
FLORIDA DEPARTMENT OF
ENVIRONMENTAL PROTECTION

Management Standards for Hazardous Waste Pharmaceuticals

Hazardous Waste Pharmaceuticals' Management Standards

- New regulations under part 266 subpart P for the management of hazardous waste (HW) pharmaceuticals by healthcare facilities and reverse distributors.
- Conditional exemption for DEA controlled substances
- Redefines when containers are RCRA Empty
- Establishes EPA policy on status of unsold retail items managed at reverse logistics centers
- Prohibition on sewering of HW pharmaceuticals
- Amendment to P075 Acute HW listing for nicotine & salts

Effective Dates

- August 21, 2019 – State of Florida Effective Date
- June 26, 2019 – Florida adopts Part 266 Subpart P, the sewering prohibition and nicotine amendment by reference

- August 16, 2019 – Florida repeals the Universal Pharmaceutical Waste Regulation, 62-730.186, F.A.C.

Sewer Prohibition

- As of August 21, 2019, healthcare facilities are prohibited from discharging hazardous waste pharmaceuticals to a sewer system
- Applies to all generators, including VSQG's
- Includes HW controlled substances and HW pharmaceutical wastage

Exclusion Amendment

- The following materials are not solid waste for the purposes of this Part: Domestic sewage; and
- Any mixture of domestic sewage and other wastes that passes through a sewer system to a publicly-owned treatment works (POTW) for treatment, except as prohibited by §§ 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

40 CFR 261.4(a)(1)(ii)

Pretreatment Standards

Prohibited Discharges

Specific Prohibitions

- 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

40 CFR 403.5(b)(1)

Amendment of the Nicotine Listing

EPA is amending the P075 listing for nicotine to exempt FDA approved over-the-counter nicotine replacement therapies

- **EPA has concluded 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**

≠ P075


40 CFR Part 266 Subpart P

Applicability

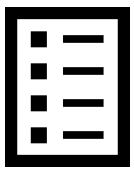
The final rule applies to healthcare facilities that generate, accumulate, or otherwise handle hazardous waste pharmaceuticals and reverse distributors engaged in the management of prescription hazardous waste pharmaceuticals.

40 CFR 266.500

New Definitions

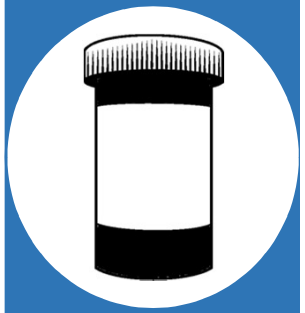
- Pharmaceutical
- Hazardous Waste Pharmaceutical
  - Non-Creditable HW Pharmaceutical
  - Potentially Creditable HW Pharmaceutical
  - Evaluated HW Pharmaceutical
- Healthcare Facility
  - Long-Term Care Facility
- Household pharmaceutical waste
- Reverse Distributor

40 CFR 266.500



Pharmaceutical

- 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



40 CFR 266.500

Pharmaceutical

Pharmaceuticals Includes, but is 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

Pharmaceuticals does NOT include:

- Dental Amalgam
- Sharps
- Medical Waste

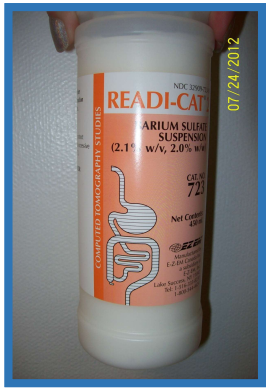
Dietary Supplement Label

Drug Facts Label

Hazardous Waste Pharmaceutical

A pharmaceutical that is a solid waste as defined in 40 CFR 261.2

- **Exhibits one or more characteristics identified in Part 261 Subpart C or**
- **Is listed in Part 261 Subpart D**



40 CFR 266.500

Hazardous Waste Pharmaceutical

What is not 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
- 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)

40 CFR 266.500

Hazardous Waste Pharmaceutical

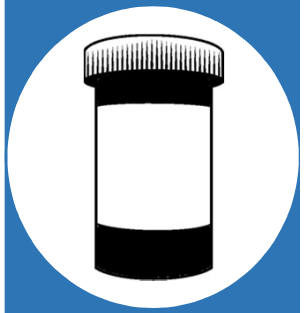
3 Types of HW Pharmaceuticals:

- Non-Creditable HW Pharmaceuticals
- Potentially Creditable HW Pharmaceuticals
- Evaluated HW Pharmaceuticals

40 CFR 266.500

Non-Creditable HW Pharmaceutical

- A prescription (RX) 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

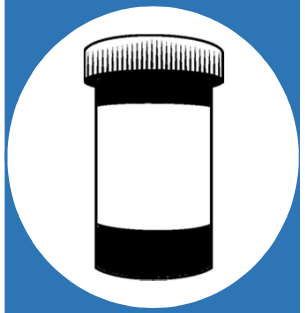


40 CFR 266.500

Non-Creditable HW

Examples include, but are not limited to:

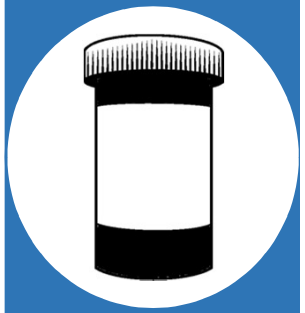
- Free samples of pharmaceuticals received by healthcare facilities
- Investigational drugs
- Pharmaceuticals more than 1 year past their expiration date
- Residues of pharmaceuticals remaining in empty containers
- Floor sweepings and spill cleanup from spills of pharmaceuticals & PPE
- Pharmaceuticals removed from original container & repackaged for dispensing
- Pharmaceuticals in leaking or damaged packaging
- Dispensed pharmaceuticals returned to pharmacy after third-party payer compensation received



40 CFR 266.500

Potentially Creditable HW Pharmaceutical

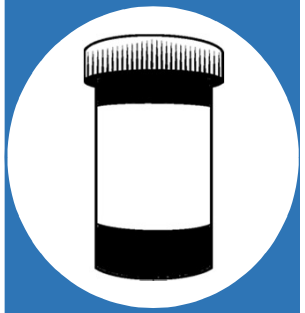
- A prescription HW pharmaceutical that has a reasonable expectation to receive manufacturer credit and is
  - In original manufacturer packaging (except pharmaceuticals that were subject to a recall)
  - Undispensed; and
  - Unexpired or less than 1 year past expiration date
- This term does not include evaluated HW pharmaceuticals or non-prescription pharmaceuticals (e.g., OTC drugs, dietary supplements, homeopathic drugs)



40 CFR 266.500

Evaluated HW Pharmaceutical

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



40 CFR 266.500

Non-creditable vs. Potentially Creditable HW

	Non-creditable HW pharmaceuticals	Potentially creditable HW pharmaceuticals
Labeling	☑	None
Container Standards	☑	None
Maximum Accumulation Time	☑	None
Hazardous Waste Determinations*	☑	☑
Over-managing non-hazardous pharmaceuticals & commingling with HW pharmaceuticals	Allowed	Allowed
Include HW pharmaceuticals on BR	No	No

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

Healthcare Facility

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 OTC pharmaceuticals, dietary supplements, homeopathic drugs, or prescription pharmaceuticals

40 CFR 266.500

Healthcare Facility

Healthcare Facility includes, but is not limited to:

- Wholesale distributors
- Hospitals
- Psychiatric hospitals
- Ambulatory surgical centers
- Health clinics
- Physician's offices
- Optical & Dental providers
- Chiropractors
- Long-Term care facilities
- Pharmacies (including compounding)
- Retailers of pharmaceuticals
- Veterinary clinics & hospitals

Healthcare Facility does NOT include:

- Pharmaceutical manufacturers
- Reverse distributors
- Reverse logistics centers

40 CFR 266.500

A licensed entity that helps with activities of daily living, including managing and administering pharmaceuticals to one or more individuals at the facility

40 CFR 266.500

Long-Term Care Facility

Long-Term Care Facility includes, but is not limited to:

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

Long-Term Car Facility does NOT include:

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

Household Waste Pharmaceutical

- A pharmaceutical that is a solid waste, as defined in 261.2, but is excluded from being hazardous waste under 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; and
  - The waste stream must be composed primarily of materials found in wastes generated by consumers in their homes

40 CFR 266.500 & 261.4(b)(1)

Reverse Distributor

- Means 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 EPA's definition of a reverse distributor

40 CFR
266.500

Applicability

Do I have to comply with Subpart P?

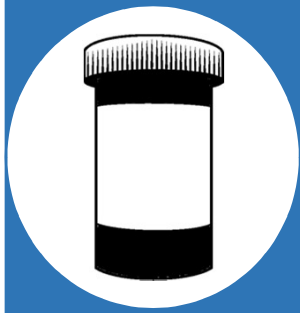
A healthcare facility that is a VSQG when counting all of its HW, including both its HW pharmaceuticals and its non-pharmaceutical HW, remains subject to § 262.14 (VSQG Requirements) and is not subject to this subpart, except for §§ 266.505 (Sewering Prohibition) and 266.507 (Empty Containers) and the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

40 CFR 266.501(a)

Applicability

- A healthcare facility that is a SQG, 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.

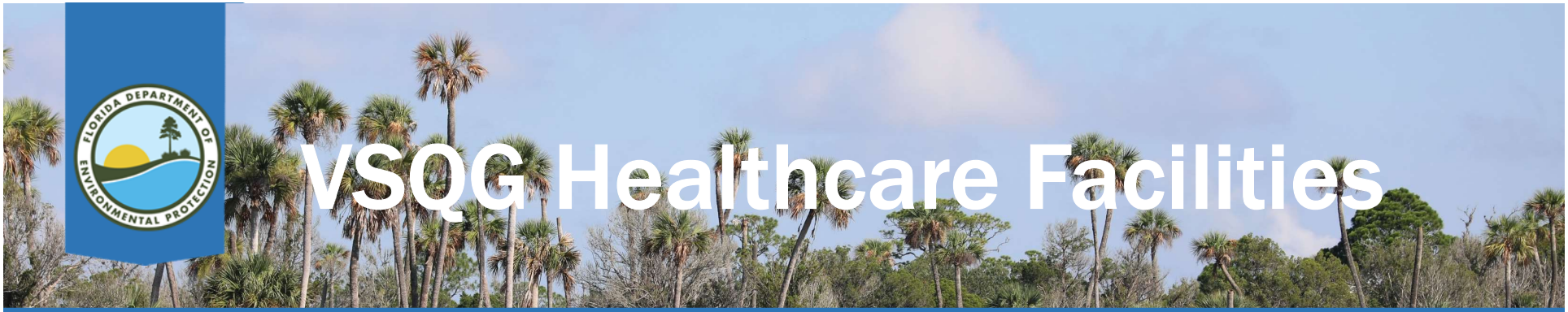
- In other words, Subpart P applies to a healthcare facility that generates:
  - More than 100 kg of hazardous waste per calendar month; or
  - More than 1 kg of acute hazardous waste per calendar month; or
  - More than 100 kg of any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill into or on any land or water of any acute hazardous wastes listed in 261.31 or 261.33(e) per calendar month



VSQG Healthcare Facilities

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 § 266.501(d) (**opting into ALL Subpart P**) for the of HW pharmaceuticals as an alternative to complying with § 262.14 (VSQG Requirements) and the optional provisions of § 266.504

[40 CFR 266.501(b)]



VSQG Healthcare Facilities

Non-Optional Provisions

VSQGs that do not opt into Subpart P

- **Must still comply with the hazardous waste sewering prohibition**
- **Must comply with the empty container standards**
- **May comply with the optional provisions of 266.504**

[40 CFR 266.501]

VSQG Healthcare Facilities

Optional Provisions

- 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

[40 CFR 266.504]

VSQG Healthcare Facilities

Optional Provisions

- 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 Part 266 Subpart P, except the sewer prohibition
  - A Long-Term Care facility with more than 20 beds must demonstrate that it is a VSQG

[40 CFR 266.504]

How Does This Effect My Generator Category?

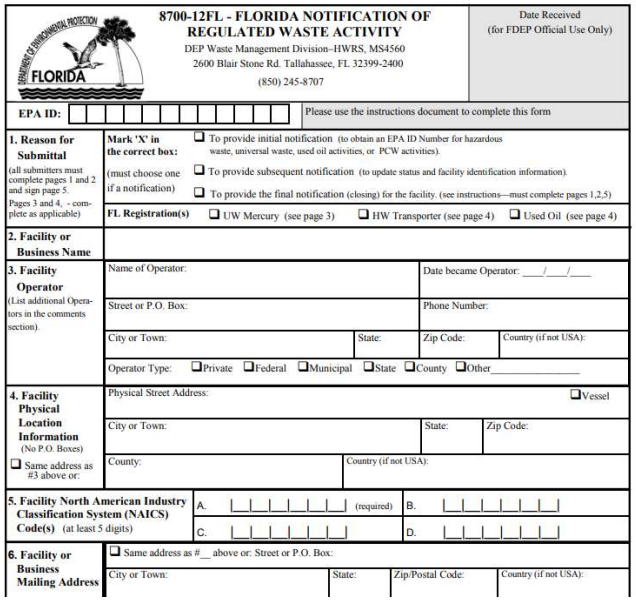
- There are no generator categories for hazardous waste pharmaceuticals under Subpart P
- Non-pharmaceutical hazardous waste remains subject to the Part 262 generator regulations and the associated generator categories.
- Complying with Subpart P may allow you to drop a generator category (e.g. your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

Healthcare Facilities Standards

- <u>Notification</u>: All Healthcare facilities must notify DEP using 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.

  - Facilities not required to submit a biennial report in 2020 for their non-pharmaceutical HW must notify within 60 days of the rule going into effect, October 21, 2019

  - Facilities that are required to submit a biennial report may notify on their normal biennial reporting cycle, by March 1, 2020
  - A copy of the notification must be kept on file for as long as the healthcare facility is subject to this Subpart



8700-12FL - FLORIDA NOTIFICATION OF REGULATED WASTE ACTIVITY

DEP Waste Management Division–HWRS, MS4560
2600 Blair Stone Rd. Tallahassee, FL 32399-2400
(850) 245-8707

Date Received (for FDEP Official Use Only)

EPA ID:

Please use the instructions document to complete this form

1. Reason for Submittal (all submitters must complete pages 1 and 2 and sign page 5. Pages 3 and 4, - complete as applicable)

Mark 'X' in the correct box: (must choose one if a notification)

- ❑ To provide initial notification (to obtain an EPA ID Number for hazardous waste, universal waste, used oil activities, or PCW activities).
- ❑ To provide subsequent notification (to update status and facility identification information).
- ❑ To provide the final notification (closing) for the facility. (see instructions—must complete pages 1,2,5)

FL Registration(s) ❑ UW Mercury (see page 3) ❑ HW Transporter (see page 4) ❑ Used Oil (see page 4)

2. Facility or Business Name

3. Facility Operator (List additional Operators in the comments section).

Name of Operator: | Date became Operator: ___/___/___
Street or P.O. Box: | Phone Number:
City or Town: | State: | Zip Code: | Country (if not USA):
Operator Type: ❑Private ❑Federal ❑Municipal ❑State ❑County ❑Other_____

4. Facility Physical Location Information (No P.O. Boxes)

❑ Same address as #3 above or:

Physical Street Address: ❑Vessel
City or Town: | State: | Zip Code:
County: | Country (if not USA):

5. Facility North American Industry Classification System (NAICS) Code(s) (at least 5 digits)

A. |_|_|_|_|_|_| (required) B. |_|_|_|_|_|_|
C. |_|_|_|_|_|_| D. |_|_|_|_|_|_|

6. Facility or Business Mailing Address

❑ Same address as #__ above or: Street or P.O. Box:
City or Town: | State: | Zip/Postal Code: | Country (if not USA):

[40 CFR 266.502(a)(1)]

Healthcare Facilities Standards

- Withdrawal: A Healthcare facility that operated under Part 266 Subpart P but becomes a VSQG and elects to withdraw from this Subpart must notify DEP using 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 withdrawal on file for 3 years from the date of the signature on the notification form.

[40 CFR 266.502(a)(2)]

DEA Controlled Substances

- Only a small number of HW that are also DEA controlled substances
- 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)
- HW pharmaceuticals must be:
  - Managed in compliance with sewer prohibition
  - Collected, stored, transported, and disposed of in accordance with DEA regulations for controlled substances

[40 CFR 266.506(a)]

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, 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

DEA Controlled Substances

Conditions for Exemption

Destroyed by a method DEA has publicly deemed in writing to meet their non-retrievable standard of destruction or combusted at:

- A permitted large municipal waste combustor
- A permitted small municipal waste combustor
- A permitted hospital, medical and infectious waste incinerator
- A permitted commercial and industrial solid waste incinerator
- A permitted hazardous waste combustor

[40 CFR 266.506(b)

Empty Containers

- Residues of HW in empty containers

- Containers of HW pharmaceuticals are subject to § 266.507 for determining when they are considered empty, in lieu of this section, except as provided by § 266.507(c) and (d)

40 CFR 261.7(c)

Empty Containers

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

* No triple rinsing of containers with acute hazardous waste pharmaceuticals

Standards for Non-Creditable Hazardous Waste Pharmaceuticals – found at 40 CFR 266.502

[40 CFR 266.502]

Healthcare Facilities Standards

HW Determination for Non-Creditable HW pharmaceuticals

- A healthcare facility that generates a solid waste that is a non-creditable pharmaceutical must determine whether that pharmaceutical is a HW pharmaceutical
- 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

[40 CFR 266.502(c)]

Healthcare Facilities Standards

Container Standards

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

[40 CFR 266.502(d)(1)]

Healthcare Facilities Standards

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

[40 CFR 266.502(d)(3)]

Healthcare Facilities Standards

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**

[40 CFR 266.502(d)(4)]

Healthcare Facilities Standards

The HW pharmaceuticals not suitable for incineration include:

- Characteristic metal wastes (i.e., D004–D011; D043?)
- Listed wastes U151 (mercury), U205 (selenium sulfide), and P012 (arsenic trioxide) what about osmium tetroxide?
- Unless they contain greater than 1% total organic carbon
- Clarification of the LDR Dilution Prohibition & Combustion of Inorganic Metal Bearing Waste **EPA Memo Re: Clarification**

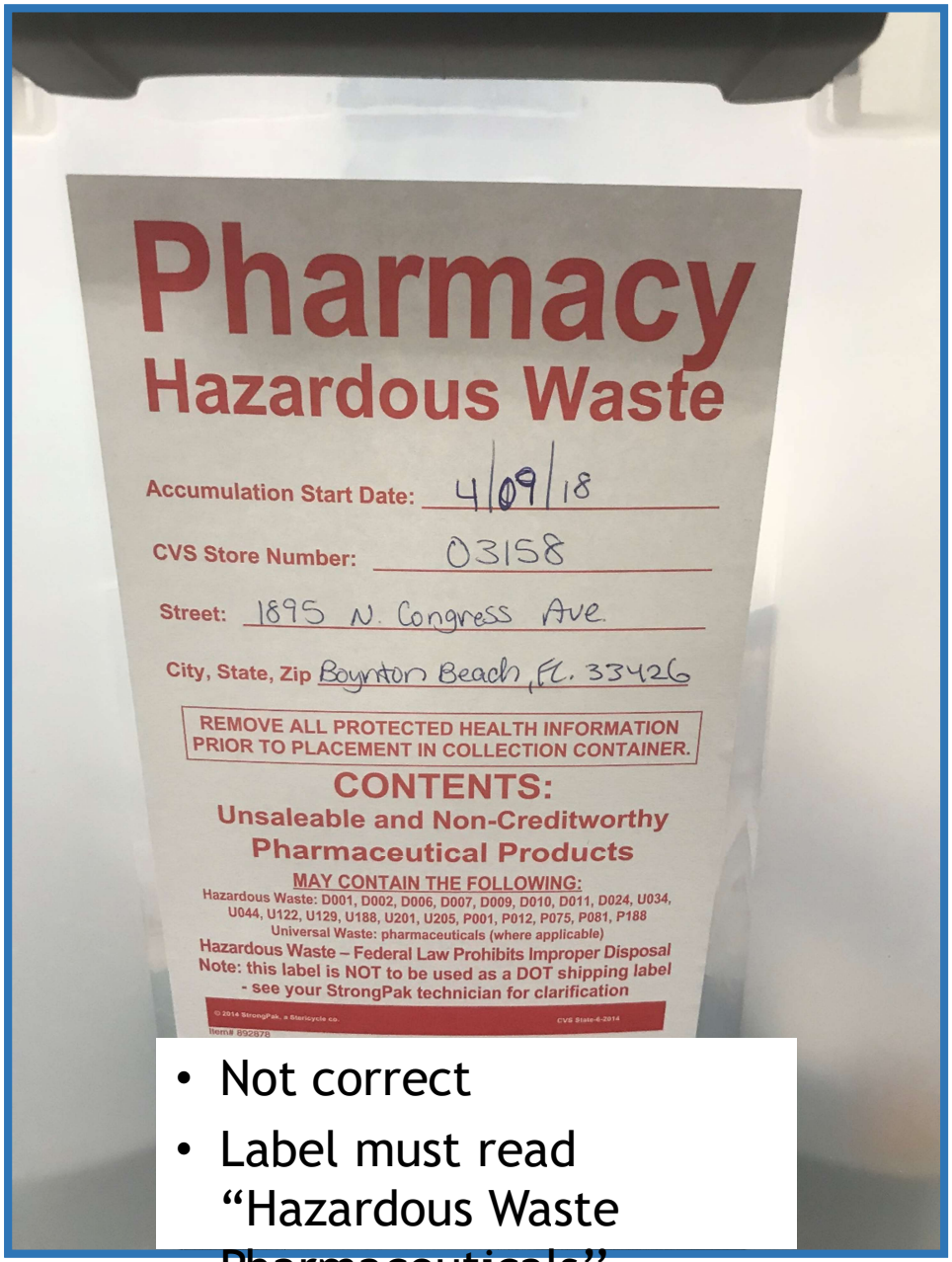
[40 CFR 268 Appendix XI]

Healthcare Facilities Standards

Labeling

- A healthcare facility must label or clearly mark each container of non-creditable HW pharmaceuticals with the phrase “Hazardous Waste Pharmaceuticals”
- NOTE: Hazard or waste code (except those prohibited from combustion) of the HW Pharmaceutical is not required to be on the container

[40 CFR 266.502(e)]



- Not correct
- Label must read "Hazardous Waste Pharmaceuticals"

Healthcare Facilities Standards

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:

- 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

[40 CFR 266.502(f)]

Healthcare Facilities Standards

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 - determine if waste is restricted from land disposal
  - Except, it is not required to identify the HW codes on the land disposal restriction notification

[40 CFR 266.502(g)]

Healthcare Facilities Standards

Shipping Non-Creditable HW Pharmaceuticals

- A healthcare facility must ship non-creditable HW pharmaceuticals off-site to a designated facility (Permitted RCRA TSD) in compliance with:
- Before transporting, or offering for transport off-site:
  - Package the waste in accordance with DOT regulations on hazardous materials
  - Label each package in accordance with DOT regulations on hazardous materials
  - Mark each package in accordance with DOT regulations on hazardous materials

[40 CFR 266.508(a)(1)]

Healthcare Facilities Standards

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 Part 262 Subpart B, except:**
  - **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 "PHARMS" or "PHRM" in Item 13 of EPA Form 8700–22**

[40 CFR 266.508(a)(2)]

Healthcare Facilities Standards

- 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)
- 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)

[40 CFR 266.502]

Healthcare Facilities Standards

Training of Personnel Managing Non-Creditable HW Pharmaceuticals

- 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

[40 CFR 266.502(b)]

Healthcare Facilities Standards

- **Recordkeeping Requirements:**
  - **Manifest copies - 3 years**
  - **Exception reports – 3 years**
  - **Test results, waste analyses, and HW determinations – 3 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**

[40 CFR 266.502(j)]

Healthcare Facilities Standards

Response to spills

- 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

[40 CFR 266.502(k)]

Healthcare Facilities Standards

Accepting HW pharmaceuticals from off-site VSQG healthcare facility:

- A healthcare facility may accept non-creditable HW pharmaceuticals from an off-site healthcare facility that is a VSQG under § 262.14, without a permit, provided the receiving healthcare facility:
  - Is under the control of the same 'person' or has a contractual/documented business relationship whereby the receiving healthcare facility supplies pharmaceuticals to the VSQG
  - Is operating under 40 CFR Part 266 Subpart P
  - Manages the HW pharmaceuticals that it receives in compliance with Subpart P
  - Keeps records of HW pharmaceutical shipments it receives for 3 years

[40 CFR 266.502(l)]

Healthcare Facilities Standards

- Standards for <u>Potentially Creditable</u> Hazardous Waste Pharmaceuticals – found at 40 CFR 266.503

[40 CFR 266.503]

Healthcare Facilities Standards

- Hazardous waste determination for potentially creditable pharmaceuticals
  - 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

[40 CFR 266.503(a)]

Healthcare Facilities Standards

- There are no accumulation time limits, container standards or labeling requirements for potentially creditable HW pharmaceuticals.

[40 CFR 266.503(e)]

Healthcare Facilities Standards

Accepting potentially creditable HW pharmaceuticals from off-site VSQG healthcare facility:

- A healthcare facility may accept potentially creditable HW pharmaceuticals from an off-site healthcare facility that is a VSQG under § 262.14, without a permit, provided the receiving healthcare facility:
  - Is under the control of the same 'person' or has a contractual/documented business relationship whereby the facility supplies pharmaceuticals to the VSQG
  - Is operating under 40 CFR Part 266 Subpart P
  - Manages the HW pharmaceuticals that it receives in compliance with Subpart P
  - Keeps records of HW pharmaceutical shipments it receives for 3 years

[40 CFR 266.503(b)]

Healthcare Facilities Standards

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

[40 CFR 266.503(c)]

Healthcare Facilities Standards

Shipping Potentially Creditable HW Pharmaceuticals

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

[40 CFR 266.509(b)]

Healthcare Facilities Standards

Shipping 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

[40 CFR 266.509(b)]

Healthcare Facilities Standards

Shipping Potentially Creditable HW Pharmaceuticals

- 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

[40 CFR 266.509(c)]

Healthcare Facilities Standards

Response to spills of potentially creditable HW pharmaceuticals

- 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

[40 CFR 266.503(f)]

Healthcare Facilities Standards

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 3 three years from the date of shipment:
  - The confirmation of delivery; and
  - 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

[40 CFR 266.503(e)]


FLORIDA DEPARTMENT OF
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