

Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine: Changes for Healthcare Facilities

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Presumption –

Audience has previous knowledge of hazardous waste rules...

Terms used –

- Hazardous waste determination
 - Listed
 - Characteristic
- Generator status (size)
 - Very small, Small and Large quantity generators
- DEQ id number
 - Notification and annual reporting

Terms used continued –

Pharmaceutical hazardous waste = **Hazardous waste pharmaceuticals**

Non-pharmaceutical hazardous waste = **Other hazardous waste**

Non-hazardous waste pharmaceuticals = **Pharmaceuticals that aren't hazardous**

Pharmaceutical Rule and P075 Amendment

P075



Specific listing amendment limited to....

3

Food and Drug Administration approved over the counter nicotine replacement therapies

Pharmaceutical Rule



Management standards for healthcare facilities & reverse distributors



Waste and sector specific!



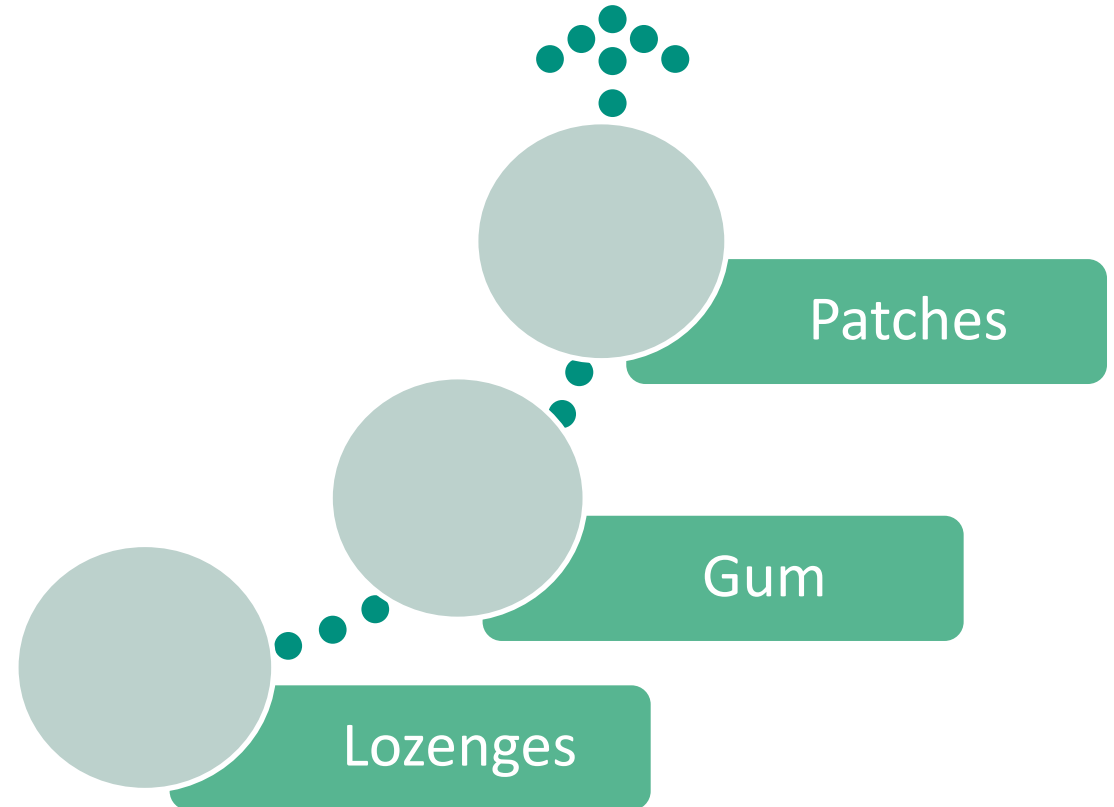
Prohibits sewerage and ensures best ultimate disposal

P075: Nicotine Replacement Therapies

P075 Amendment

P075¹54-11-5 Nicotine & salts

(Does not include patches, gums and lozenges that are FDA-approved over-the-counter nicotine replacement therapies)



Pharmaceutical Rule: What? Who?

- Pharmaceutical hazardous waste
- Healthcare facilities
 - Small or Large Quantity Generators for **All** their hazardous waste
 - *pharmaceutical hazardous waste & non-pharmaceutical hazardous waste*

hazardous waste pharmaceuticals + all other hazardous waste

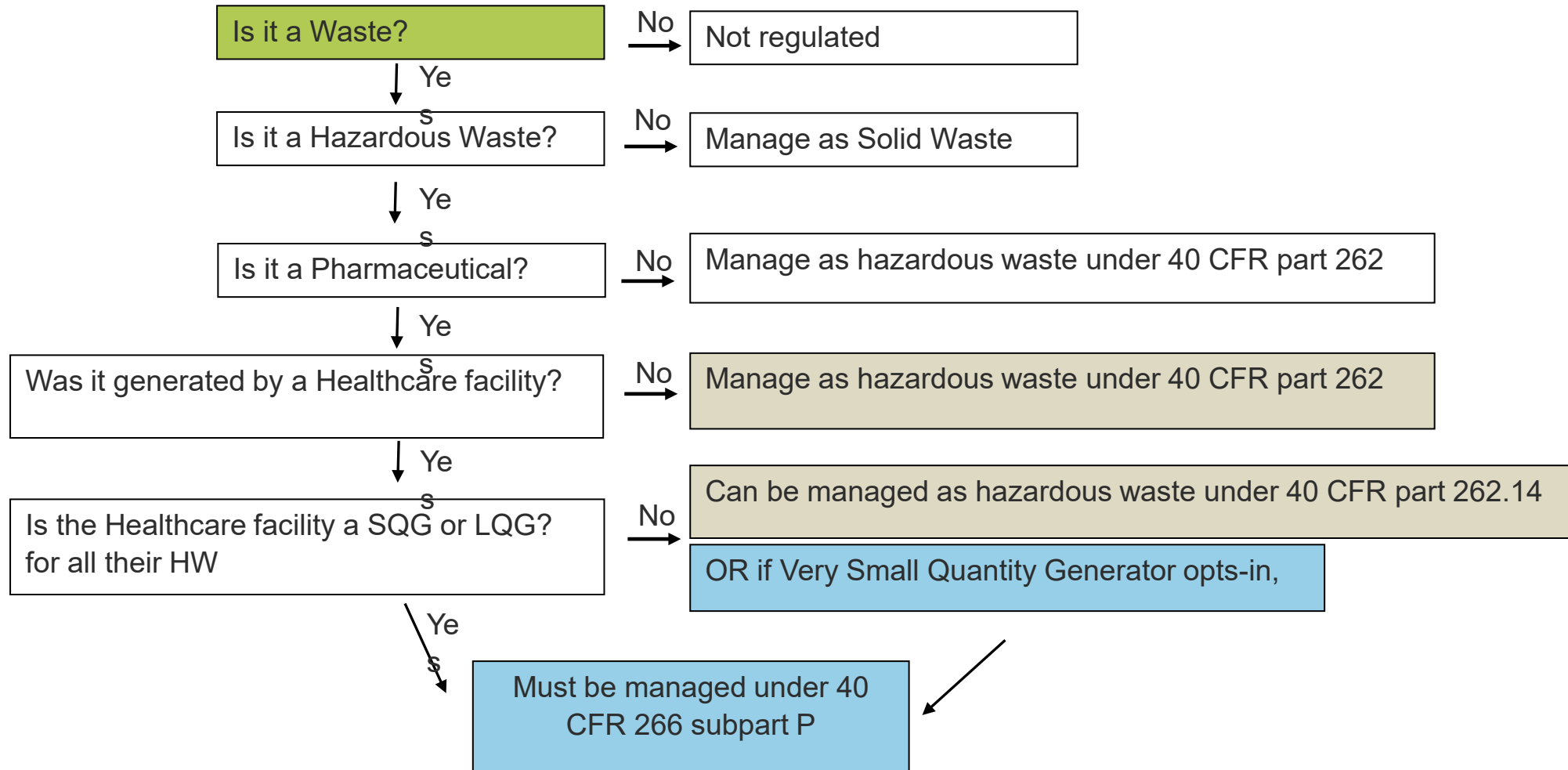
- Reverse distributors

Sector and Waste Specific

Who is subject to
the new
Pharmaceutical
Rule?

Are you
automatically in
because of your total
hazardous wastes
AND sector?

Pharmaceutical Rule Overview



Pharmaceutical Examples (waste specific)

- Dietary supplements
- Prescription and OTC drugs
- Homeopathic drugs
- Investigational new drugs
- Residues of pharmaceuticals in non-empty containers
- PPE-contaminated with pharmaceuticals
- Cleanup material from spills of pharmaceuticals

Dental amalgam, sharps and medical waste ARE NOT pharmaceuticals

Solvents??

Pharmaceutical Hazardous Wastes ??

Arsenic Trioxide (P012)

Nicotine (P075)

Phentermine (P046)

Physostigmine salicylate
(P188)

Warfarin >0.3% (P001)

Epinephrine base (P042)

Nitroglycerin (P081)

Physostigmine (P204)

Chloral hydrate (U034)

Cyclophosphamide (U058)

Dichlorodifluoromethane
(U075)

Diethylstilbestrol (U089)

Hexachlorophene (U132)

Melphalan (U151)

Mitomycin C (U010)

Phenol (U188)

Resorcinol (U201)

Selenium sulfide (U205)

Trichloromonofluoromethane
(U121)

Uracil mustard (U237)

Chlorambucil (U035)

Daunomycin (U059)

Lindane (U0129)

Mercury (U151)

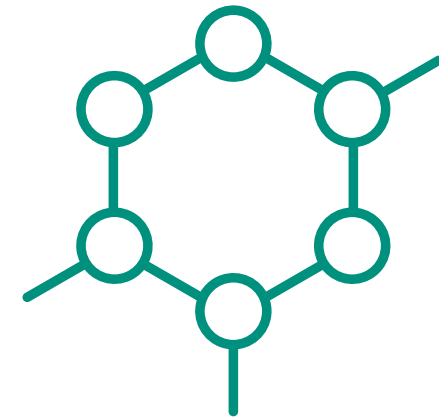
Paraldehyde (U182)

Reserpine (U200)

Saccharin (U202)

Streptozotocin (U206)

Warfarin \leq 0.3% (U248)



Healthcare Facilities (sector specific)

Wholesale distributors

Military medical logistics facilities

Hospitals and psychiatric hospitals

Health clinics, physicians' offices, chiropractors

Optical and dental providers

Pharmacies

Long-term care facilities

Veterinary clinics



Not healthcare facilities

- Pharma manufacturers
- Reverse distributors

Healthcare Facilities and Reverse Distributors

Hazardous waste
pharmaceuticals

Non-creditable

Potentially
creditable

Evaluated

Healthcare Facilities

Hazardous waste
pharmaceuticals

Non-creditable

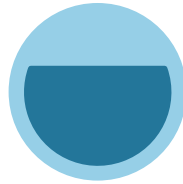
Potentially
creditable

Different Pharmaceutical Hazardous Wastes



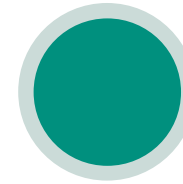
Non-Creditable

Prescription or non-prescription with no expectation of credit, and
Broken or leaking
Repackaged
Dispensed
Expired >1 yr
Investigational new drugs
Contaminated PPE
Floor sweepings
Clean-up material



Potentially Creditable

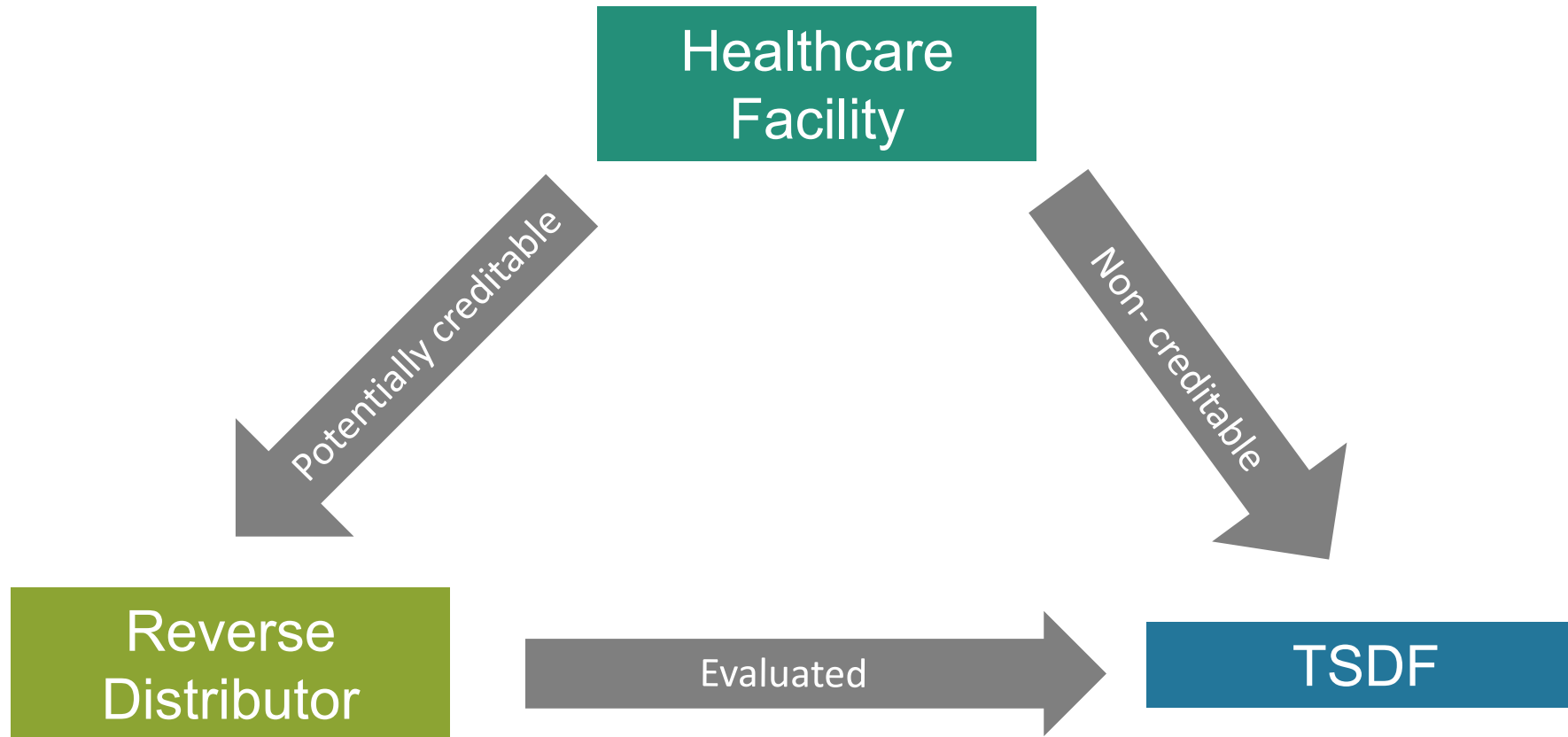
Prescription with a reasonable expectation of receiving a manufacturer credit, and
In original manufacturer packaging
Undispensed
Unexpired or less than 1-yr past expiration



Evaluated

No further evaluation or verification of manufacturer credit is necessary

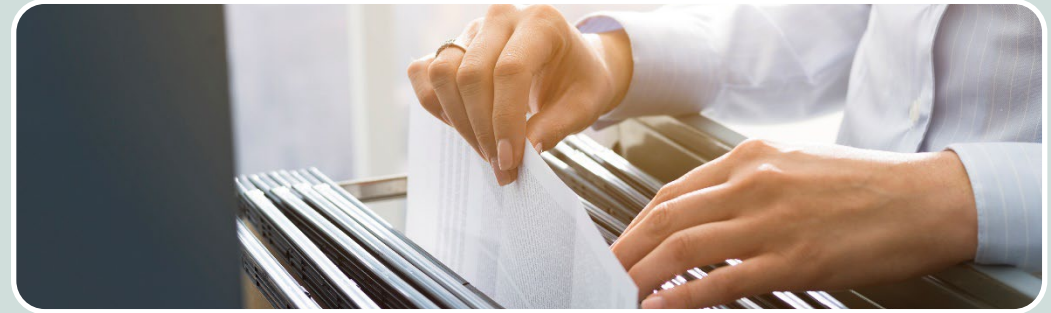
Pharmaceutical Rule: Waste Flow



Notification/withdraw - Healthcare Facility



Notify DEQ of activity as a healthcare facility or a reverse distributor – using the site identification form within 60 days of being subject to 266 subpart P



If withdrawing as a Very Small Quantity Generator, notify DEQ using the DEQ site identification form
Must submit withdrawal before operating under 262.14 – must keep copy of withdrawal for 3 yrs from date of signature on withdrawal notification

Notification in YDO

14. Additional Regulated Waste Activities

1. Pharmaceutical Activities (operating under 40 CFR Subpart P for the management of hazardous waste pharmaceuticals)

Yes No

1a. Withdrawing from Pharmaceutical Activities

Yes No

14. Additional Regulated Waste Activities

1. Pharmaceutical Activities (operating under 40 CFR Subpart P for the management of hazardous waste pharmaceuticals)

Yes No

Healthcare Facility

Reverse Distributor

1a. Withdrawing from Pharmaceutical Activities

Yes No

Withdraw in YDO

14. Additional Regulated Waste Activities

1. Pharmaceutical Activities (operating under 40 CFR Subpart P for the management of hazardous waste pharmaceuticals)

Yes No

Healthcare Facility

Reverse Distributor

1a. Withdrawing from Pharmaceutical Activities

Yes No

! If withdrawing from pharmaceutical activities, "No" must be selected for "Pharmaceutical Activities".

! In order for a Healthcare Facility to withdraw from Subpart P, Generator Status must not equal Large Quantity Generator (LQG) or Small Quantity Generator (SQG).

Healthcare Facilities Management Standards

	Non-creditable HW Pharms	Potentially creditable HW Pharms
Notification	<input checked="" type="checkbox"/> Healthcare facilities Notify	
Labeling	Hazardous waste Pharmaceuticals	None
Container standards	<input checked="" type="checkbox"/>	None
Max accumulation time	1- year (UW like)	None
Biennial reporting	*None	*None
Employee training	<input checked="" type="checkbox"/>	None?
Weekly inspections	None	None
Manifest	<input checked="" type="checkbox"/> PHARMS or PHRM	None

*No reporting – just notify; VSQGs *opt-in/withdraw*

Container Standards/Labeling - Healthcare Facility

	Potentially creditable	Non-creditable
Container standards	*No	-Yes-
Labelling	*No	Hazardous waste Pharmaceuticals

**Remember potentially creditable definition*

Accumulation Time - Healthcare Facility

	Potentially creditable	Non-creditable
Accumulation time limit	*None	-Yes- One year or less <i>-Label each container with date</i> <i>-Inventory system</i> <i>-Designated area</i>

**Remember potentially creditable definition*

Employee Training - Healthcare Facility

Potentially creditable

- No

Non-creditable

- **Yes** - must ensure all personnel managing 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.



Manifesting non-creditable hazardous waste pharmaceuticals

Waste codes:



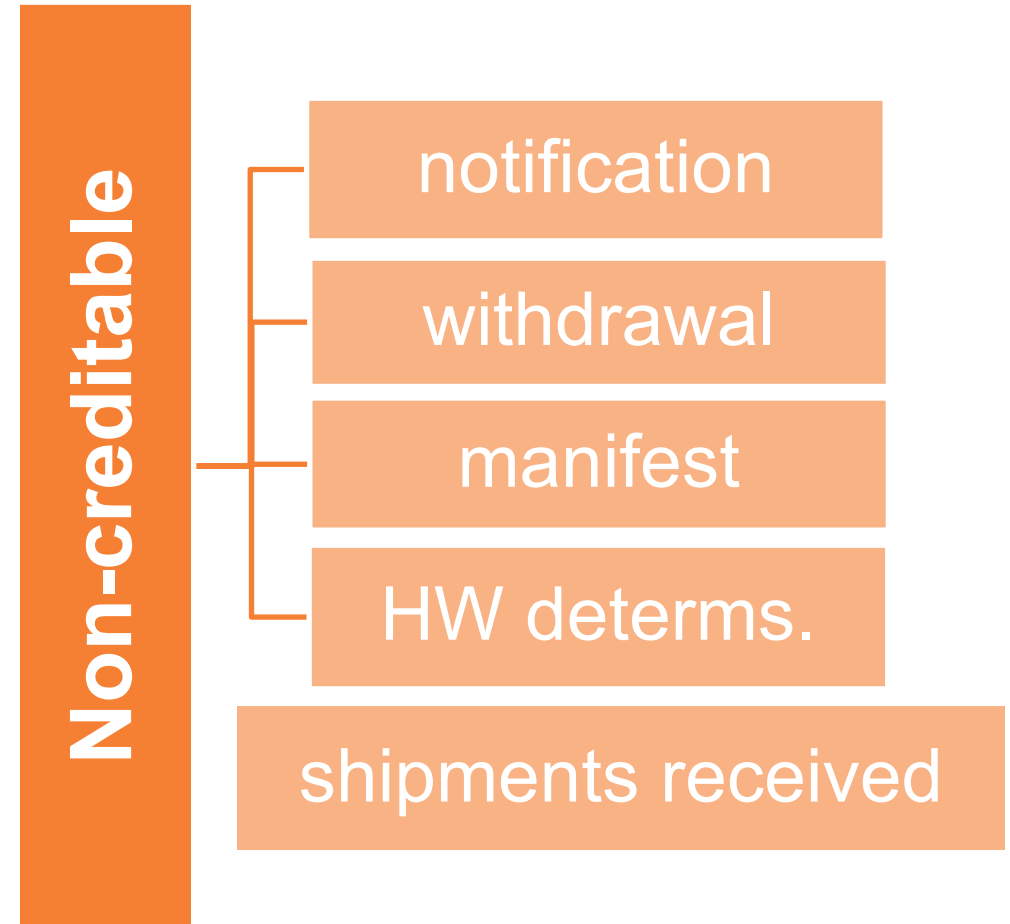
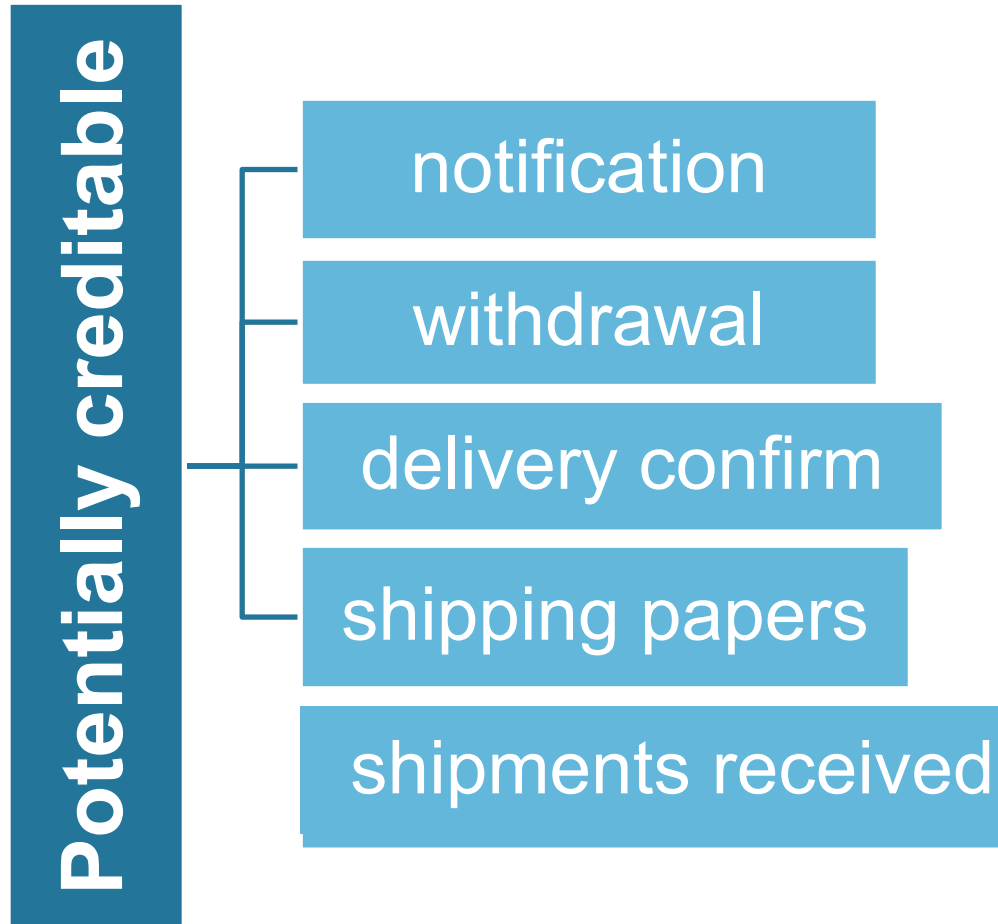
10. Containers		11. Total Quantity	12. Unit Wt./Vol.	13. Waste Codes		
No.	Type					
3	DM	1.65	G	PHARMS	214	
1	CF	2.00	P	D001	352	
5	DM	6.00	P	D001	352	

Facility's Phone:

Shipping - Healthcare Facility

	Potentially creditable (49 CFR parts 171-180, if Haz Mat)	Non-creditable (containers for shipping)
	*49 CFR 171.8 – NOT a HW	
Packaging	-	49 CFR parts 172, 173 and 180
Labelling	-	49 CFR parts 172 subpart E
Marking	-	49 CFR parts 172 subpart D
Placarding	-	49 CFR parts 172 subpart F
Manifesting	NO	40 CFR 262 Subpart B
Delivery Confirm	receive delivery confirm	receive signed manifest

Recordkeeping – Healthcare Facility



Pharmaceutical Rule: VSQG Optional Provisions

VSQGs - for both HW Pharma and non-pharma HW:

- May send potentially creditable pharma to Reverse Distributor
- May send “*HW pharma” to another Healthcare Facility
 - *HCF meets 266.502(l), 503(b)*
- May send HW pharma to an LQG
 - *VSQG meets 262.14(a)(5)(viii), LQG meets 262.17(f)*

Long-term Care Facilities that are VSQGs:

- May dispose HW pharma, with exceptions, in on-site receptacle of a Drug Enforcement Agency authorized collector
- With 20 beds or less is presumed to be a VSQG

Pharmaceutical Rule: Empty Containers

Type of Container	RCRA Empty: Non-Acute HWP	RCRA Empty: Acute HWP
Stock/Dispensing Bottles (1 liter or 10,000 pills) and Unit Dose Containers	Remove Contents	Remove Contents
Syringes	Fully Depress Plunger	Fully Depress Plunger
IV Bags	Fully Administer Contents If not empty, then meet 40 CFR § 261.7(b)(1)	Fully Administer Contents If not empty, then manage as non-creditable HW pharma
Other Containers (includes, but is not limited to: inhalers, aerosols, neutralizers, and tubes or ointments, gels or creams)	Meets 40 CFR § 261.7(b)(1) or (2)	Cannot be RCRA Empty. Manage as non-creditable HW pharma

Pharma and P075: Oregon Adoption

P075: Adopted by reference.

Pharmaceutical Rule:

- Adopted by reference, except less than 20 bed long-term care facility Very Small Quantity Generator presumption - **OAR 340-100-0002(3)**
- Tailored to Oregon state rules - **OAR 340-102-0500**
 - Notification on Oregon Site Identification form
 - Reverse Distributors report annually to DEQ, not biennially to EPA
 - For empty container residuals follow 110 gals not 119 gals per DEQ definitions

Benefits for Healthcare Facilities

for hazardous waste pharmaceuticals

- Accumulate on site for 1 year
- Basic training requirements
- No longer -
 - large generator for 1 kg of acute hazardous waste
 - subject to satellite accumulation area rules
 - specify hazardous waste codes on manifests
 - perform weekly inspections
 - report annually to DEQ

for hazardous waste pharmaceuticals

Prohibitions for Healthcare Facilities

for hazardous waste pharmaceuticals

- Must not be sewerered
- Pharmaceutical hazardous waste must end up at a permitted hazardous waste facility for final disposal
- Only potentially creditable hazardous waste pharmaceuticals can be sent to a Reverse Distributor

Technical Assistance: Regional Contacts

Northwest Region

Clackamas, Clatsop, Columbia, Multnomah, Tillamook, and Washington counties

- Pete Anderson, 503-229-5070
- Alex Bertolucci, 503-229-5336

Western Region

Benton, Coos, Curry, Douglas, Jackson, Josephine, Lane, Lincoln, Linn, Marion, Polk and Yamhill counties

- Bart Collinsworth, 503-378-5071

Eastern Region

Baker, Crook, Deschutes, Gilliam, Grant, Harney, Hood River, Jefferson, Klamath, Lake, Malheur, Morrow, Sherman, Umatilla, Union, Wallowa, Wasco, and Wheeler counties

- Brian Allen 541-633-2014