



MANAGEMENT STANDARDS FOR HAZARDOUS WASTE PHARMACEUTICALS

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MANAGEMENT STANDARDS FOR HAZARDOUS WASTE PHARMACEUTICALS

New regulations were established for the management of Hazardous Waste (HW) pharmaceuticals by healthcare facilities and reverse distributors. These regulations:

- Create conditional exemption for Drug Enforcement Administration (DEA) controlled substances.
- Redefine when Subpart P containers are Resource Conservation and Recovery Act (RCRA) empty.
- Establish U.S. Environmental Protection Agency (EPA) policy on status of unsold retail items managed at reverse logistics centers.
- Create prohibition on sewerage of HW pharmaceuticals.
- Amends P075 Acute HW listing for nicotine and salts.

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FEDERAL REGULATION EFFECTIVE DATES



(Photo: Dental Recycling North America)

- The federal regulation became effective Aug. 21, 2019.
- Part 266 Subpart P becomes effective **after** authorized states adopt the rule.
 - States are required to adopt Subpart P by July 1, 2021 or 2022.
- The nicotine amendment becomes effective after authorized states adopt the rule.
 - States are not required to adopt the amendment.
- The sewer prohibition became effective in ALL states, regardless of whether Subpart P is adopted.
 - This prohibition applies to ALL generators, including Very Small Quantity Generators (VSQGs).

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STATE OF FLORIDA EFFECTIVE DATES



- Aug. 21, 2019
 - The nicotine amendment and Part 266 Subpart P were adopted and became effective in Florida
- June 26, 2019
 - Florida adopts 40 Code of Federal Regulations (CFR) 266 Subpart P, the sewerage prohibition and nicotine amendment by reference.
- Aug. 16, 2019
 - Florida repeals the Universal Pharmaceutical Waste Regulation, 62-730.186, Florida Administrative Code (F.A.C.).

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SEWER PROHIBITION

As of Aug. 21, 2019, healthcare facilities are prohibited from discharging HW pharmaceuticals to a sewer system.

This applies to all generators, including VSQGs and includes HW controlled substances and HW pharmaceutical wastage.



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SEWER PROHIBITION EXCLUSION AMMENDMENT

The following materials are not solid waste for the purposes of 40 CFR 261:

- Domestic sewage.
- Any mixture of domestic sewage and other waste that passes through a sewer system to a publicly-owned treatment works (POTW) for treatment, **except as prohibited by 40 CFR 266.505** and Clean Water Act requirements at 40 CFR 403.5(b). "Domestic sewage" means untreated sanitary wastes that pass through a sewer system.

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PRETREATMENT STANDARDS SPECIFIC PROHIBITED DISCHARGES

The following pollutants shall not be introduced into a POTW:

- Pollutants which create a fire or explosion hazard in the POTW, including, but not limited to, waste streams with a closed cup flashpoint of less than 140°F (60°C).
- Pollutants which will cause corrosive structural damage to the POTW, but in no case discharges with pH lower than 5.0, unless the works is specifically designed to accommodate such discharges.

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AMENDMENT OF NICOTINE LISTING

EPA has amended the P075 listing for nicotine to exempt “Food and Drug Administration (FDA) approved over-the-counter nicotine replacement therapies”, concluding that nicotine patches, gums and lozenges do not meet the regulatory criteria for acute HW.

- Nicotine patches, gums and lozenges can be discarded as non-HW.



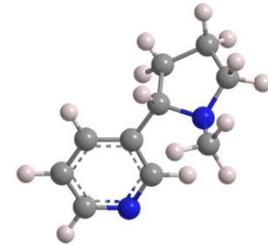
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AMENDMENT OF NICOTINE LISTING CONTINUED

Other unused formulations of nicotine will still be considered P075 when discarded, including:

- E-liquid/e-juice in e-cigarettes, cartridges or vials.
- Prescription nicotine (e.g., nasal spray, inhaler).
- Legacy pesticides containing nicotine.
- Nicotine used in research and manufacturing.



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40 CFR PART 266 SUBPART P

40 CFR Part 266 contains standards for the management of specific hazardous waste and specific types of hazardous waste management facilities, including:

- Recyclable materials used in a manner constituting disposal.
- Precious metals.
- Lead-acid batteries.
- Hazardous waste burned in boilers and industrial furnaces.
- Military munitions.
- Mixed wastes.
- Hazardous waste pharmaceuticals under 40 CFR 266 Subpart P.

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STANDARDS NOT COVERED

Although Subpart P includes regulations/guidance regarding reverse distribution of prescription pharmaceuticals and reverse logistics of unsold retail items, these standards will not be covered today.

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40 CFR PART 266 SUBPART P APPLICABILITY

The final rule applies to healthcare facilities that generate, accumulate or otherwise handle HW pharmaceuticals and reverse distributors engaged in the management of prescription HW pharmaceuticals.

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SUBPART P NEW DEFINITIONS

Below are new terms defined by the regulation:

- Pharmaceutical.
- Hazardous waste pharmaceutical.
 - Non-creditable HW pharmaceutical.
 - Potentially creditable HW pharmaceutical.
 - Evaluated HW pharmaceutical.
- Healthcare facility.
- Long-term care facility.
- Household pharmaceutical waste.
- Reverse distributor.

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NEW DEFINITIONS

PHARMACEUTICAL

- A pharmaceutical is defined as:
 - Any drug or dietary supplement for use by humans or other animals.
 - Any electronic nicotine delivery system:
 - Electronic cigarette or vaping pen.
 - Any liquid nicotine (e-liquid) packaged for retail sale for use in electronic nicotine delivery systems:
 - Pre-filled cartridges or vials.

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NEW DEFINITIONS PHARMACEUTICAL CONTINUED

The definition of “pharmaceutical” applies to finished product electronic nicotine delivery systems, including components and parts, sealed in final packaging intended for consumer use (e.g., electronic cigarettes and vaping pens) and e-liquid that is packaged for retail use in the electronic nicotine delivery systems (e.g., pre-filled cartridges and vials that are sold separately to consumers or as part of kits).

E-liquid used by manufacturers of tobacco products (as defined by the FD&C Act) is not included in the final definition of “pharmaceutical.”

That means e-liquid that is sold or distributed for further manufacturing, mixing or packaging into a finished electronic nicotine delivery system is **not** included.

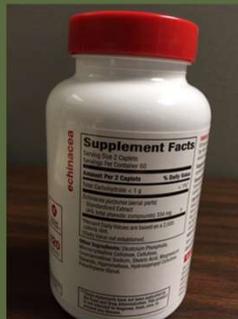
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NEW DEFINITIONS PHARMACEUTICAL CONTINUED

Pharmaceuticals include, but are not limited to:

- Dietary supplements.
- Prescription drugs.
- Over-the-counter drugs.
- Homeopathic drugs.
- Compounded drugs.
- Investigational new drugs.
- Pharmaceuticals remaining in non-empty containers.
- PPE contaminated with pharmaceuticals.
- Clean-up material from spills of pharmaceuticals.



Dietary
Supplement Label



Drug Facts Label

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NEW DEFINITIONS

HW PHARMACEUTICAL CONTINUED

The following are NOT considered a HW Pharmaceutical:

- A pharmaceutical is not a solid waste (as defined in 40 CFR 261.2) and therefore not a HW 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 HW pharmaceutical, if it has a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for its intended purpose) or reclaimed.
- A household waste pharmaceutical is a solid waste, as defined in 40 CFR 261.2, but is excluded from being a HW under 40 CFR 261.4(b)(1).

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DONATIONS

HW PHARMACEUTICAL CONTINUED

A pharmaceutical is not a solid waste if it is lawfully donated for its intended purpose, including donations to a charity, non-governmental organization or to a healthcare facility that is participating in a donation or repository program that is authorized by the state.

Repurposing pharmaceuticals happens under narrow circumstances and state donation and repository laws dictate the conditions under which pharmaceuticals may be donated.

In addition to the state regulations, the Food and Drug Administration has guidelines for the donation of pharmaceuticals for international relief efforts, as does the World Health Organization.

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NEW DEFINITIONS

HW PHARMACEUTICAL CONTINUED

HW pharmaceuticals can be further defined into three types:

- Non-creditable HW pharmaceuticals.
- Potentially creditable HW pharmaceuticals.
- Evaluated HW pharmaceuticals.

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NEW DEFINITIONS

NON-CREDITABLE HW PHARMACEUTICAL

A non-creditable HW pharmaceutical is defined as:

- A prescription HW pharmaceutical that does not have a reasonable expectation to be eligible for manufacturer credit.
- A non-prescription HW pharmaceutical that does not have a reasonable expectation to be legitimately used/reused or reclaimed.

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NEW DEFINITIONS

NON-CREDITABLE HW PHARMACEUTICAL CONTINUED

Examples of non-creditable HW pharmaceuticals include, but are not limited to:

- Free samples of pharmaceuticals received by healthcare facilities.
- Investigational drugs.
- Pharmaceuticals more than one year past their expiration date.
- Residues of pharmaceuticals remaining in non-empty containers.
- Floor sweepings and spill cleanup from spills of pharmaceuticals and personal protective equipment.
- Pharmaceuticals removed from original container and repackaged for dispensing.
- Pharmaceuticals in leaking or damaged packaging.
- Dispensed pharmaceuticals returned to pharmacy after third-party payer compensation received.

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NEW DEFINITIONS

POTENTIALLY CREDITABLE HW PHARMACEUTICAL

A potentially creditable HW pharmaceutical is defined as a prescription HW pharmaceutical that has a reasonable expectation to receive manufacturer credit; and is

- In original manufacturer packaging (except pharmaceuticals that were subject to a recall).
- Undispensed.
- Unexpired or less than one year past expiration date.

This term does not include evaluated HW pharmaceuticals or non-prescription pharmaceuticals (e.g., over-the-counter drugs, dietary supplements, homeopathic drugs).

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NEW DEFINITIONS

EVALUATED HW PHARMACEUTICAL

An evaluated HW pharmaceutical is defined as a prescription HW pharmaceutical that has been evaluated by a reverse distributor in accordance with 40 CFR 266.510(a)(3) and will not be sent to another reverse distributor for further evaluation or verification of manufacturer credit.

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NEW DEFINITIONS

HEALTHCARE FACILITY

A healthcare facility is defined as any person that is lawfully authorized to:

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

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NEW DEFINITIONS

HEALTHCARE FACILITY CONTINUED

<p>Healthcare facility includes, but is not limited to:</p> <ul style="list-style-type: none"> • Wholesale distributors. • Hospitals. • Psychiatric hospitals. • Ambulatory surgical centers. • Health clinics. • Physician's offices. • Optical and dental providers. • Chiropractors. • Long-term care facilities. • Pharmacies (including compounding). • Retailers of pharmaceuticals. • Veterinary clinics and hospitals. 	<p>Healthcare facility does NOT include:</p> <ul style="list-style-type: none"> • Pharmaceutical manufacturers. • Reverse distributors. • Reverse logistics centers.
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NEW DEFINITIONS

LONG-TERM CARE FACILITY

A long-term care facility is defined 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.

<p>Includes, but is not limited to:</p> <ul style="list-style-type: none"> • Hospice facilities. • Nursing facilities. • Skilled nursing facilities. • Nursing and skilled nursing care portions of continuing care retirement communities. 	<p>Does NOT include:</p> <ul style="list-style-type: none"> • Group homes. • Independent living communities. • Assisted living facilities. • Independent and assisted living portions of continuing care retirement communities.
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NEW DEFINITIONS

HOUSEHOLD WASTE PHARMACEUTICAL

A household waste pharmaceutical is defined as a pharmaceutical that is a solid waste, as defined in 40 CFR 261.2, but is excluded from being HW under 40 CFR 261.4(b)(1).

A household includes:

- Single/multiple residences.
- Hotels/motels.
- Bunkhouses/ranger stations/crew quarters.
- Campgrounds/picnic grounds/day-use recreation areas.

To be considered household waste, the following must be met:

- Waste must be generated by individuals on the premise of a temporary or permanent residence.
- The waste stream must be composed primarily of materials found in wastes generated by consumers in their homes.

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NEW DEFINITIONS

RESVERSE DISTRIBUTOR

A reverse distributor is defined as any person that receives and accumulates prescription pharmaceuticals that are potentially creditable HW pharmaceuticals for the purpose 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

- A DEA-registered reverse distributor may or may not meet the EPA's definition of a reverse distributor.

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VSQG APPLICABILITY

“A healthcare facility that is a VSQG when counting all of its HW, including both its HW pharmaceuticals and its non-pharmaceutical HW, remains subject to 40 CFR 262.14 (VSQG Requirements) and is not subject to this subpart, **except** for 40 CFR 266.505 (Sewering Prohibition) and 40 CFR 266.507 (Empty Containers) and the optional provisions of 40 CFR 266.504.”

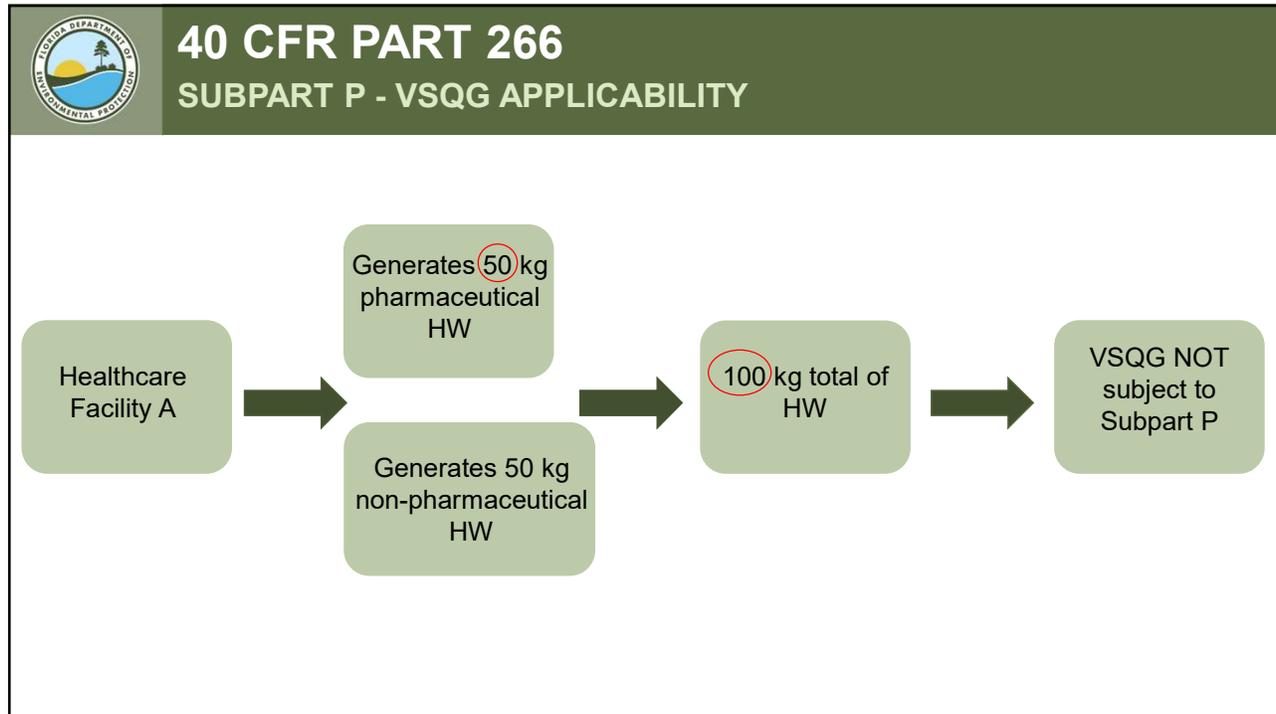
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40 CFR PART 266 SUBPART P - VSQG APPLICABILITY

“A healthcare facility that is a VSQG when counting all of its HW, including both its HW pharmaceuticals and its non-pharmaceutical HW, has the option of complying with 40 CFR 266.501(d) (**opting into** ALL Subpart P) for the management of HW pharmaceuticals as an alternative to complying with 40 CFR 262.14 (VSQG Requirements) and the optional provisions of 40 CFR 266.504.”

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40 CFR PART 266
SUBPART P - VSQG COMPLIANCE

VSQGs that do not opt into Subpart P:

- Must still comply with the hazardous waste sewerage prohibition.
- Must comply with the empty container standards.
- May comply with the optional provisions of 40 CFR 266.504.

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40 CFR PART 266

SUBPART P - VSQG COMPLIANCE

A VSQG healthcare facility can continue to send potentially creditable HW pharmaceuticals to a reverse distributor.

A VSQG healthcare facility can send its HW pharmaceuticals off-site to another healthcare facility provided the receiving healthcare facility:

- Meets 266.502(l) – Under control of same ‘person’, manages the non-creditable HW pharmaceuticals in compliance with 266 Subpart P.
- Meets 266.503(b) – Under control of same ‘person’, manages the potentially creditable HW pharmaceuticals in compliance with 266 Subpart P.

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40 CFR PART 266

SUBPART P - VSQG COMPLIANCE

A long-term care facility that is a VSQG can dispose of its HW pharmaceuticals in an on-site collection receptacle that complies with DEA regulations.

- DEA collection receptacles can only be used for controlled substances that are from the ultimate user.

A long-term care facility with 20 beds or fewer will be “presumed” to be a VSQG and not subject to 40 CFR 266 Subpart P, except the sewer prohibition.

- A long-term care facility with more than 20 beds must demonstrate that it is a VSQG.

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40 CFR PART 266

SUBPART P – SQG/LQG APPLICABILITY

A healthcare facility that is a small quantity generator (SQG), large quantity generator (LQG) or reverse distributor when counting all of its HW, including both its HW pharmaceuticals and its non-pharmaceutical HW, must comply with Subpart P.

In other words, Subpart P applies to a healthcare facility that generates:

- More than 100 kg of hazardous waste per calendar month; or
- More than 1 kg of acute hazardous waste per calendar month; or
- More than 100 kg of any residue or contaminated soil, water or other debris resulting from the cleanup of a spill into or on any land or water of any acute hazardous wastes listed in 40 CFR 261.31 or 261.33(e) per calendar month.

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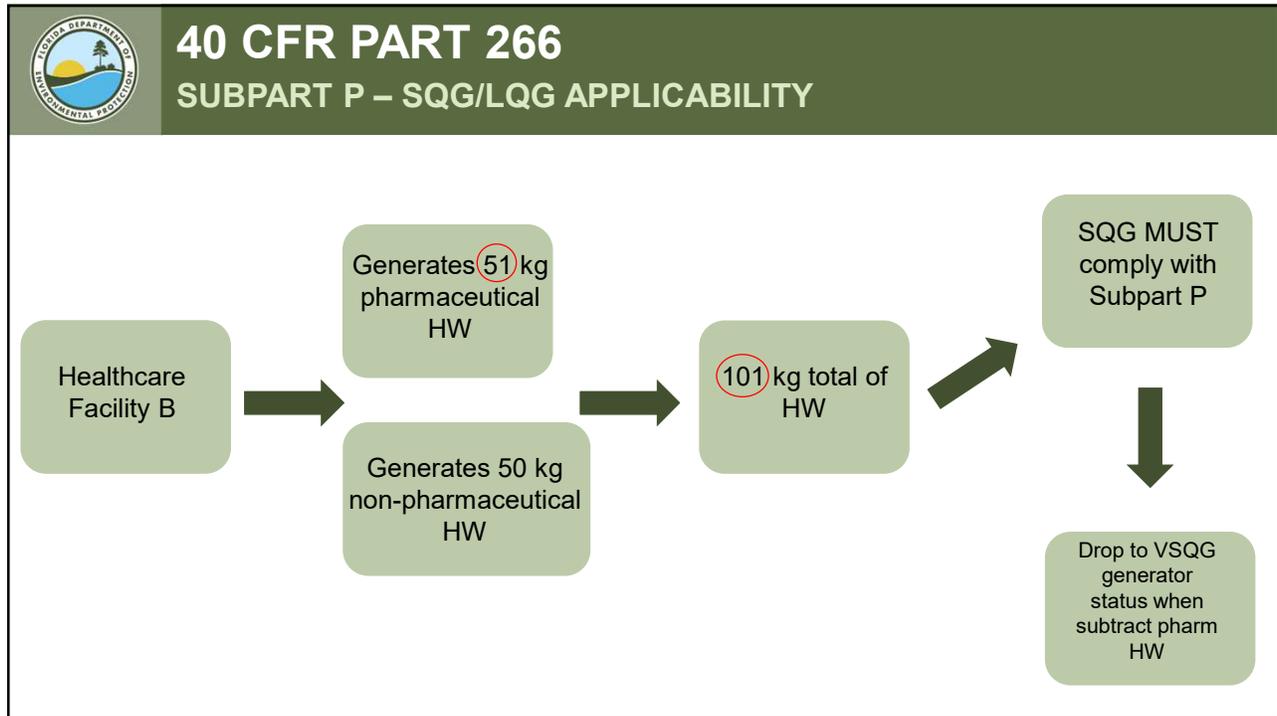
40 CFR PART 266

SUBPART P – SQG/LQG APPLICABILITY

How does this effect generator category?

- There are no generator categories for HW pharmaceuticals under Subpart P.
- Non-pharmaceutical HW remains subject to the 40 CFR 262 generator regulations and the associated generator categories.
- Complying with Subpart P may allow you to drop a generator category (e.g., your facility generates over the VSQG thresholds and is therefore subject to Subpart P for its HW pharmaceuticals but becomes a VSQG for its non-pharmaceutical HW after complying with Subpart P because it is no longer required to count its HW pharmaceuticals toward its generator category).

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HEALTHCARE FACILITY STANDARDS NOTIFICATIONS

All healthcare facilities must notify DEP using the U.S. EPA Site Identification Form, 8700-12, or the Florida Notification of Regulated Waste Activity Form, 8700-12FL, that they are operating under 40 CFR Part 266 Subpart P.

- This includes VSQGs opting in to Subpart P.

A copy of the notification must be kept on file for as long as the healthcare facility is subject to this Subpart.

EPA ID Number OMB# 2050-0024; Expires 04/30/2024

D. Pharmaceutical Activities

1. Operating under 40 CFR Part 266, Subpart P for the management of hazardous waste pharmaceuticals—if "Yes", mark only one. Note: See the item-by-item instructions for definitions of healthcare facility and reverse distributor.

a. Healthcare Facility

b. Reverse Distributor

2. Withdrawing from operating under 40 CFR Part 266, Subpart P for the management of hazardous waste pharmaceuticals. Note: You may only withdraw if you are a healthcare facility that is a VSQG for all of your hazardous waste, including hazardous waste pharmaceuticals.

12. Eligible Academic Entities with Laboratories—Notification for opting into or withdrawing from managing laboratory hazardous wastes pursuant to 40 CFR Part 262, Subpart K.

A. Opting into or currently operating under 40 CFR Part 262, Subpart K for the management of hazardous wastes in laboratories—if "Yes", mark all that apply. Note: See the item-by-item instructions for definitions of types of eligible academic entities.

1. College or University

2. Teaching Hospital that is owned by or has a formal written affiliation with a college or university

3. Non-profit institute that is owned by or has a formal written affiliation with a college or university

B. Withdrawing from 40 CFR Part 262, Subpart K for the management of hazardous wastes in laboratories.

13. Episodic Generation

Are you an SQG or VSQG generating hazardous waste from a planned or unplanned episodic event, lasting no more than 60 days, that moves you to a higher generator category. If "Yes", you must fill out the Addendum for Episodic Generator.

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HEALTHCARE FACILITY STANDARDS NOTIFICATIONS

A healthcare facility that operated under 40 CFR 266 Subpart P, but becomes a VSQG and **elects to withdraw** from this Subpart must notify DEP using U.S. EPA Site Identification Form, 8700-12, or the Florida Notification of Regulated Waste Activity Form, 8700-12FL, that they are no longer operating under 40 CFR Part 266 Subpart P.

The notification form must be submitted before the facility can begin operating as a VSQG under 40 CFR 262.14.

- A healthcare facility must keep a copy of its 40 CFR 266.502(a)(1) withdrawal on file for three years from the date of the signature on the notification form.

EPA ID Number	<input type="text"/>	OMB# 2050-0024; Expires 04/30/2024
D. Pharmaceutical Activities		
<input type="checkbox"/> Y <input type="checkbox"/> N	1. Operating under 40 CFR Part 266, Subpart P for the management of hazardous waste pharmaceuticals—if "Yes", mark only one. Note: See the item-by-item instructions for definitions of healthcare facility and reverse distributor.	
	<input type="checkbox"/> a. Healthcare Facility	
	<input type="checkbox"/> b. Reverse Distributor	
<input checked="" type="checkbox"/> Y <input type="checkbox"/> N	2. Withdrawing from operating under 40 CFR Part 266, Subpart P for the management of hazardous waste pharmaceuticals. Note: You may only withdraw if you are a healthcare facility that is a VSQG for all of your hazardous waste, including hazardous waste pharmaceuticals.	
12. Eligible Academic Entities with Laboratories —Notification for opting into or withdrawing from managing laboratory hazardous wastes pursuant to 40 CFR Part 262, Subpart K.		
<input type="checkbox"/> Y <input type="checkbox"/> N	A. Opting into or currently operating under 40 CFR Part 262, Subpart K for the management of hazardous wastes in laboratories—if "Yes", mark all that apply. Note: See the item-by-item instructions for definitions of types of eligible academic entities.	
	<input type="checkbox"/> 1. College or University	
	<input type="checkbox"/> 2. Teaching Hospital that is owned by or has a formal written affiliation with a college or university	
	<input type="checkbox"/> 3. Non-profit Institute that is owned by or has a formal written affiliation with a college or university	
<input type="checkbox"/> Y <input type="checkbox"/> N	B. Withdrawing from 40 CFR Part 262, Subpart K for the management of hazardous wastes in laboratories.	
13. Episodic Generation		
<input type="checkbox"/> Y <input type="checkbox"/> N	Are you an SQG or VSQG generating hazardous waste from a planned or unplanned episodic event, lasting no more than 60 days, that moves you to a higher generator category, if "Yes", you must fill out the Addendum for Episodic Generator.	

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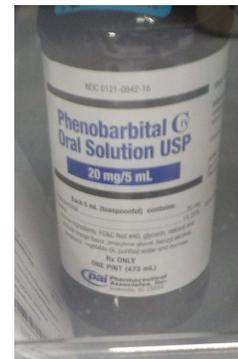


HEALTHCARE FACILITY STANDARDS DEA CONTROLLED SUBSTANCES

Subpart P has two new conditional exemptions for healthcare facilities and reverse distributors for:

- RCRA HW that are also DEA controlled substances.
- Household waste pharmaceuticals collected in DEA authorized collection receptacles (kiosks).

Only a small number of HWs are also DEA controlled substances.



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 HEALTHCARE FACILITY STANDARDS DEA CONTROLLED SUBSTANCES					
Name of Drug	Other Name(s)	Medical Uses	RCRA HW Code	DEA CS Schedule	Comment
Chloral; Chloral hydrate	Acetaldehyde, trichloro-; Aquachloral, Notec, Somnote, Supprettes	Sedative	D034 Toxic	IV	Used in hospital pediatric units; common ingredient in vet anesthetics
Fentanyl sublingual spray	Subsys	Analgesic	D001 Ignitable	II	Ignitable due to alcohol content
Phenobarbital	Bellergal-S, Donnatal, Luminal	Anticonvulsant	D001 Ignitable	IV	Ignitable due to alcohol content
Testosterone gels/solutions	Androgel, Axiron, Fortesta, Testim	Hormone	D001 Ignitable	III	Ignitable due to alcohol content
Valium injectable gel	Diazepam, Diastat	Anti-anxiety	D001 Ignitable	IV	Ignitable due to alcohol content

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 HEALTHCARE FACILITY STANDARDS DEA CONTROLLED SUBSTANCES
<p>DEA Controlled Substances Conditions for Exemption for HW pharmaceuticals:</p> <ul style="list-style-type: none"> • Managed in compliance with sewer prohibition. • Collected, stored, transported and disposed of in accordance with DEA regulations for controlled substances. • Destroyed by a method DEA has publicly deemed in writing to meet their non-retrievable standard of destruction or combusted at a permitted: <ul style="list-style-type: none"> ○ large municipal waste combustor. ○ small municipal waste combustor. ○ hospital, medical and infectious waste incinerator. ○ commercial and industrial solid waste incinerator. ○ hazardous waste combustor.

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HEALTHCARE FACILITY STANDARDS

DEA CONTROLLED SUBSTANCES

Sequestration devices may be used to ensure that:

- DEA controlled substances are not **diverted**.
- Pharmaceuticals are adsorbed into activated carbon or denatured by a chemical digestant.



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HEALTHCARE FACILITY STANDARDS

DEA CONTROLLED SUBSTANCES

Contents of sequestration devices should be managed as either hazardous or non-hazardous pharmaceutical waste, depending on what is put into them.

If they are used solely for DEA controlled substances (hazardous and non-hazardous) they may go to a permitted non-hazardous incinerator.

They may not be put in the trash!

If a sequestration device will NOT be used solely for controlled substances, then the hospital should take the conservative approach and manage the device as a hazardous waste accumulation container and send it to a hazardous waste incinerator.



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HEALTHCARE FACILITY STANDARDS EMPTY CONTAINER STANDARDS

40 CFR 261.7: Residues of HW in empty containers:

- “Containers of HW pharmaceuticals are subject to 40 CFR 266.507 for determining when they are considered empty, in lieu of this section, except as provided by 40 CFR 266.507(c) and (d)”
 - This citation refers to the traditional definition of RCRA-empty in 40 CFR 261.

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HEALTHCARE FACILITY STANDARDS EMPTY CONTAINER STANDARDS



Stock bottles, dispensing bottles, vials or ampules (not to exceed 1 liter or 10,000 pills) or unit-dose containers (unit-dose packet, cup, wrapper, blister pack or delivery device) are considered empty when the pharmaceuticals have been removed and the residues are not regulated as HW provided pharmaceuticals have been removed **using practices commonly employed** to remove materials from that type of container.

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HEALTHCARE FACILITY STANDARDS

EMPTY CONTAINER STANDARDS

“A container that has held a HW that is a compressed gas is considered empty when the pressure in the container approaches atmospheric.”



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HEALTHCARE FACILITY STANDARDS

EMPTY CONTAINER STANDARDS

Syringes are considered empty and the residues are not regulated as HW provided the contents have been removed by **fully depressing the plunger of the syringe.**

If not empty and containing a HW pharmaceutical, the syringe must be managed and disposed of as a non-creditable HW pharmaceutical.



(Photo: Jim Gathany 2003)

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HEALTHCARE FACILITY STANDARDS

EMPTY CONTAINER STANDARDS

Intravenous (IV) bags are considered empty provided 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).



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HEALTHCARE FACILITY STANDARDS

EMPTY CONTAINER STANDARDS

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 and 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.
- Creams.



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HEALTHCARE FACILITY STANDARDS

EMPTY CONTAINER STANDARDS

A container, or an inner liner removed from a container that has held any HW, except a waste that is a compressed gas or that is identified as an acute hazardous waste listed in 40 CFR 261.31 or 261.33(e) is empty if:

- 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 no more than 2.5 centimeters (1 inch) of residue remain on the bottom of the container or inner liner.

OR

- No more than 3% 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.

OR

- No more than 0.3 % by weight of the total capacity of the container remains in the container or inner liner if the container is greater than 119 gallons.

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HEALTHCARE FACILITY STANDARDS

EMPTY CONTAINER STANDARDS

Container	"RCRA Empty"	
	Non-acute HW pharmaceuticals	Acute HW pharmaceuticals*
Stock/dispensing bottles (1 L or 10,000 pills) and unit-dose containers	Remove contents	Remove contents
Syringes	Fully depress plunger	Fully depress plunger
IV Bags	Fully administer contents or 40 CFR 261.(b)(1)	Fully administer contents
Other Containers	40 CFR 261.7(b)(1) or (2)	Can not be RCRA empty

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HEALTHCARE FACILITY STANDARDS

NON-CREDITABLE HW PHARMACEUTICALS

The standards for non-creditable hazardous waste pharmaceuticals can be found in 40 CFR 266.502.

Under 40 CFR 266.502(c), a healthcare facility that generates a solid waste that is a non-creditable pharmaceutical must determine whether that pharmaceutical is a HW pharmaceutical.

- This applies to both potentially creditable and non-creditable waste pharmaceuticals.
- If a healthcare facility chooses to manage ALL of its non-creditable waste pharmaceuticals as non-creditable HW then individual determinations are not necessary.

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HEALTHCARE FACILITY STANDARDS

NON-CREDITABLE HW PHARMACEUTICALS - CONTAINERS

A healthcare facility must place non-creditable hazardous waste pharmaceuticals in a container that is:

- Structurally sound.
- Compatible with its contents.
- Lacking evidence of leakage, spillage or damage that could cause leakage.



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HEALTHCARE FACILITY STANDARDS

NON-CREDITABLE HW PHARMACEUTICALS - STORAGE

Ignitable or reactive HW pharmaceuticals or commingled incompatible HW pharmaceutical containers must be managed so the container does not have the potential to:

- Generate extreme heat or pressure, fire or explosion or violent reaction.
- Produce uncontrolled toxic mists, fumes, dust or gases in sufficient quantities to threaten human health.
- Produce uncontrolled flammable fumes or gases in sufficient quantities to pose a risk of fire or explosion.
- Damage the structural integrity of the container.
- Through other like means threaten human health or the environment.

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HEALTHCARE FACILITY STANDARDS

NON-CREDITABLE HW PHARMACEUTICALS - STORAGE

A healthcare facility must keep containers of non-creditable HW pharmaceuticals **closed and secured** in a manner that prevents unauthorized access to its contents.



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HEALTHCARE FACILITY STANDARDS NON-CREDITABLE HW PHARMACEUTICALS - STORAGE

A healthcare facility *may* accumulate HW pharmaceuticals and non-HW waste pharmaceuticals in the same container, except that non-creditable HW pharmaceuticals prohibited from being combusted because of the dilution prohibition of 40 CFR 268.3(c) must be accumulated in separate containers and labeled with all applicable HW codes. These include:

- Characteristic metal wastes (i.e., D004–D011).
- Listed wastes U151 (mercury), U205 (selenium sulfide) and P012 (arsenic trioxide).
 - Unless they contain greater than 1% total organic carbon:
 - [Clarification of the LDR Dilution Prohibition and Combustion of Inorganic Metal Bearing Waste](#)

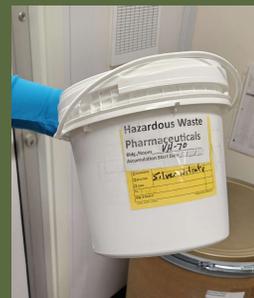
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HEALTHCARE FACILITY STANDARDS EMPTY CONTAINER STANDARDS- LABELING

A healthcare facility must label or clearly mark each container of non-creditable HW pharmaceuticals with the phrase “Hazardous Waste Pharmaceuticals.”

Hazard or waste code (except those prohibited from combustion) of the HW pharmaceutical is not required to be on the container.



ACCEPTABLE



UNACCEPTABLE

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NON-CREDITABLE HW PHARMACEUTICALS ACCUMULATION TIME

A healthcare facility may accumulate non-creditable HW pharmaceuticals on site for **one year or less** without a permit.

Methods for documenting accumulation time include:

- Marking the container with the date the HW pharmaceuticals became a waste.
- Maintaining an inventory system that identified the date the HW pharmaceuticals being accumulated first became a waste.
- Placing the HW pharmaceuticals in a specific area and identifying the earliest date any of the HW pharmaceuticals in the area became a waste.

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NON-CREDITABLE HW PHARMACEUTICALS LAND DISPOSAL RESTRICTIONS

HW pharmaceuticals generated by a healthcare facility are subject to the land disposal restrictions of 40 CFR Part 268.

The healthcare facility must comply with 40 CFR 268.7(a) requirements (determining if waste is restricted from land disposal), except, it is not required to identify the HW codes on the land disposal restriction notification.

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NON-CREDITABLE HW PHARMACEUTICALS SHIPPING

A healthcare facility must ship non-creditable HW pharmaceuticals off-site to a designated facility permitted RCRA treatment, storage and disposal facility (TSD).

Before transporting or offering for transport off-site, one must package, label and mark the waste in accordance with Florida Department of Transportation (DOT) regulations on hazardous materials.

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NON-CREDITABLE HW PHARMACEUTICALS SHIPPING

Mark each container of 119 gallons or less with the following words and information:

- “HAZARDOUS WASTE — Federal Law Prohibits Improper Disposal. If found, contact the nearest police or public safety authority or the U.S. Environmental Protection Agency”
- Healthcare facility’s or reverse distributor’s name and address.
- Healthcare facility’s or reverse distributor’s EPA identification number.
- Manifest Tracking Number.

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NON-CREDITABLE HW PHARMACEUTICALS SHIPPING

A healthcare facility must ship non-creditable HW pharmaceuticals off-site to a designated facility (permitted RCRA TSD) in compliance with manifest requirements of 40 CFR 262 Subpart B, except that:

- A healthcare facility shipping non-creditable HW pharmaceuticals is not required to list all applicable HW codes in Item 13 of EPA Form 8700–22.
- A healthcare facility shipping non-creditable HW pharmaceuticals must write the word “PHRM” or “PHARMS” in Item 13 of EPA Form 8700–22.

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NON-CREDITABLE HW PHARMACEUTICALS SHIPPING

Procedures for managing rejected shipments of non-creditable HW pharmaceuticals are found at 40 CFR 266.502(h).

Procedures for exception reporting by healthcare facilities for missing copies of the manifest are found at 40 CFR 266.502(i)(2).

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NON-CREDITABLE HW PHARMACEUTICALS REPORTING AND TRAINING

Reporting

Healthcare facilities are not subject to biennial reporting requirements under 40 CFR 262.41 with respect to non-creditable HW pharmaceuticals per 40 CFR 266.502(i)(1).

Training

A healthcare facility must ensure that all personnel that manage non-creditable hazardous waste pharmaceuticals are **thoroughly familiar with proper waste handling and emergency procedures relevant to their responsibilities during normal facility operations and emergencies.**

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NON-CREDITABLE HW PHARMACEUTICALS RECORDKEEPING

A healthcare facility must keep:

- Manifest copies for a period of three years.
- Exception reports for a period of three years.
- Test results, waste analyses and HW determinations for a period of three years from the date the waste was last sent for treatment, storage or disposal.

All records must be readily available upon request by an inspector.

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NON-CREDITABLE HW PHARMACEUTICALS SPILL RESPONSE

A healthcare facility must immediately contain all spills of non-creditable HW pharmaceuticals and manage the spill clean-up materials as non-creditable HW pharmaceuticals in accordance with the requirements of this subpart.

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NON-CREDITABLE HW PHARMACEUTICALS ACCEPTING HW PHARMACEUTICALS

A healthcare facility may accept non-creditable HW pharmaceuticals from an off-site healthcare facility that is a VSQG under 40 CFR 262.14, without a permit, provided the receiving healthcare facility:

- Is under the control of the same 'person' or has a contractual/documentated business relationship whereby the receiving healthcare facility supplies pharmaceuticals to the VSQG.
- Is operating under 40 CFR 266 Subpart P.
- Manages the HW pharmaceuticals that it receives in compliance with Subpart P.
- Keeps records of HW pharmaceutical shipments it receives for three years.

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HEALTHCARE FACILITY STANDARDS POTENTIALLY CREDITABLE HW PHARMACEUTICALS

The standards for potentially creditable HW pharmaceuticals can be found in 40 CFR 266.503.

Under 40 CFR 266.503(a), a healthcare facility that generates a solid waste that is a potentially creditable pharmaceutical must determine if it is a potentially creditable HW pharmaceutical.

A healthcare facility may choose to manage its potentially creditable non-HW pharmaceuticals as potentially creditable HW pharmaceuticals under this subpart.

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POTENTIALLY CREDITABLE HW PHARMACEUTICALS STORAGE/LABELING/ACUMULATION TIME

For potentially creditable HW pharmaceuticals there are no:

- Accumulation time limits.
- Container standards.
- Labeling requirements.

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POTENTIALLY CREDITABLE HW PHARMACEUTICALS ACCEPTING HW PHARMACEUTICALS

A healthcare facility may accept potentially creditable HW pharmaceuticals from an off-site healthcare facility that is a VSQG under 40 CFR 262.14, without a permit, provided the receiving healthcare facility:

- Is under the control of the same 'person' or has a contractual/documentated business relationship whereby the facility supplies pharmaceuticals to the VSQG.
- Is operating under 40 CFR 266 Subpart P.
- Manages the HW pharmaceuticals that it receives in compliance with Subpart P.
- Keeps records of HW pharmaceutical shipments it receives for three years.

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POTENTIALLY CREDIBLE HW PHARMACEUTICALS SENDING HW PHARMACEUTICALS

Healthcare facilities are prohibited from sending HW other than potentially creditable HW pharmaceuticals to a reverse distributor.

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POTENTIALLY CREDITABLE HW PHARMACEUTICALS SPILL RESPONSE

A healthcare facility must immediately contain all spills of potentially creditable HW pharmaceuticals and manage the spill clean-up materials as non-creditable HW pharmaceuticals in accordance with the requirements of this subpart.

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POTENTIALLY CREDITABLE HW PHARMACEUTICALS SHIPPING

A healthcare facility or reverse distributor who transports or offers for transport potentially creditable HW pharmaceuticals off-site to a reverse distributor **must comply** with all applicable U.S. DOT regulations in 49 CFR parts 171 through 180 for any potentially creditable HW pharmaceutical that meets the definition of hazardous material in 49 CFR 171.8.

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POTENTIALLY CREDITABLE HW PHARMACEUTICALS DELIVERY CONFIRMATION

Upon receipt of each shipment of potentially creditable HW pharmaceuticals, the receiving reverse distributor must provide confirmation (paper or electronic) to the healthcare facility or reverse distributor that initiated the shipment that the shipment has arrived at its destination and is under the custody and control of the reverse distributor.

If delivery confirmation is not received within 35 calendar days, the healthcare facility or reverse distributor that initiated the shipment must contact the carrier and the intended recipient (i.e., the reverse distributor) promptly to report that the delivery confirmation was not received and to determine the status of the potentially creditable hazardous waste pharmaceuticals.

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POTENTIALLY CREDITABLE HW PHARMACEUTICALS RECORDKEEPING

A healthcare facility that initiates a shipment of potentially creditable HW pharmaceuticals to a reverse distributor must keep the following records (paper or electronic) for each shipment for three years from the date of shipment:

- The confirmation of delivery.
- The shipping paper prepared in accordance with 49 CFR Part 172 Subpart C, if applicable.

All records must be readily available upon request by an inspector.

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HW PHARMACEUTICALS OVERVIEW

	Non-creditable HW pharmaceuticals	Potentially creditable HW pharmaceuticals
Labeling	<input checked="" type="checkbox"/>	None
Container Standards	<input checked="" type="checkbox"/>	None
Maximum Accumulation Time	<input checked="" type="checkbox"/>	None
Hazardous Waste Determinations*	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Over-managing non-hazardous pharmaceuticals and commingling with HW pharmaceuticals	Allowed	Allowed
Include HW pharmaceuticals on BR	No	No

*Not required for either type of managing all pharmaceutical waste as hazardous

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RESOURCES

A 10-Step Blueprint for Managing Pharmaceutical Waste in US Healthcare Facilities:

- <https://www.epa.gov/hwgenerators/management-hazardous-waste-pharmaceuticals>

Florida DEP List of Hazardous Waste Pharmaceuticals (NOT comprehensive-only a starting point):

- <https://floridadep.gov/waste/permitting-compliance-assistance/documents/list-hazardous-waste-pharmaceuticals>

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