
MANAGEMENT STANDARDS FOR HAZARDOUS WASTE PHARMACEUTICALS

and Amendment to the P075 Listing for Nicotine

HAWAII HAZARDOUS WASTE PROGRAM

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Part II

Environmental Protection Agency

40 CFR Part 261, 262, 264, et al.
Management Standards for Hazardous Waste Pharmaceuticals and
Amendments to the P075 Listing for Nicotine; Final Rule

Condensed
& Abridged

CAUTION: OVERVIEW ONLY

APPLICABILITY & EFFECTIVE DATE

Part of rule	Applicability	Effective date
Sewer ban	Healthcare Facilities & Reverse Distributors	August 21, 2019
P075 listing amendment	All generators	June 25, 2020
Empty container definition	All generators	June 7, 2021
40 CFR 266 subpart P	Healthcare Facilities & Reverse Distributors	June 7, 2021

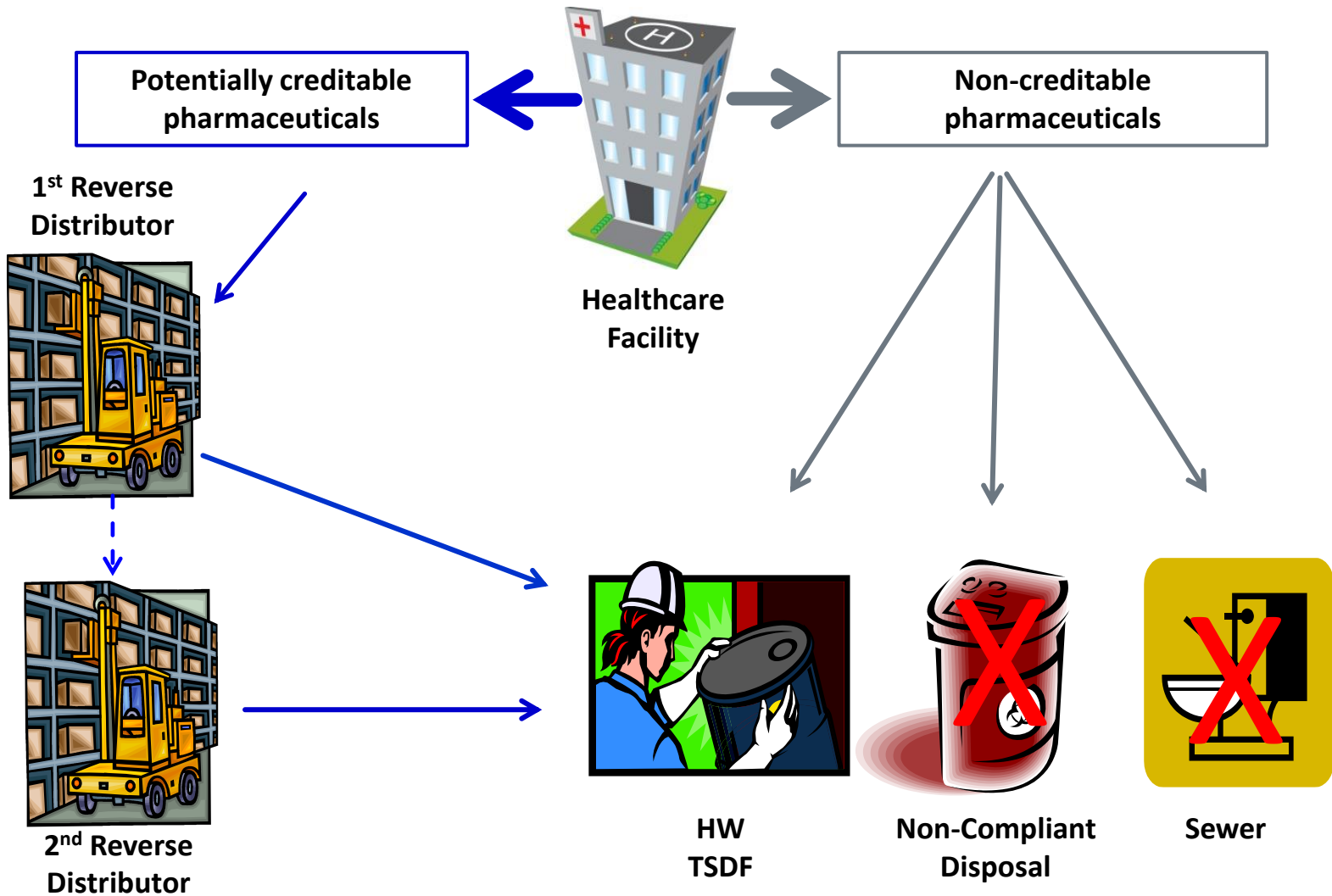
SEWER BAN

- Effective August 21, 2019
- Hazardous waste pharmaceuticals may not be sewerered
- Applies to all healthcare facilities, including VSQGs
- EPA and DOH discourage sewerering of any pharmaceuticals by any entity

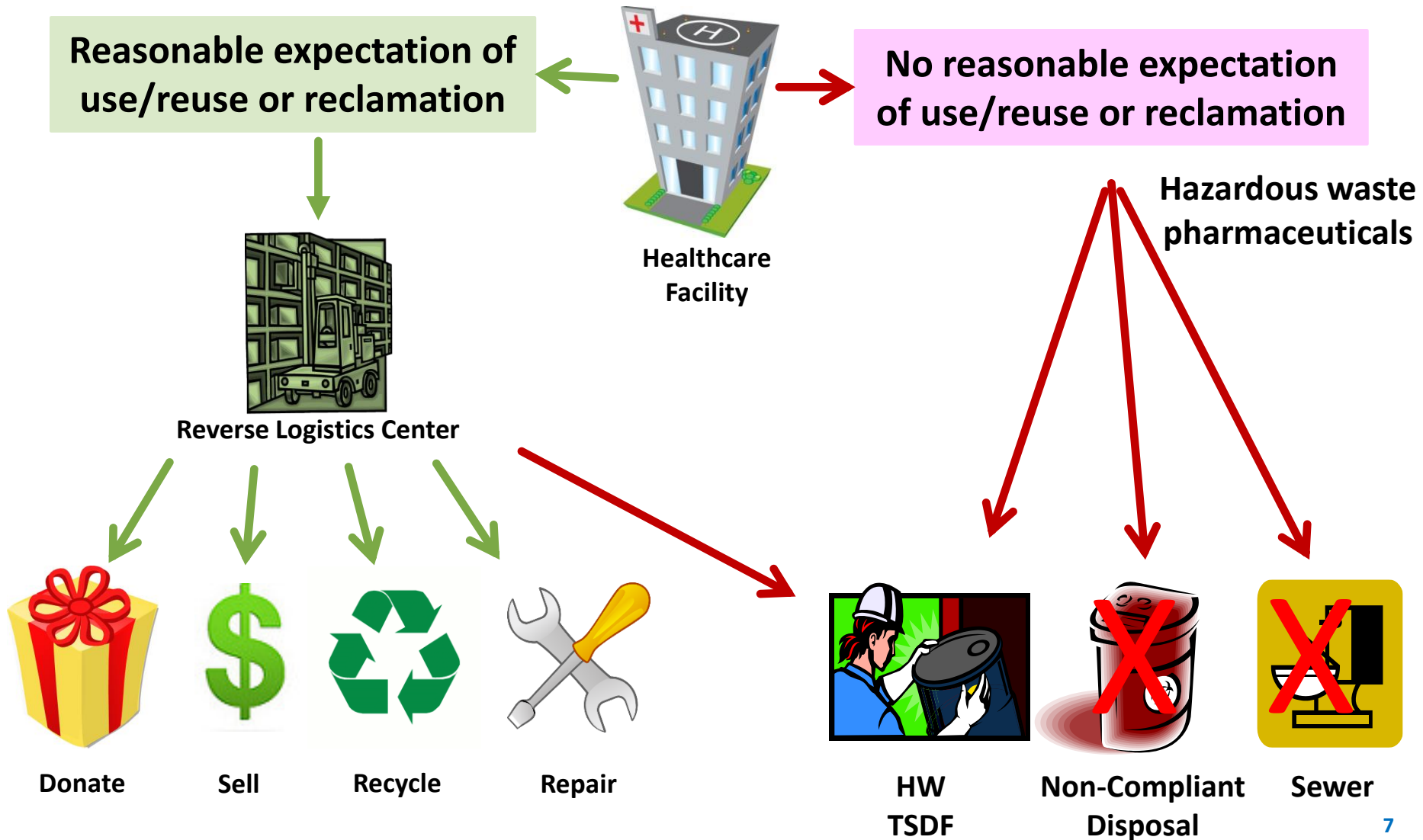
EMPTY CONTAINER DEFINITION

	Non-acute HW Pharms	Acute HW Pharms
Stock/dispensing bottles (up to 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 Or §261.7(b)(1)	Fully administer contents
Other containers	§261.7(b)(1) or (2)	<u>Can not be RCRA empty</u>

Reverse distribution - Rx HW pharms



Reverse logistics - Non-Rx pharms, retail items



Pharmaceutical

- any drug or dietary supplement for use by humans or other animals
- ~~electronic nicotine delivery system (ENDS)~~
- ~~liquid nicotine/e-liquid packaged for retail sale for use in ENDS~~



Pharmaceutical

- 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

Does **NOT** include:

- Dental amalgam
- Sharps
- Medical waste
- Electronic nicotine delivery systems (ENDS), e.g., e-cigarettes, vaping pens
- Nicotine e-liquid/juice packaged for retail sale for use in ENDS, e.g., pre-filled cartridges or vials

Pharmaceutical - §266.501 Applicability

Pharmaceuticals NOT subject to RCRA regulation:

- Reasonable expectation of being legitimately used/reused or reclaimed
- Recalled*
- Under preservation order, or during an investigation or judicial proceeding*
- Investigational new drugs*
- Household waste pharmaceuticals, including collected DEA controlled substances (with conditions in §266.506)

* Become subject to Subpart P when decision is made to discard

Healthcare facility

Any person that is lawfully authorized to:

- (1) Provide preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, and counseling, service, assessment or procedure with respect to the physical or mental condition, or functional status, of a human or animal or that affects the structure or function of the human or animal body; or

Healthcare facility

Any person that is lawfully authorized to:

- (1) Provide...care...of a human or animal...; or
- (2) Distribute, sell, or dispense pharmaceuticals, including over-the-counter pharmaceuticals, dietary supplements, homeopathic drugs, or prescription pharmaceuticals

Healthcare facility

Includes, but is not limited to:

- Wholesale distributors
- Third-party logistics providers ('3PLs') that serve as forward distributors
- Military medical logistics facilities
- Hospitals
- Psychiatric hospitals
- Ambulatory surgical centers
- Health clinics
- Physicians' offices
- Optical and dental providers
- Chiropractors
- Long-term care facilities**

- Ambulance services
- Pharmacies
- Long-term care pharmacies
- Mail-order pharmacies
- Retailers of pharmaceuticals
- Veterinary clinics & hospitals

Does **NOT** include:

- Pharmaceutical manufacturers
- Reverse Distributors
- Reverse Logistics centers
- ENDS Retailers

Hazardous waste

Non-pharmaceutical
HW

**Hazardous waste
pharmaceutical**

Non-HW
pharmaceutical

Pharmaceutical

Hazardous waste

Non-pharmaceutical HW

Rx

Potentially creditable HW pharmaceutical → Evaluated HW pharmaceutical

Non-creditable HW pharmaceutical

Non-Rx

Non-HW pharmaceutical

Pharmaceutical

3 Types of HW Pharmaceuticals

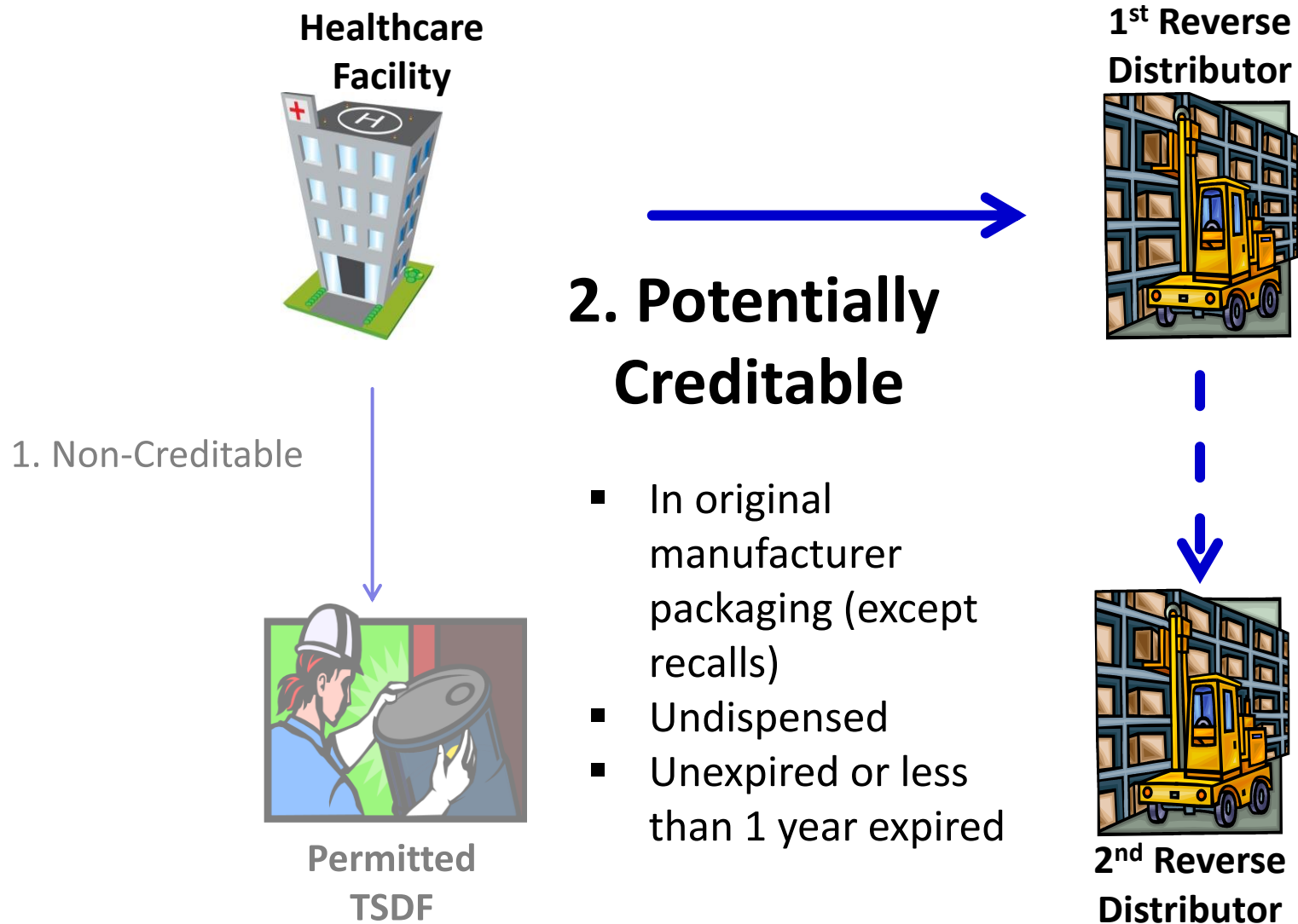


Permitted
TSDF

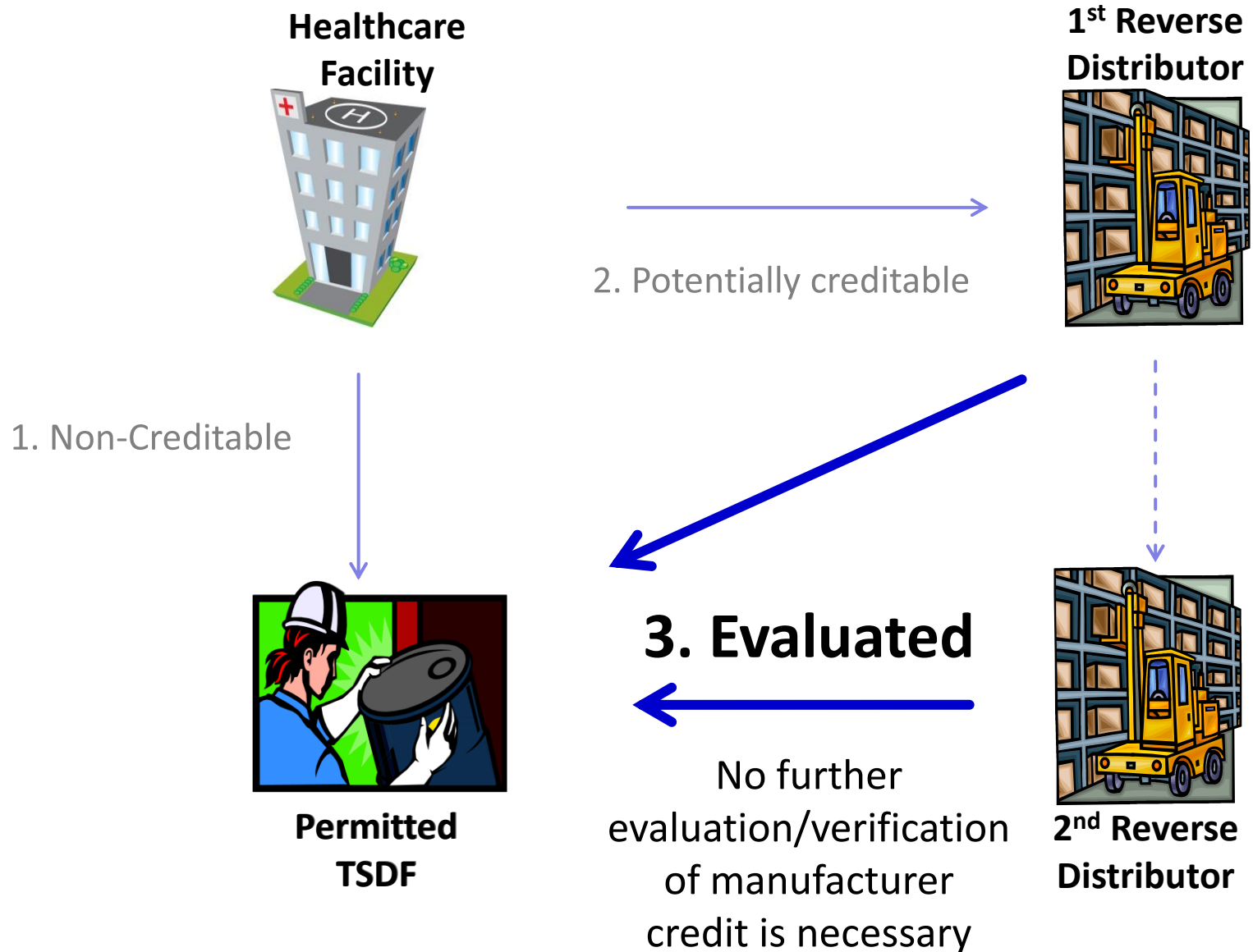
1. Non-Creditable

- Dispensed
- Broken or leaking
- Repackaged
- >1 year expired
- Investigational new drugs
- Free samples
- Residues
- Floor sweepings
- Contaminated PPE
- Spill clean-up material

3 Types of HW Pharmaceuticals



3 Types of HW Pharmaceuticals



COMMON HW PHARMS

- D001: usually due to alcohol content
- D002
- P-listed: arsenic trioxide, nicotine, phentermine, physostigmine, physostigmine salicylate, warfarin >0.3%
- U listed: chloral hydrate , chloroform, formaldehyde, lindane, paraldehyde, phenol, reserpine, saccharin, selenium sulfide
- U-listed chemo: mitomycin, chlorambucil, cyclophosphamide, melphalan

DETERMINING APPLICABILITY

1. Count all hazardous waste → applicability of subpart P

- Include HW pharms
- **Include potentially creditable HW pharms**
- Include non-pharm HW
- Include all types of Universal Waste

> 100 kg/mo HW or > 1 kg/mo acute HW → subject to subpart P

2. Count only HW subject to chapter 11-262.1 → generator category for notification and 11-262.1 regulations

- Exclude HW pharms
- Exclude UW

NON-HW PHARMS TO MANAGE WITH CARE

- More than one active ingredient on the P- or U-list
- Chemotherapy agents characterized as bulk wastes
- Meets NIOSH hazardous drug criteria
- $LD50 \leq 50 \text{ mg/kg}$
- Carcinogenic or endocrine disrupting compounds
- Vitamin/mineral preparations containing heavy metals

BUT WHO'S COUNTING?

- Once subject to subpart P, all healthcare facilities are regulated the same
- Healthcare facilities *operating under subpart P* do not have to:
 - Track monthly generation of HW pharmaceuticals
 - Segregate acute and non-acute HW pharmaceuticals
- Healthcare facilities *managing all waste pharmaceuticals as HW* do not have to keep documentation of HW determinations

GENERAL REQUIREMENTS

- Notification by August 6, 2021
(within 60 days of effective date, June 7)
- Employee training
- Hazardous waste determinations
- Reporting and recordkeeping
 - 3 years
 - Exception reporting (60 days)
- Spill response

ON-SITE ACCUMULATION

For non-creditable pharmaceuticals:

- Label “Hazardous waste pharmaceuticals”
- Containers
 - Structurally sound, compatible with contents, lack evidence of leakage spillage, or damage
 - Special requirements for ignitable/reactive
 - Closed
 - Secured in a manner than prevents unauthorized access to contents
- Maximum accumulation time 1 year

SEGREGATE NON-COMBUSTIBLE

- Metal bearing wastes prohibited from dilution in a combustion unit
- Label with hazardous waste codes
 - D004-D011 arsenic, barium, cadmium, chromium, lead, mercury, selenium, silver
 - P012 arsenic trioxide
 - U151 mercury
 - U205 selenium disulfide

LIQUIDS AND AEROSOLS

- Sealed plastic bag or other outer container
- Reduce the risk of spills and release

ON-SITE ACCUMULATION

HEALTHCARE FACILITY	Non-creditable HW pharms	Potentially creditable HW pharms
Labeling	✓	None
Container standards	✓	None
Max accumulation time	✓	None
HW determinations*	✓	✓

*Not required if all pharmaceutical waste is managed as hazardous waste

SHIPPING: NON-CREDITABLE

- To RCRA permitted TSDF
- Use a HW transporter & HW manifest
 - PHARMS or PHRM on manifest in item 13
 - Segregate metal bearing wastes prohibited from dilution in a combustion unit and label with HW codes
- Keep records for 3 years

SHIPPING: POTENTIALLY CREDITABLE

- To Reverse Distributor
- Neither manifest nor HW transporter required (can use common carrier)
- Shipper must receive delivery confirmation from reverse distributor
 - 35 days from date the shipment was sent
 - Electronic delivery confirmation okay
- Keep records for 3 years

VSQG HEALTHCARE FACILITIES

Count all hazardous waste – both HW pharmaceuticals & non-pharmaceutical HW

- Remain subject to §262.14
- Subject to subpart P ONLY for:
 - Sewer prohibition
 - Empty containers
 - Optional provisions of §266.504

VSQG HEALTHCARE FACILITIES

- Can send potentially creditable HW pharmaceuticals to reverse distributor
- Can send HW pharmaceuticals to a healthcare facility under control of the same person
- A VSQG long-term care facility can dispose of its HW pharmaceuticals (but not its DEA controlled substances) in an on-site collection receptacle that complies with DEA regulations

VSQG CONSOLIDATION

To receive and manage HW pharmaceuticals from a VSQG healthcare facility, a healthcare facility must:

- Be under the control of the same “person” OR supply the VSQG with pharmaceuticals
- Operate under 40 CFR Part 266 subpart P & manage the received pharmaceuticals under subpart P
- Keep records of shipments received for 3 years

COMPARING VSQG CONSOLIDATION

Subpart P VSQG consolidation	Generator Improvements Rule VSQG consolidation
Can be used by VSQG healthcare facilities only for HW pharms	Can be used by VSQG healthcare facilities for both HW pharms and non-pharmaceutical HW
Fewer conditions	More conditions
Receiving healthcare facility must be: <ul style="list-style-type: none">• under the control of the same person as the VSQG, or• the supplier of the pharmaceuticals	Receiving facility must be: <ul style="list-style-type: none">• under the control of the same person as the VSQG
Receiving healthcare facility does not have to be an LQG	Receiving facility must be an LQG

A VSQG WHO OPTS IN

- Opt in/opt out notification
- Must comply with all subpart P standards for healthcare facilities
- Cannot use the optional provisions in section 266.504
 - Subpart P consolidation
- Still has to keep track of monthly generation amounts for non-pharmaceutical waste to verify VSQG status

SUMMARY

Management Standard Elements	Standards for Healthcare Facilities
	Potentially Creditable
On-site accumulation	<ul style="list-style-type: none"> • No standards • No time limit
Shipping to Reverse Distributor	<ul style="list-style-type: none"> • Confirmation of delivery • Common carrier
	Non-Creditable
On-site accumulation	<ul style="list-style-type: none"> • UW-like standards • 1 year maximum
Shipping to TSDF	<ul style="list-style-type: none"> • Manifest (PHARMS or PHRM) • HW transporter

CONDITIONAL EXEMPTION

- HW pharmaceuticals that are also DEA controlled substances

CONDITIONAL EXEMPTION

- Sewer ban
- Collected, stored, and transported, in compliance with DEA requirements
- Destroyed by a method DEA has deemed in writing to meet their non-retrievable standard OR combusted at a permitted:
 - Large or small municipal waste combustor
 - Hospital, medical and infectious waste incinerator
 - Commercial and industrial solid waste incinerator
 - Hazardous waste combustor

RESOURCES

- DOH HW rules page & guidance
- EPA pharms rule website
 - Rule
 - FAQ
- Recorded webinar by EPA
- EPA guidance for managing pharms

RESOURCES

- Healthcare Environmental Resource Center (HERC)
 - Provides pollution prevention and environmental compliance assistance information for the healthcare sector.
 - Receives funding from EPA through the National Compliance Assistance Centers program
- Guidance for safe disposal of household waste pharmaceuticals
- Retail strategy & reverse logistics policy

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