

**HAZARDOUS WASTE
PHARMACEUTICALS &
AMENDMENT TO THE NICOTINE
LISTING (P075)**



**ENVIRONMENTAL
QUALITY**

WASTE MANAGEMENT & RADIATION CONTROL

Presentation Overview

- * Why
- * Definitions
- * Applicability
- * Management Standards
- * Nicotine Waste



Pharmaceutical Rule Adoption

Pharmaceutical Rule Adopted by Utah – Effective
Date September 14, 2020



**WASTE MANAGEMENT
& RADIATION CONTROL**

GOALS OF THE PHARMACEUTICAL RULE

1. Tailored regulations to prevent diversion to black market
2. Eliminate intentional sewerage of hazardous waste pharmaceuticals



DEFINITIONS

- * Pharmaceutical
- * Hazardous Waste Pharmaceutical



3 Types of HW Pharmaceuticals

Healthcare
Facility



I. Non-Creditable

- Broken or leaking
- Repackaged
- Dispensed
- Expired > 1 yr
- Investigational new drugs
- Contaminated PPE
- Floor sweepings
- Clean-up material

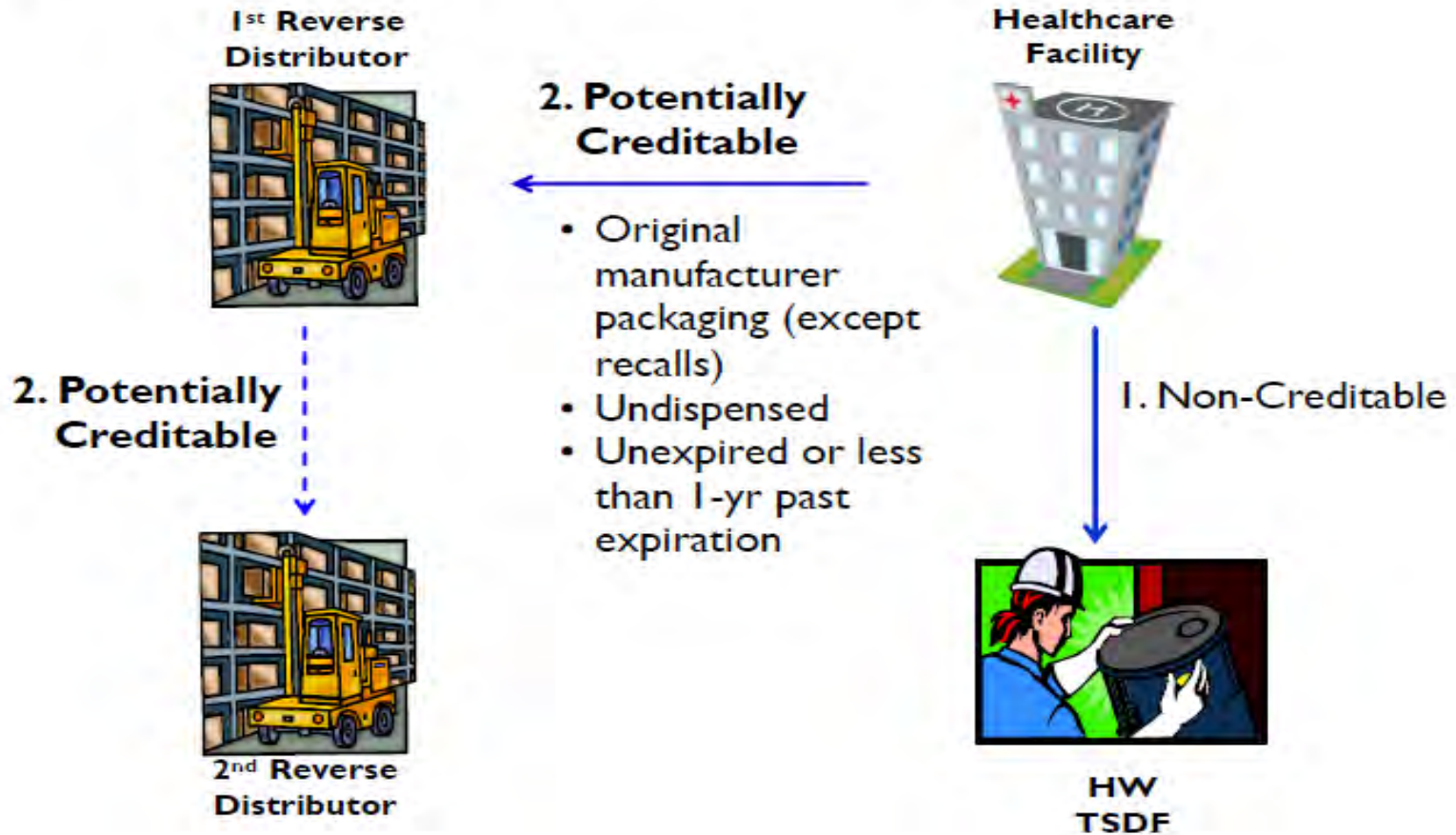


HW
TSDF

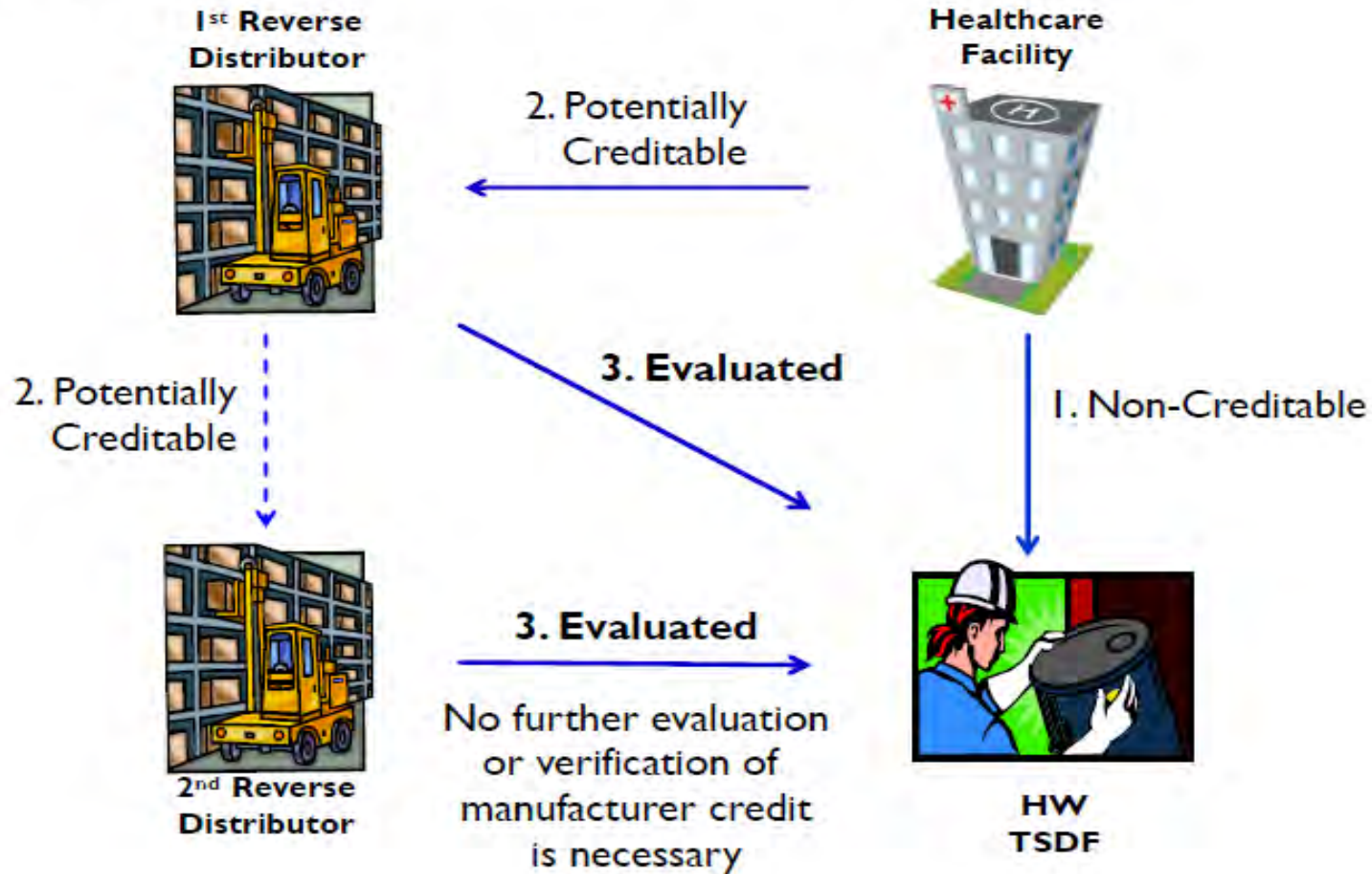


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3 Types of HW Pharmaceuticals



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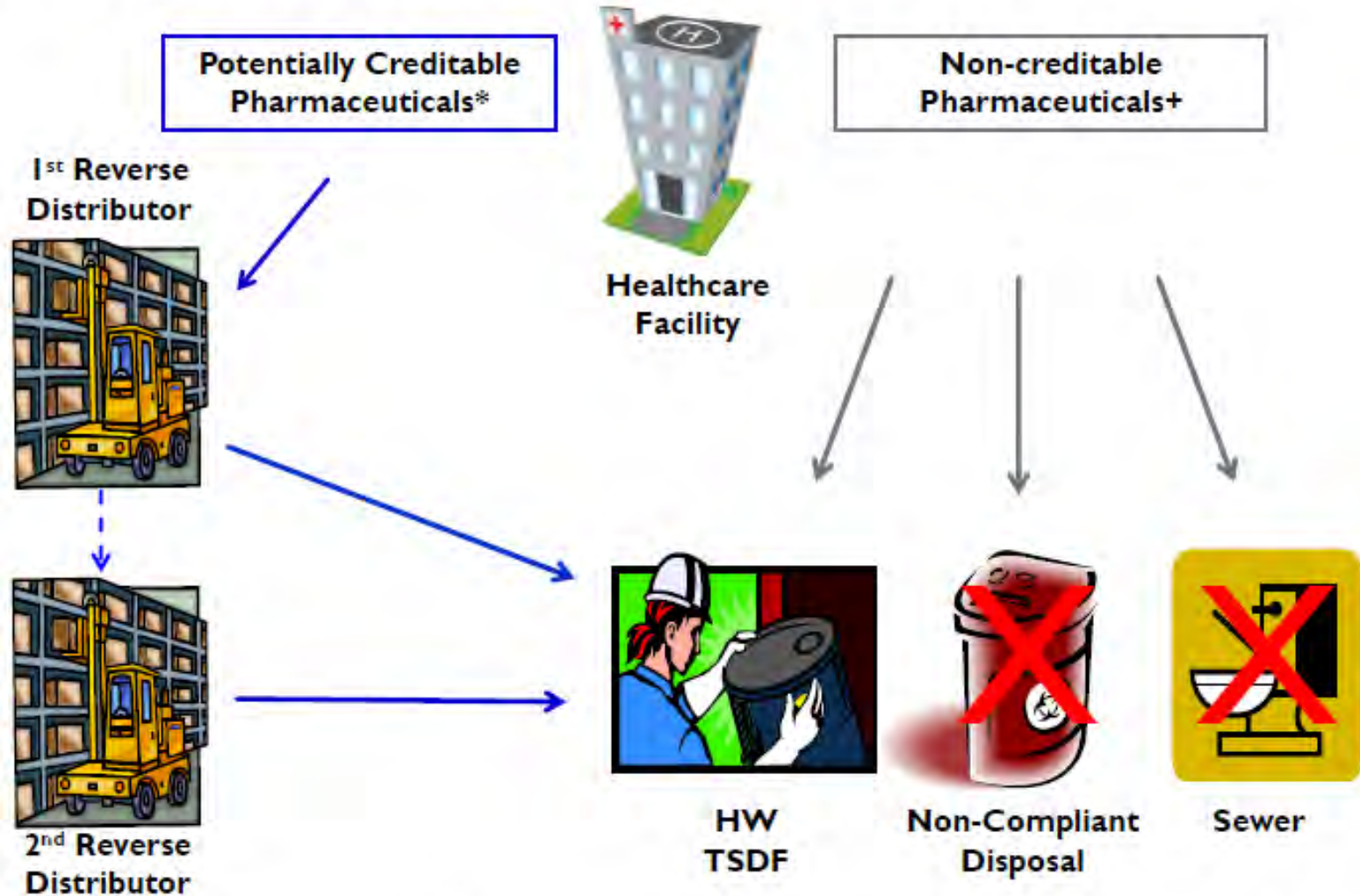


DEFINITIONS

- * Healthcare Facility
- * Reverse Distributor



Reverse Distribution of Rx HW Pharmaceuticals



* Unsold/unused pharmaceuticals that have a reasonable expectation of receiving credit from the manufacturer
+ Pharmaceuticals with no reasonable expectation of receiving credit from the manufacturer

APPLICABILITY

R315-262-10

Hazardous waste pharmaceuticals must be managed under Part 266

- * Healthcare Facilities that generate **above** Very Small Quantity Generator (VSQG) amounts of hazardous waste
- * **All** Reverse Distributors



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SEWER PROHIBITION

- * Healthcare Facilities and Reverse Distributors **MAY NOT** sewer Hazardous Waste Pharmaceuticals
- * Hazardous wastes that are DEA controlled substances are also subject to the sewer prohibition
- * The sewer prohibition is effective **NOW**



HEALTHCARE FACILITY MANAGEMENT STANDARDS

- * Notification
- * Training
- * Hazardous Waste Determinations
 - * Commingling
- * Non-creditable Hazardous Waste Pharmaceuticals
- * Potentially Creditable Hazardous Waste Pharmaceuticals



**WASTE MANAGEMENT
& RADIATION CONTROL**

HEALTHCARE FACILITY NOTIFICATION

Facilities that are not required to submit a biennial report must have notified by **November 14, 2020**

Facilities that are required to submit a biennial report may notify on normal biennial report reporting cycle by **March 1, 2022**



**WASTE MANAGEMENT
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HEALTHCARE FACILITY TRAINING

All personnel managing non-creditable hazardous waste pharmaceuticals must be thoroughly familiar with proper waste handling and emergency procedures relevant to their responsibilities during normal facility operations and emergencies.



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HEALTHCARE FACILITY HAZARDOUS WASTE DETERMINATIONS

- * Hazardous Waste Determinations: must determine whether a waste pharmaceutical is a hazardous waste pharmaceutical
- * Commingling: may accumulate hazardous and non-hazardous waste pharmaceuticals in the same container



HEALTHCARE FACILITY

Hazardous Waste Pharmaceuticals

Non-creditable hazardous waste pharmaceuticals

- * Label “Hazardous Waste Pharmaceuticals”
- * Containers that are structurally sound and compatible
- * Closed and secured
- * Accumulate for 1 year

Potentially creditable hazardous waste pharmaceuticals

- * No labeling, containers standards or accumulation time



HEALTHCARE FACILITY STANDARDS

	Non-creditable HW Pharms	Potentially Creditable HW Pharms
Labeling	✓	None
Container Standards	✓	None
Maximum Accumulation Time	✓	None
Hazardous waste determinations*	✓	✓
Over-managing non-hazardous pharmaceuticals & commingling with hazardous waste pharmaceuticals	Allowed	Allowed
Include hazardous waste pharmaceuticals on BR	No	No

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

EMPTY CONTAINERS

- * Applies to any/all containers for hazardous waste pharmaceuticals
- * Residues remaining in “RCRA Empty” containers are not regulated as hazardous waste
- * No Triple Rinsing



EMPTY CONTAINER STANDARDS

	“RCRA EMPTY”	
	Non-acute HW Pharms	Acute HW Pharms*
Stock/Dispensing Bottles (1 liter or 10,000 pills) & Unit-dose containers	Remove contents	Remove contents
Syringes	Fully depress plunger	Fully depress plunger
IV Bags	Fully administer contents or § 261.7(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

VSQG HEALTHCARE FACILITIES

- * Cannot sewer pharmaceuticals
- * Pharmaceutical Rule Empty Container Standards apply
- * Can opt into Subpart P
- * Comply with VSQG requirements & optional provisions of Subpart P



**WASTE MANAGEMENT
& RADIATION CONTROL**

LONG-TERM CARE FACILITIES

- 20 beds or fewer
- On-site collection receptacles
- Greater than 20 beds



SHIPPING HW PHARMACEUTICALS

Potentially Creditable

- * Manifest and hazardous waste transporter are **NOT** required
- * Common carrier is ok
- * Delivery confirmation required

Non-creditable & Evaluated

- * Manifest & hazardous waste transporter required
- * TSDF required
- * Healthcare Facility - use "PHARMS" on manifest
- * Reverse distributor - use hazardous waste codes on manifest

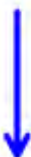


FLOW OF HW PHARMACEUTICALS



- Maximum transfers allowed between RDs
- 180 days after evaluation allowed at each RD

HCF/Pharmacy



1st RD
can be a
manufacturer



2nd RD
can be a
manufacturer



3rd RD
must be a
manufacturer



HW
TSDF

REVERSE DISTRIBUTOR MANAGEMENT STANDARDS

- * Potentially Creditable Hazardous Waste Pharmaceuticals ONLY
- * Notification
- * Inventory
- * Accumulation



WASTE MANAGEMENT
& RADIATION CONTROL

REVERSE DISTRIBUTOR MANAGEMENT STANDARDS

Potentially creditable hazardous waste pharmaceuticals

- * No specific labeling or container standards
- * Not included on biennial report

Evaluated hazardous waste pharmaceuticals

- * Designate onsite accumulation area
- * Labeling
- * Weekly inspections
- * Container standards
- * Training & Contingency Plan
- * Hazardous waste codes prior to transport
- * Include on Biennial Report



NICOTINE



**WASTE MANAGEMENT
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Nicotine Regulation

Nicotine is an acute hazardous waste that is listed as P075 due to its acute toxicity.

- * P075 - Nicotine, and salts; this listing does not include patches, gums and lozenges that are FDA approved **over-the-counter** nicotine replacement therapies
- * Unused formulations of nicotine are still considered P075 when discarded, including:
 - E-liquids/e-juices in e-cigarettes, cartridges, or vials
 - Prescription nicotine (e.g., nasal spray, inhaler)
 - Legacy pesticides containing nicotine
 - Nicotine used in research and manufacturing



NICOTINE REPLACEMENT THERAPIES

- EPA has concluded that nicotine patches, gums and lozenges do not meet the regulatory criteria for acute hazardous waste
- Nicotine patches, gums and lozenges can be discarded as non-hazardous waste



≠ P075



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