sewering ban regulation, other state and federal regulatory programs prohibit the discharge of hazardous waste (including pharmaceuticals) to septic tanks, privately owned treatment works and federally owned treatment works.

The sewering ban applies to all hazardous waste pharmaceuticals including those that are generated through the course of operations, those that are also DEA controlled substances, and those which are collected through household pharmaceutical "take-back" collection programs.

While the sewering ban expressly prohibits healthcare facilities from sewering hazardous waste pharmaceuticals, DNREC strongly encourages that non-hazardous waste pharmaceutical also not be sewered.

Empty Container Residues (§§261.7 and 266.507)

Historically, containers of acute hazardous waste pharmaceuticals were not considered "RCRA empty" and could not be disposed of as non-hazardous waste until containers were empty of product and triple rinsed to remove the residues left by the product. As such, healthcare facilities elected to dispose of the entire empty container as an acute hazardous waste in lieu of completing the triple rinsing process.

The Pharmaceutical Rule includes regulations that allow generators to manage empty containers of both acute and non-acute hazardous waste pharmaceuticals as "RCRA empty" without triple rinsing the containers as long as the container is emptied through commonly employed normal methods. For example, a bottle of pills is commonly emptied through normal use when all of the pills have been given out to patients or to fill a prescription. Conversely, an IV bag containing medication that is only half administered to a patient can't be cut open and drained into a container to be considered "empty" because that is not how IV bags are emptied through normal use. On the next page, you will find a table that states what "RCRA empty" means for common types of hazardous waste pharmaceuticals containers found in healthcare settings. There are four different standards based on container type, such as, stock bottles, syringes, IV bags and other containers.

If the hazardous waste pharmaceutical container meets the empty container standard, the container and the residues are not regulated as hazardous waste. However, if the container does not, or cannot, meet the empty container standards, the container and the contents must be managed as non-creditable hazardous waste pharmaceuticals.

	Non-acute HW Pharms	Acute HW Pharms*
Stock Bottle, Dispensing Bottle, Ampule, or Vial (stock containers up to 1 liter or 10, 000 pills) and Unit-Dose Containers (e.g., blister pack, cup, wrapper, etc.)	Remove contents	Remove contents
Syringes	Fully depress plunger	Fully depress plunger
IV Bags	Fully administer contents or §261.7(b)(1)	Fully administer contents
Other Containers (e.g., Inhalers, Aerosol Cans, Tubes of Ointment/Gels/Creams, etc.)	§261.7(b)(1) or (2) "RCRA empty"	Cannot be RCRA empty (manage as non-creditable hazardous waste pharmaceutical)

*No required triple rinsing of containers of acute hazardous waste pharmaceuticals.

Household Waste Pharmaceuticals Collection Event Exemption (§266.506)

While household generated waste pharmaceuticals are exempt from DRGHW, it doesn't mean that households aren't frequent generators of waste pharmaceuticals that have the potential to cause harm to humans and the environment. Thus, efforts are made by pharmacies, hospitals, municipalities, and the DEA to encourage participation in disposal options that do not involve landfilling or sewering to keep waste pharmaceuticals from being accessible for abuse and from building up in the ecosystem. These specialized "take-back" collection programs and events are exempt from DRGHW as long as the entity collecting the waste pharmaceuticals does not sewer any of the waste pharmaceuticals, collects and stores them in compliance with DEA regulations for controlled substances, and ensures they are ultimately destroyed in a manner that meets the DEA's "non-retrievable standards."

This fact sheet is a summary provided as a courtesy to businesses. It is not intended as a substitute for 7 DE Admin. Code 1302, Delaware's *Regulations Governing Hazardous Waste* (DRGHW), Parts 260-266, 268, 273 and 279.
regulations.delaware.gov/AdminCode/title7/1000/1300/1302/

Department of Natural Resources
and Environmental Control
Compliance and Permitting Section
89 Kings Hwy
Dover, DE 19901
302-739-9403
dnrec.delaware.gov
de.gov/dwhs