

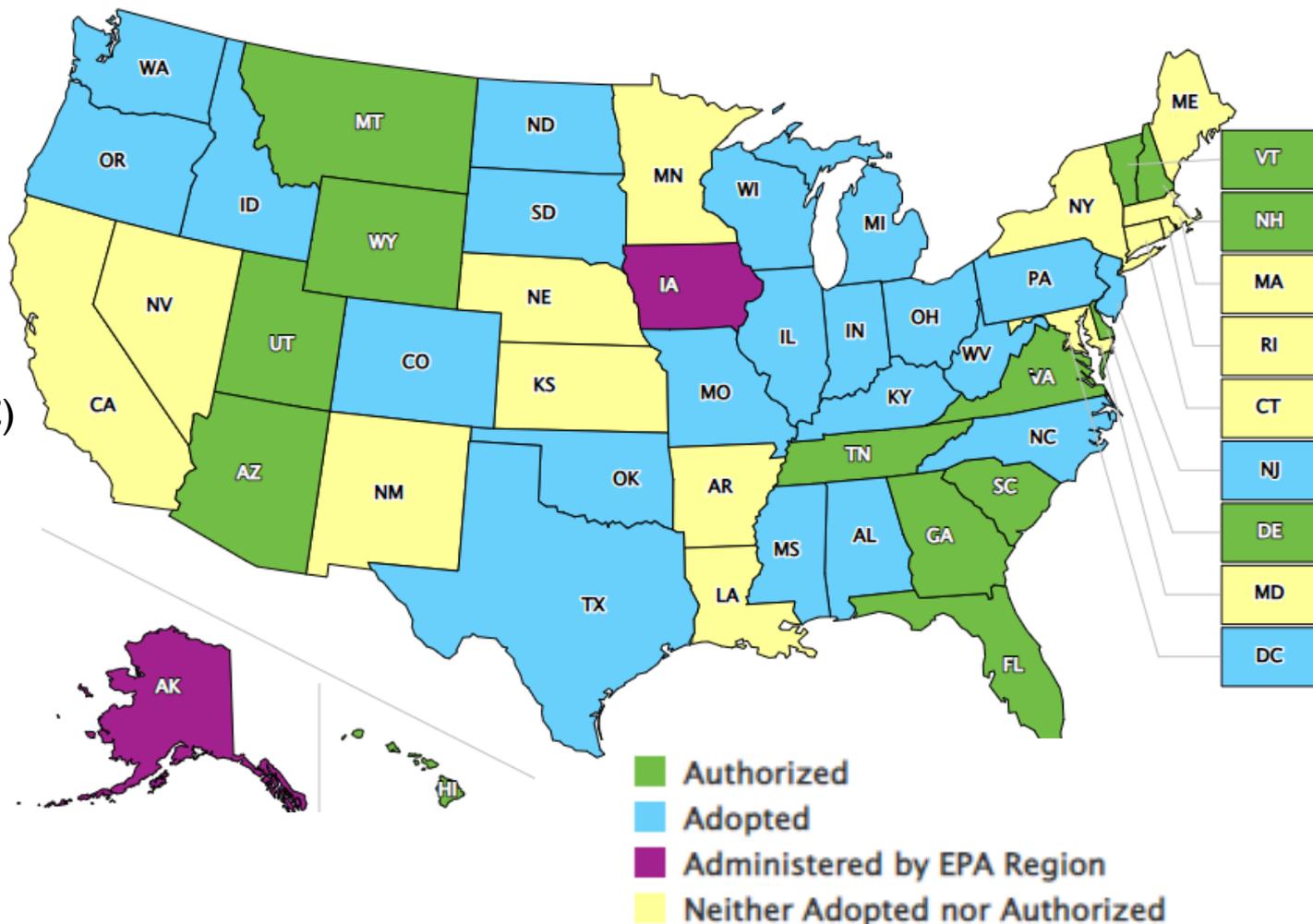
HAZARDOUS WASTE PHARMACEUTICALS RULE

NEWMOA ROUNDTABLE
AUGUST 26, 2025

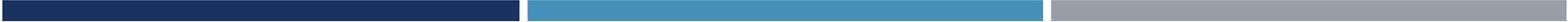
KRISTIN FITZGERALD, US EPA

STATE ADOPTION OF PART 266 SUBPART P

Effective in:
Indian country
4 Territories
37 States
(count includes DC)



As of June 30, 2025



PART 266 SUBPART P OVERVIEW

SECTION I



OVERVIEW OF PART 266 SUBPART P

- Subpart P is a waste-specific and sector-specific final rule
 - for the management of hazardous waste pharmaceuticals
 - at healthcare facilities and reverse distributors
- These hazardous wastes and this sector are already regulated under RCRA
- We did not newly apply RCRA regulations to hazardous waste pharmaceuticals at healthcare facilities and reverse distributors
- We are changed HOW they are regulated under RCRA moving forward
 - GOAL: to create regulations that a better fit for the management of hazardous waste pharmaceuticals at healthcare facilities and reverse distributors

TYPES OF HAZ WASTE PHARMACEUTICALS

There are 3 types of *Hazardous Waste Pharmaceuticals*:

1. Non-creditable hazardous waste pharmaceutical
2. Potentially creditable hazardous waste pharmaceutical
3. Evaluated hazardous waste pharmaceutical

3 Types of HW Pharmaceuticals

Healthcare Facility



I. Non-creditable HW Pharmaceuticals

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



HW
TSDF

3 Types of HW Pharmaceuticals

1st Reverse Distributor



2. Potentially Creditable



2nd Reverse Distributor

2. Potentially Creditable HW Pharmaceuticals

- Original manufacturer packaging (except recalls)
- Undispensed
- Unexpired or less than 1-yr past expiration
- Reasonable expectation of receiving manufacturer credit

Healthcare Facility

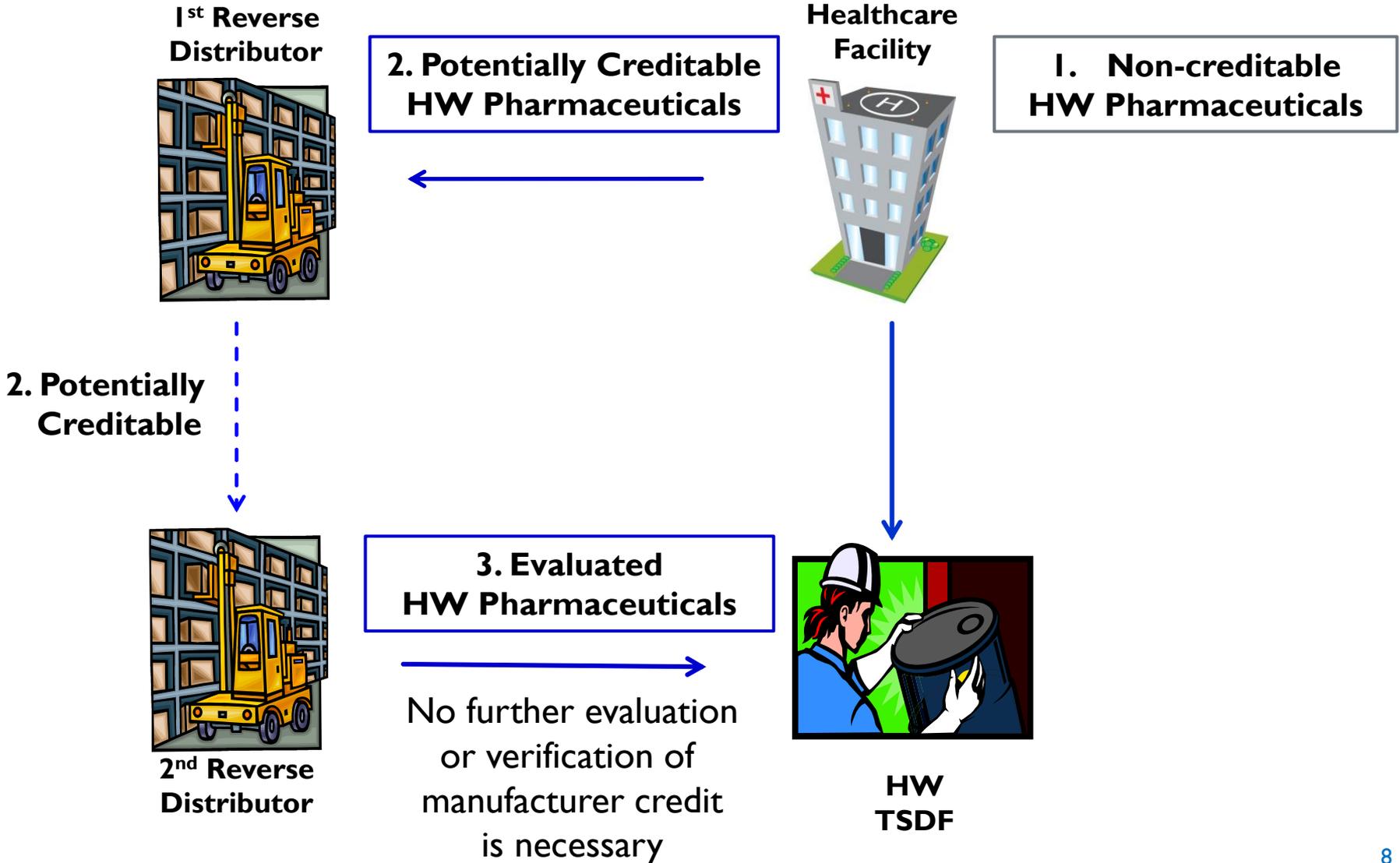


1. Non-creditable HW Pharmaceuticals

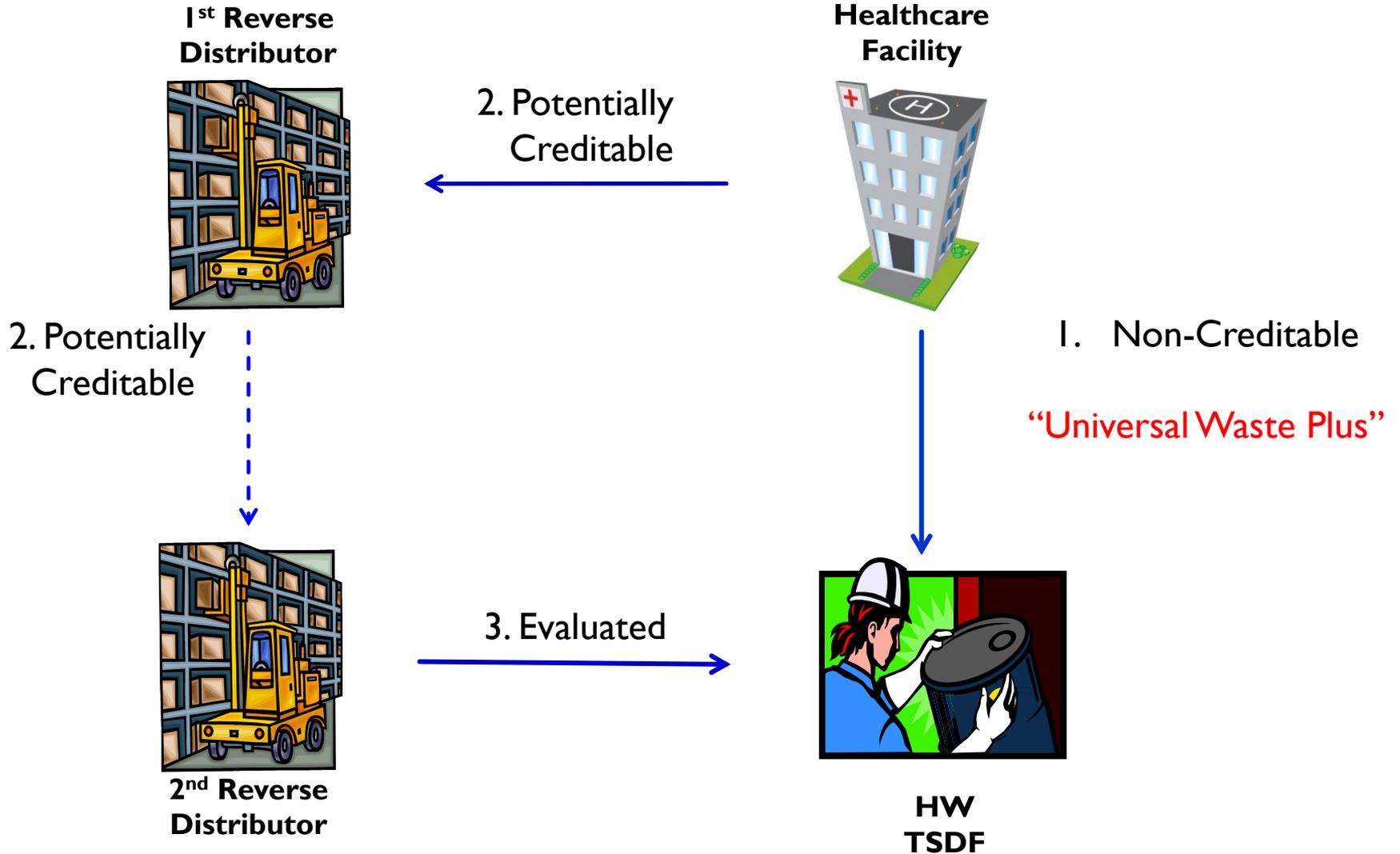


HW TSDF

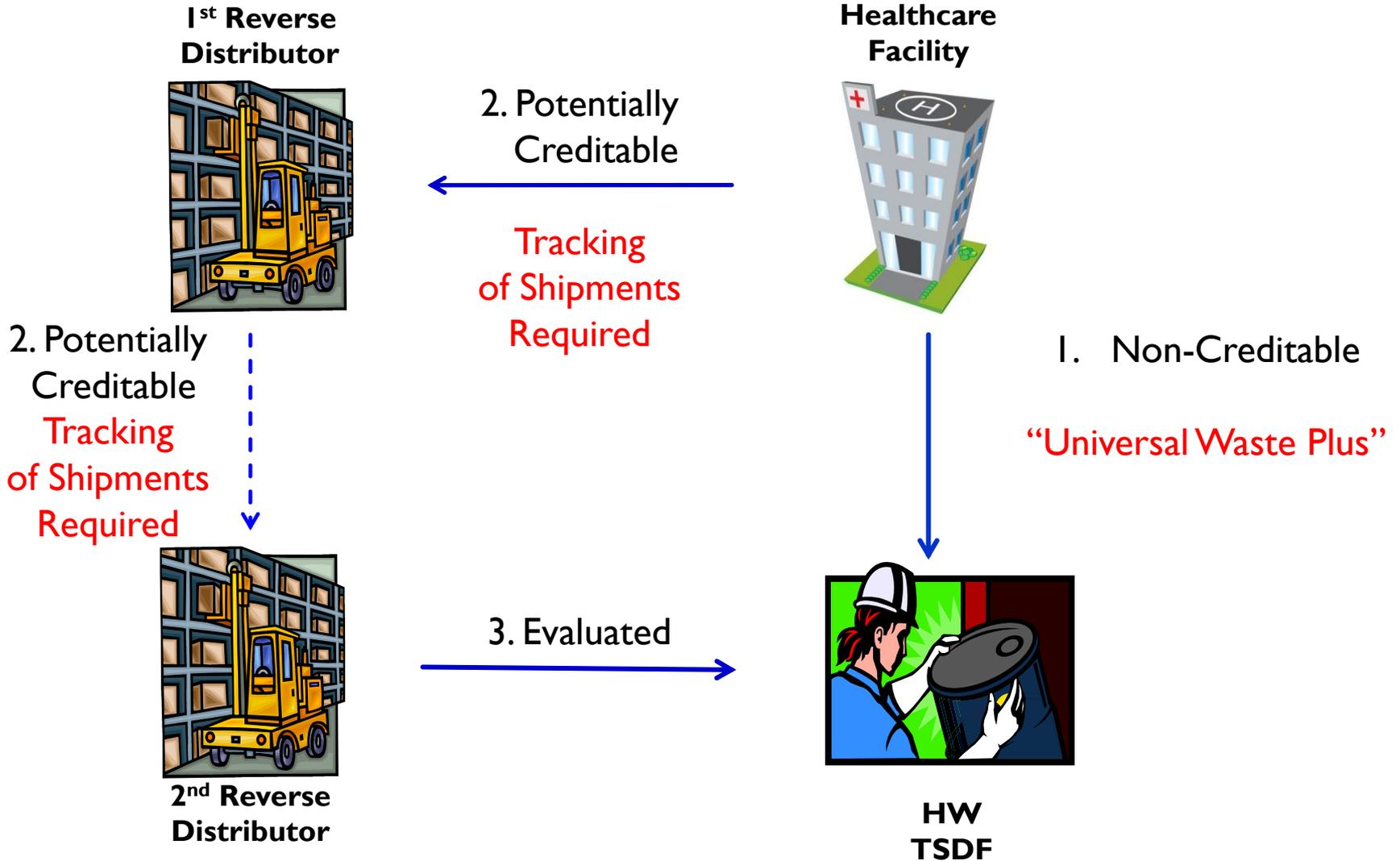
3 Types of HW Pharmaceuticals



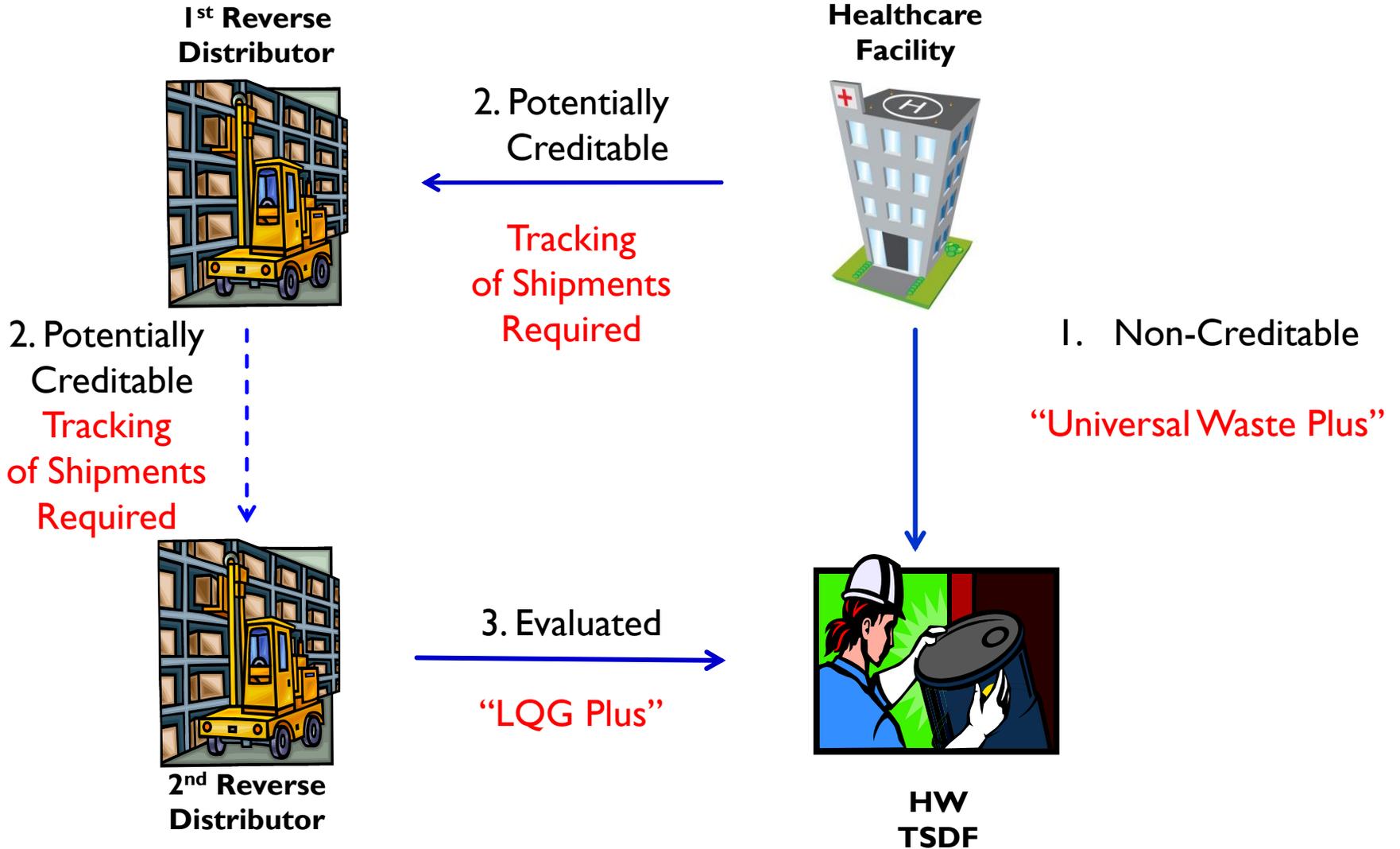
3 Types of HW Pharmaceuticals



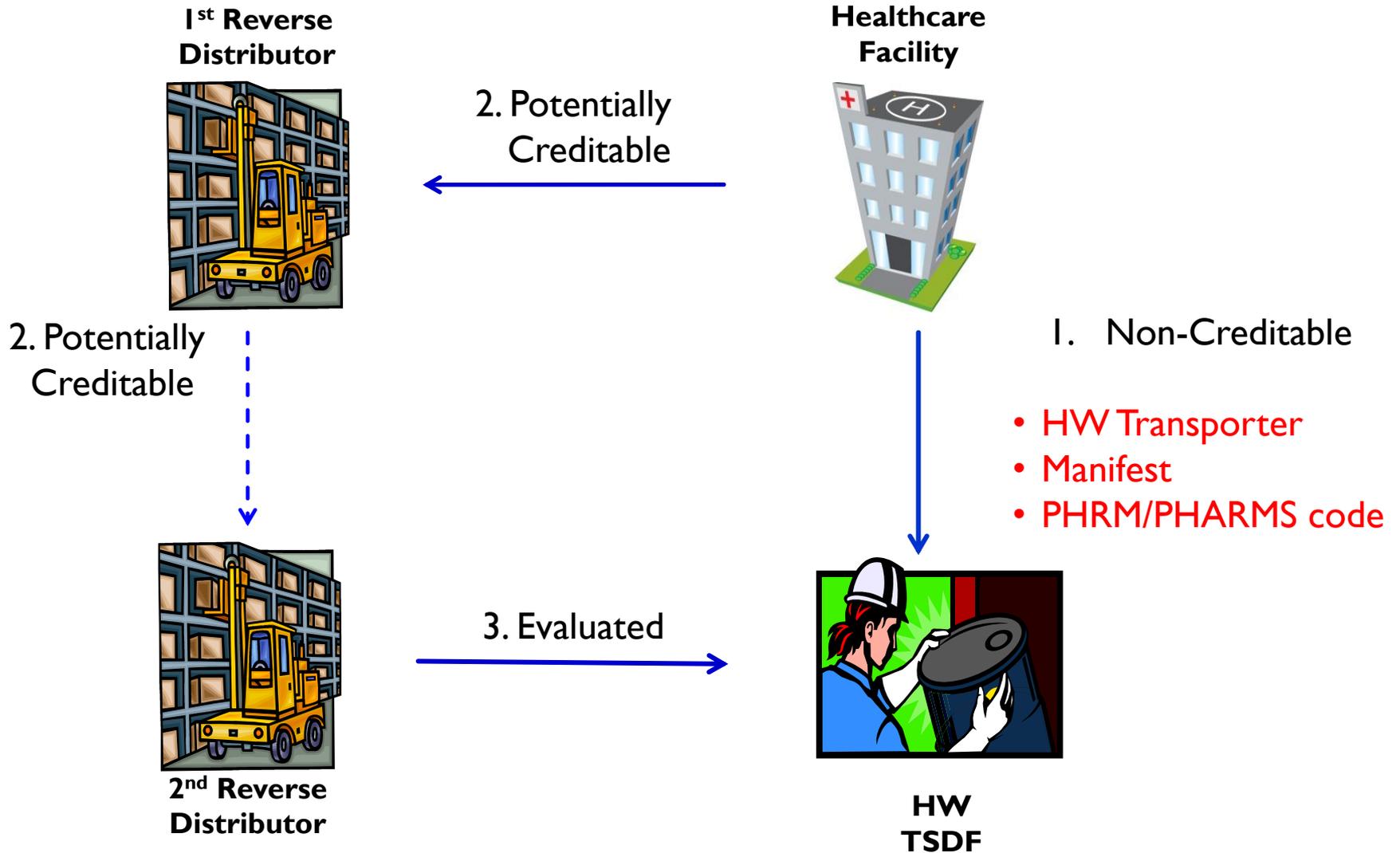
3 Types of HW Pharmaceuticals



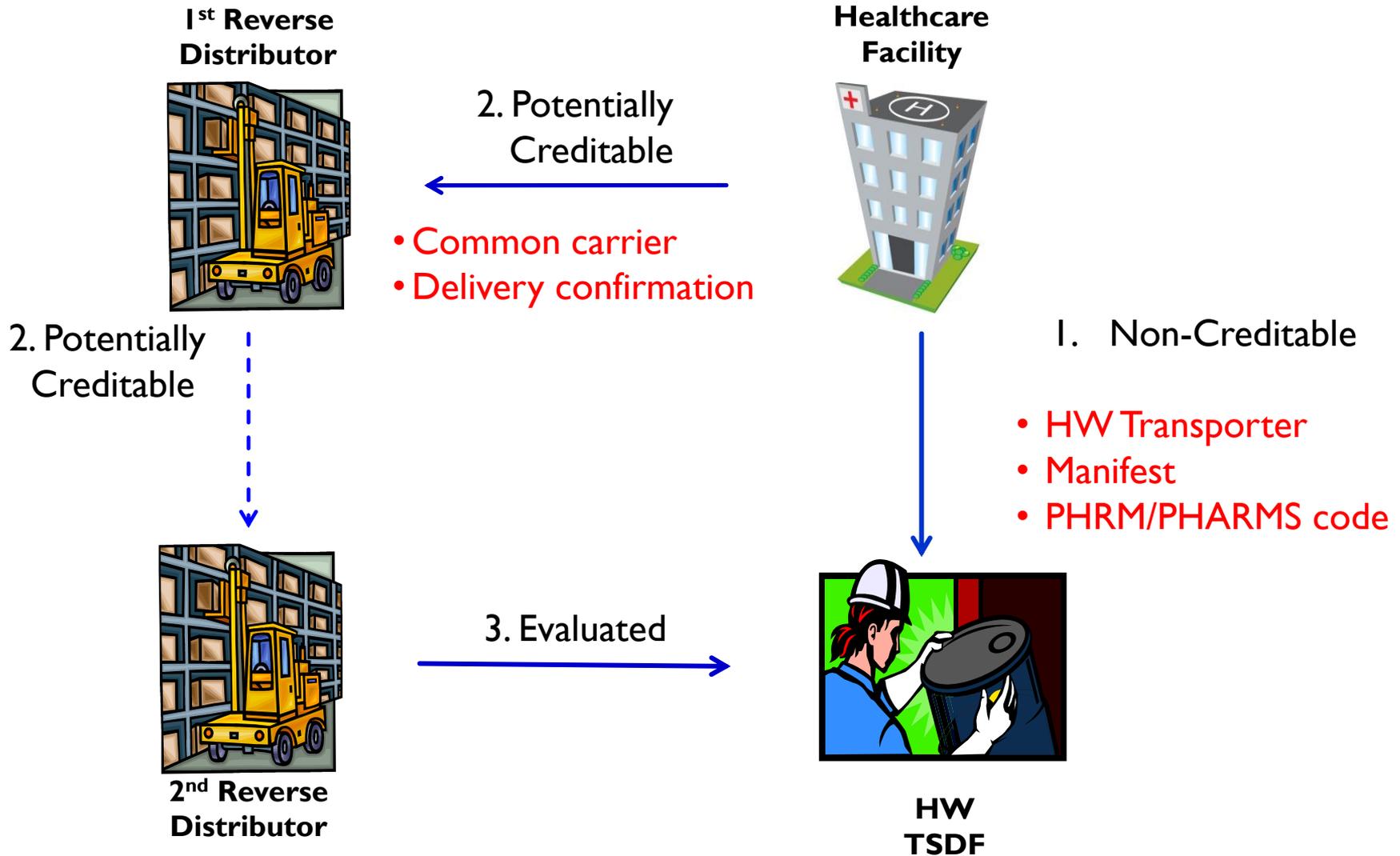
3 Types of HW Pharmaceuticals



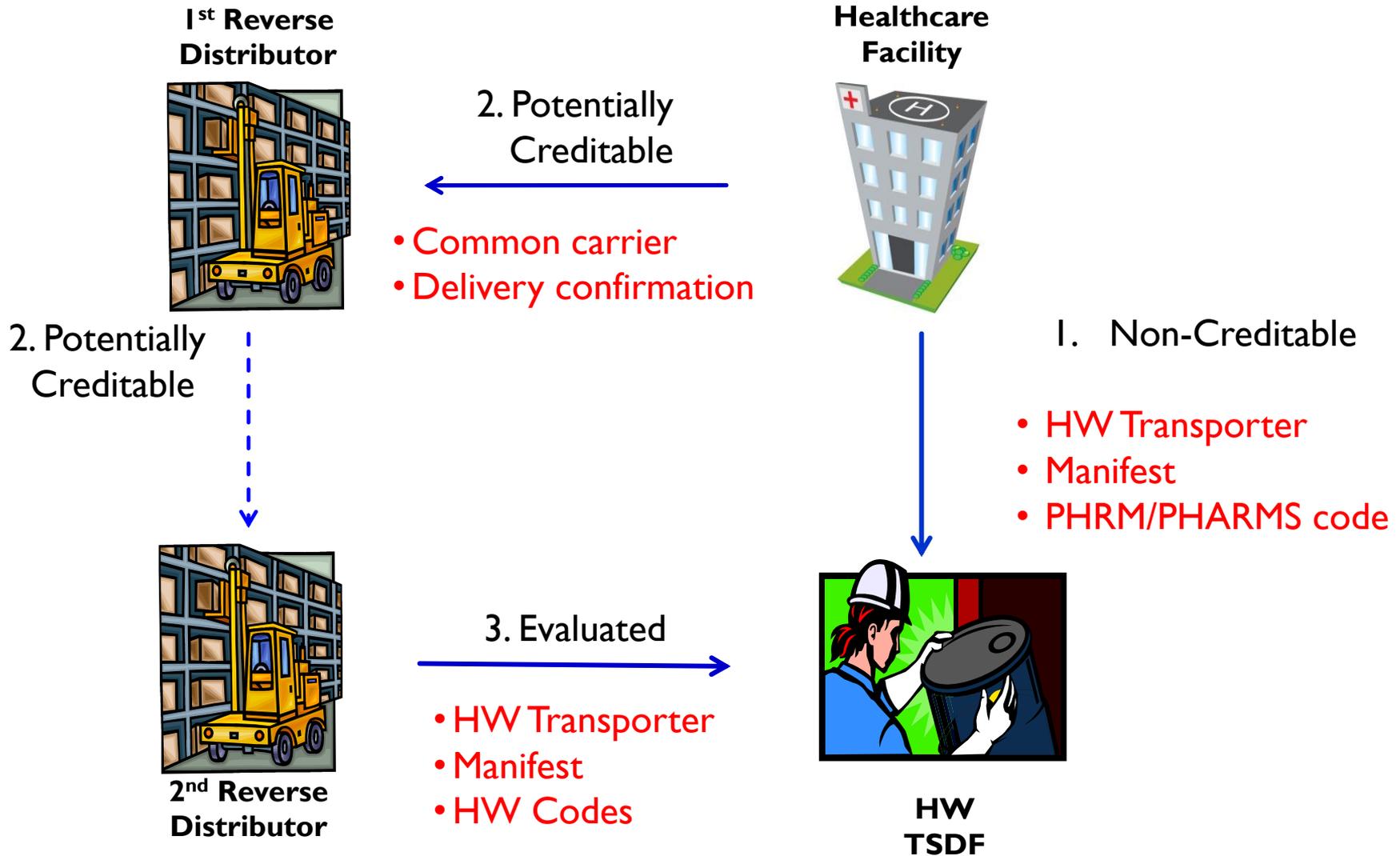
Shipments of HW Pharmaceuticals



Shipments of HW Pharmaceuticals



Shipments of HW Pharmaceuticals

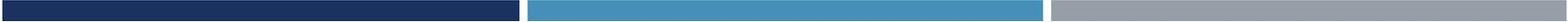


OTHER PROVISIONS OF SUBPART P

- Four optional provisions for VSQG healthcare facilities that have not opted into Subpart P (§266.504)
- Prohibition sewerage hazardous waste pharmaceuticals (§266.505)
- Two conditional exemptions for hazardous waste pharmaceuticals that are also controlled substances (§266.506)
- New empty container standards for containers found in healthcare settings (§266.507)
 - Single-dose containers, syringes, IV bags, other

SECTION II - 3 HOT TOPICS

1. To count or not to count...
2. Reasonable expectation of receiving manufacturer credit
3. Sequestration units



TO COUNT OR NOT TO COUNT...

SECTION 2 - HOT TOPIC I



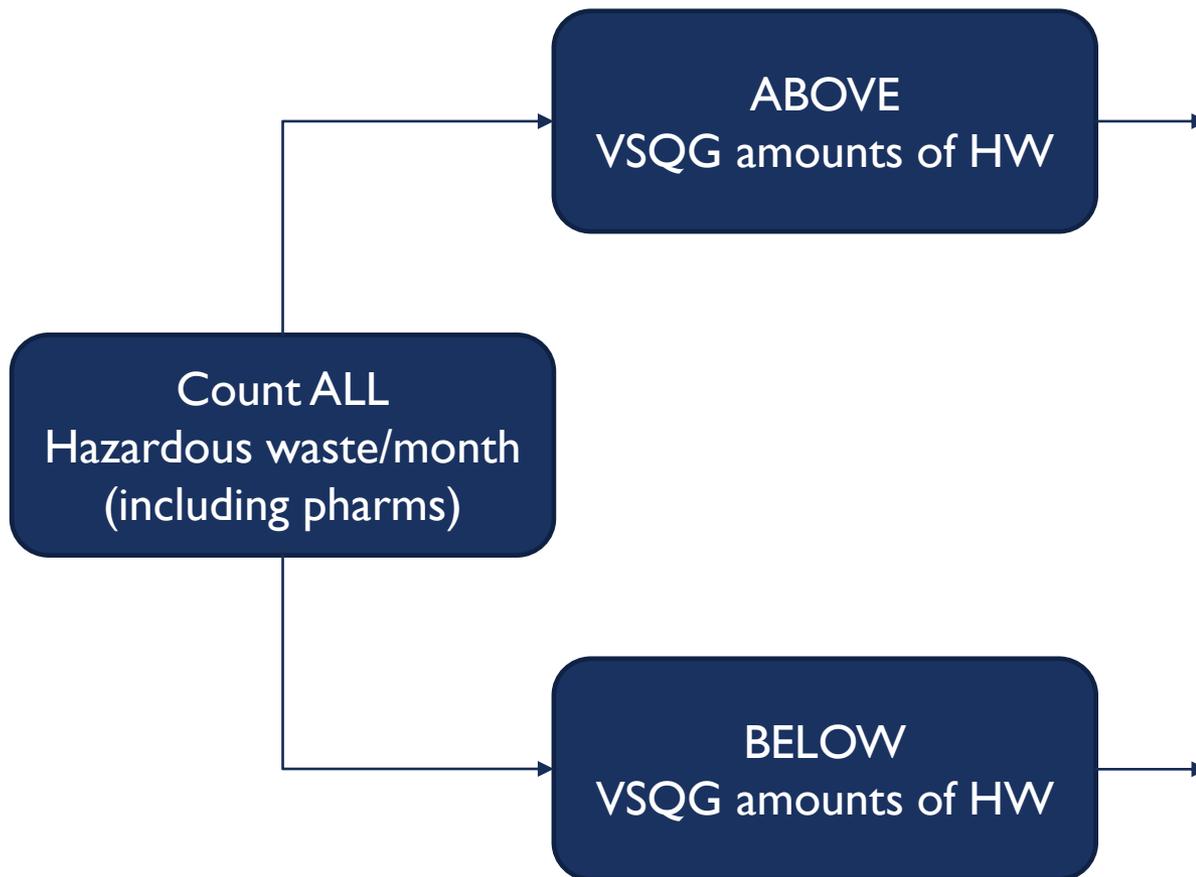
TWO ASPECTS OF COUNTING

1. Determining whether Subpart P applies at a healthcare facility
2. Operating under Subpart P

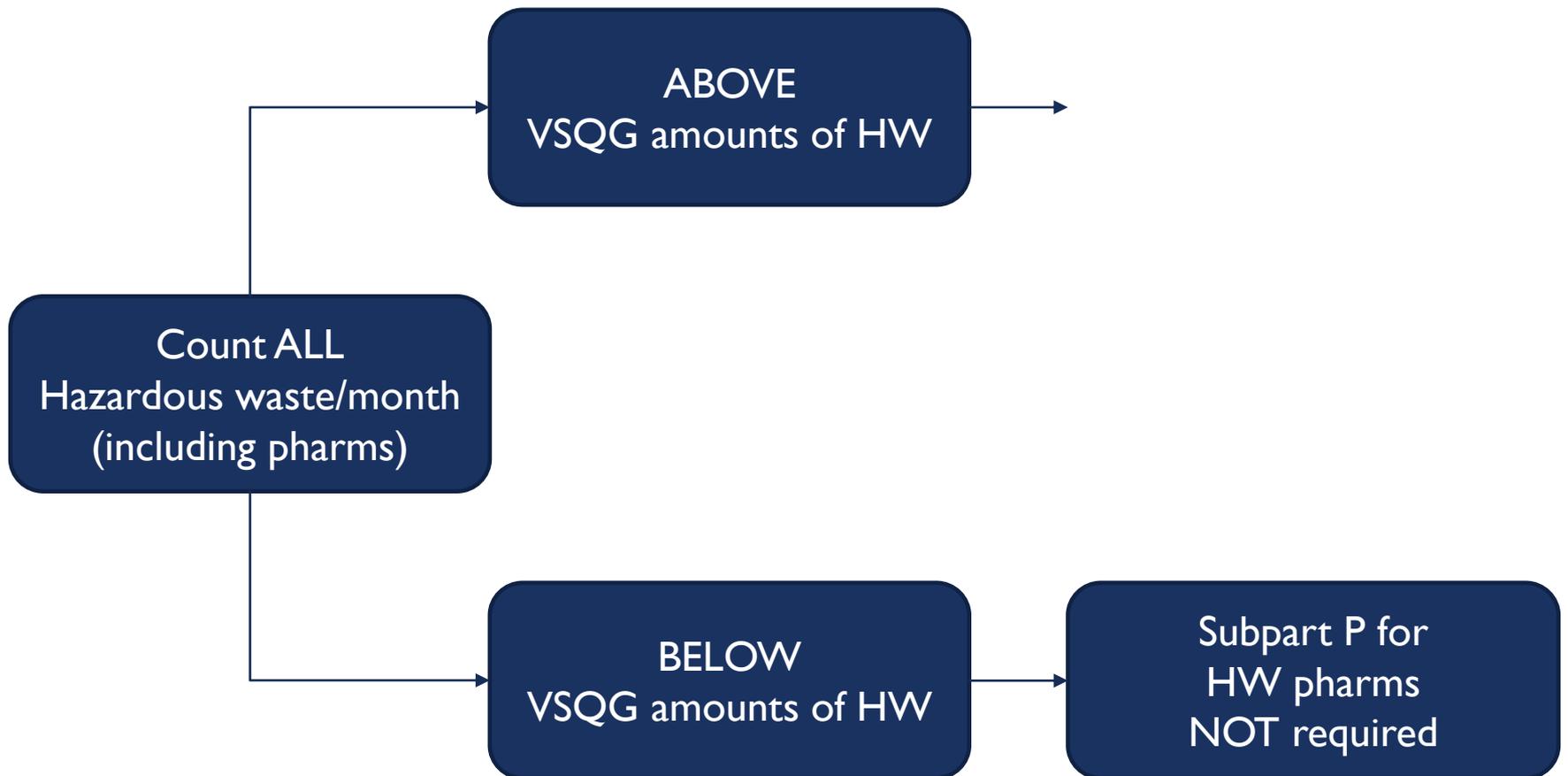
DOES SUBPART P APPLY?



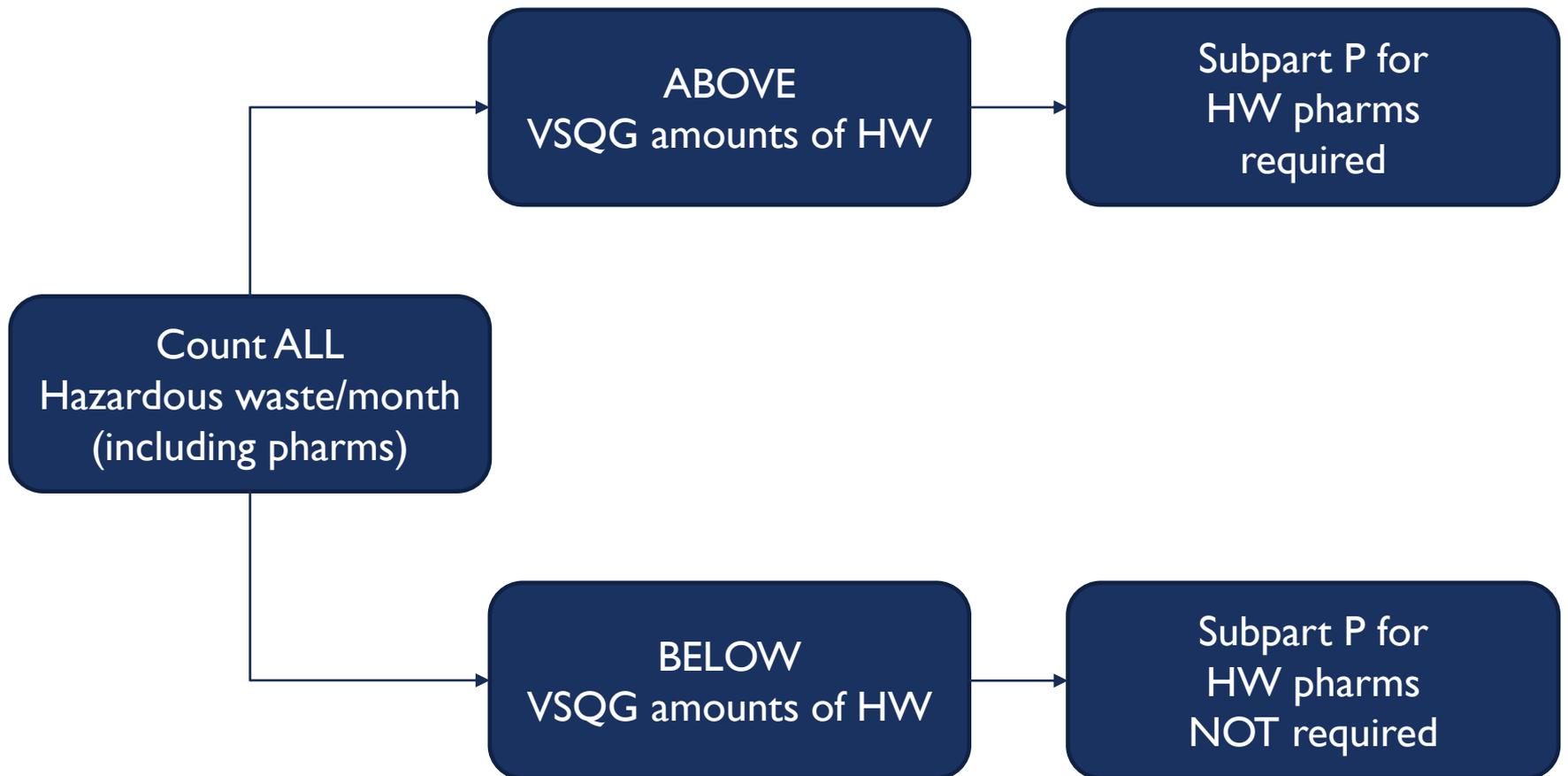
DOES SUBPART P APPLY?



DOES SUBPART P APPLY?



DOES SUBPART P APPLY?



ONCE OPERATING SUBPART P...

- Once operating under Part 266 Subpart P
 - There are NO generator categories under Part 266 Subpart P
 - All healthcare facilities are regulated the same for their hazardous waste pharmaceuticals
 - Healthcare facilities operating under Subpart P do not have to count their hazardous waste pharmaceuticals when determining generator category for the rest of their hazardous waste
- Provides an incentive to over-manage non-hazardous pharmaceuticals as hazardous without
 - Bumping up generator category
 - Incurring additional regulations

OTHER WASTES THAT DON'T GET COUNTED

- Examples of other hazardous wastes that do not count toward generator category (see § 262.13 (c))
 - Universal wastes - when managed under part 273
 - Used oil - when managed under part 279
 - Spent lead acid batteries - when managed under part 266 subpart G
- With universal waste, many generators
 - Do not bother with counting and figuring out applicability
 - Choose to manage their universal waste under part 273
- The same can be done with part 266 subpart P for pharmaceuticals

TAKE HOME MESSAGE RE: APPLICABILITY OF SUBPART P

When determining whether a healthcare facility is required to operate under subpart P, a healthcare facility must...



TAKE HOME MESSAGE RE: APPLICABILITY OF SUBPART P

When determining whether a healthcare facility is required to operate under subpart P, a healthcare facility must...

COUNT ALL of its hazardous waste,
including hazardous waste
pharmaceuticals

TAKE HOME MESSAGE RE: COUNTING UNDER SUBPART P

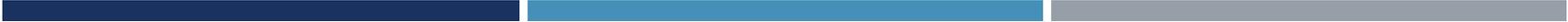
Only when a healthcare facility is operating under subpart P, can the healthcare facility...



TAKE HOME MESSAGE RE: COUNTING UNDER SUBPART P

Only when a healthcare facility is operating under subpart P, can the healthcare facility...

get the benefit of **NOT COUNTING** their hazardous waste pharmaceuticals toward determining generator category



REASONABLE EXPECTATION OF CREDIT

SECTION 2 – HOT TOPIC #2



WHAT PHARMACEUTICALS CAN GO TO AN RD?

- Potentially creditable hazardous waste pharmaceuticals
 - **Reasonable expectation** of receiving manufacturer credit
 - In original manufacture packaging
 - Not dispensed to a patient
 - Unexpired or < 1 year past expiration
- Examples that might surprise you
 - Generics can sometimes get manufacturer credit
 - Partials can sometimes get manufacturer credit

WHY RELY ON MANUFACTURER CREDIT?

- Manufacturers determine which pharmaceuticals get credit and which do not
 - Manufacturer policies can vary between customers
 - Manufacturer policies can change over time
 - But there are some fixed criteria
- The definition of potentially creditable hazardous waste pharmaceutical builds in manufacturers' fixed criteria
- The VALUE in the form of manufacturer credit
 - Creates an incentive to manage the pharmaceuticals carefully
 - Allows EPA to take a lighter regulatory touch
- Remember reverse distributors are not required to have permits, so we have to limit what they can accept to ensure they do not become de facto TSDFs

WHAT PHARMACEUTICALS CAN **NOT** GO TO AN RD?

- Containers that are leaking or damaged (although secondary packaging may be damaged)
- Drugs that are dispensed to a patient but the patient refuses to take
- Leftover drugs that are generated during patient care
- Free samples
- Investigational drugs
- Floor sweepings (“skittles”)
- Repackaged drugs (unless recalled)
- Items that you know from experience never receive credit
- Clean-up material from pharmaceutical spills
- PPE contaminated with hazardous waste pharmaceuticals
- Medical waste & sharps
- Other hazardous wastes from your healthcare facility (e.g., lab chemicals, cleaning solutions)

RECORDKEEPING AT HEALTHCARE FACILITIES

- Recordkeeping requirements for healthcare facilities with potentially creditable hazardous waste pharmaceuticals are in § 266.503(e)
- We did not include a requirement for healthcare facilities to have records related to which pharmaceuticals
 - Received credit from the reverse distributor and
 - Did not receive credit from the reverse distributor
- That is because these records are already kept as standard business records by
 - Healthcare facilities and
 - Reverse distributors

RECORDKEEPING AT HEALTHCARE FACILITIES

- Because it is not a regulatory requirement, inspectors may not cite a healthcare facility for not having the records available during an inspection
- However, inspectors may
 - Request to review the business records through an information request, and
 - Use these business records to help determine which pharmaceuticals have a “reasonable expectation” of receiving credit

PREAMBLE EXCERPTS FROM THE FINAL RULE

See pages 5846-8:

- “However, the Agency also understand that there are instances where it is well known that a pharmaceutical will not be creditable.”
- “It is not the Agency’s intent, however, for reverse distributors to serve in the capacity as TSDFs when it is well known that the manufacturer will not give credit for certain hazardous waste pharmaceuticals.”
- “EPA has added some new phrases such as “reasonable expectation of credit” to the definition [of potentially creditable hazardous waste pharmaceutical] to be clear that not all hazardous waste pharmaceuticals should be going back to reverse distributors.”

PREAMBLE EXCERPTS FROM THE FINAL RULE

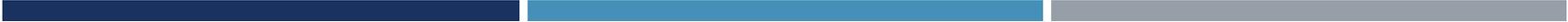
See pages 5846-8:

- “EPA’s intent is to prevent hazardous waste pharmaceuticals that are clearly ineligible for credit and are ready for disposal, due to their condition, previous use with a patient, or other reason, from being sent to the reverse distributor.”
- “A reverse distributor should not act as a hazardous waste disposal facility for healthcare facilities. It is serving as the manufacturer’s agent for determination of credit.”
- “If a reverse distributor begins to routinely receive non-creditable hazardous waste pharmaceuticals, then it is serving as a TSDf.”

PREAMBLE EXCERPTS FROM THE FINAL RULE

See page 5885:

- “This was in keeping with our position that a reverse distributor’s function in managing hazardous waste should be limited to managing hazardous waste pharmaceuticals that have a reasonable expectation of receiving manufacturer credit and not non-creditable hazardous waste pharmaceuticals or other non-pharmaceutical hazardous waste.” (emphasis added)



SEQUESTRATION UNITS

SECTION 2 – HOT TOPIC #3



DRUG “TREATMENT” SYSTEMS

- There are many brands of “drug treatment” or “drug sequestration” or “drug disposal” devices in use at hospitals
- Name some brands you have heard of

DRUG “TREATMENT” SYSTEMS

- There are many brands of “drug treatment” or “drug sequestration” or “drug disposal” devices in use at hospitals
- Name some brands you have heard of
 1. Cactus sink
 2. DeTerra
 3. CsRx
 4. Rx Carbon
 5. Rx Destroyer
 6. Rx Gon
 7. NarcX
 8. SafeMedWaste

DRUG “TREATMENT” SYSTEMS

- These units are usually used to collect DEA controlled substances:
 - Use only for disposing “**pharmaceutical wastage**” of controlled substances
 - Pharmaceutical wastage is leftover medicine that has been dispensed but not fully administered to a patient
 - Pharmaceutical wastage does not have to meet DEA’s non-retrievable standard of destruction
 - Do NOT use units for disposing **inventory** of controlled substances
- What is put into the sequestration unit will dictate how it must be managed when discarded

3 TYPES OF PHARMACEUTICAL WASTAGE

DEA
Controlled
Substance
(e.g, codeine)

DEA
+
RCRA
(e.g., diazepam)

RCRA
Hazardous
Waste
(e.g., warfarin)



Inclusion of product does not constitute an endorsement

HW THAT ARE ALSO DEA CONTROLLED SUBSTANCES

Name of Drug	Other Name(s)	Medical Uses	RCRA HW Code	DEA CS Schedule
Chloral/ Chloral hydrate	Acetaldehyde, trichloro; Aquachloral Noctec, Somnote, Suppettes	Sedative	U034 Toxic	IV
Fentanyl sublingual spray	Subsys	Analgesic	D001 ignitable	II
Phenobarbital	Bellergal-S Donnatal Luminal	Anticonvulsant	D001 ignitable	IV
Testosterone gels/solutions	Androgel Axiron Fortesta, Testim	Hormone	D001 ignitable	III
Valium injectable/gel	Diazepam Diastat	Anti-anxiety	D001 ignitable	IV

3 TYPES OF PHARMACEUTICAL WASTAGE

DEA
Controlled
Substance
(e.g, codeine)

DEA
+
RCRA
(e.g., diazepam)

RCRA
Hazardous
Waste
(e.g., warfarin)

- Regulated by DEA
- Not regulated as RCRA HW



3 TYPES OF PHARMACEUTICAL WASTAGE

DEA
Controlled
Substance
(e.g, codeine tablet)

- Regulated by DEA
- Not regulated as RCRA HW

DEA
+
RCRA
(e.g., diazepam)

- Regulated by DEA
- Conditionally exempt from RCRA

RCRA
Hazardous
Waste
(e.g., warfarin)



3 TYPES OF PHARMACEUTICAL WASTAGE

DEA
Controlled
Substance
(e.g, codeine tablet)

- Regulated by DEA
- Not regulated as RCRA HW

DEA
+
RCRA
(e.g., diazepam)

- Regulated by DEA
- Conditionally exempt from RCRA

RCRA
Hazardous
Waste
(e.g., warfarin)

- Not regulated by DEA
- Fully regulated as RCRA HW

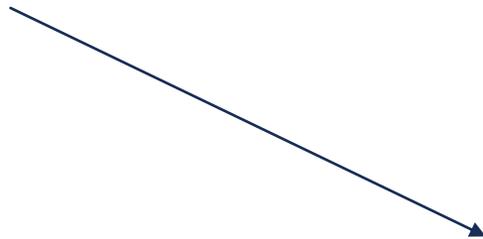


DRUG “TREATMENT” SYSTEMS

- EPA’s recommendation is to take a conservative approach
 - Odds are these units also have RCRA hazardous waste pharmaceuticals in them
 - Thus, under Subpart P, these units would be considered hazardous waste pharmaceutical accumulation containers
 - The land disposal restriction (LDR) treatment standard for most hazardous waste pharmaceuticals is combustion
 - Therefore, the units must be sent to a hazardous waste combustor in order to comply with the LDRs

LEAST LIKELY SCENARIO

DEA
Controlled
Substance
(e.g, codeine tablet)



LEAST LIKELY SCENARIO

DEA
Controlled
Substance
(e.g, codeine tablet)

Not regulated as RCRA
hazardous waste

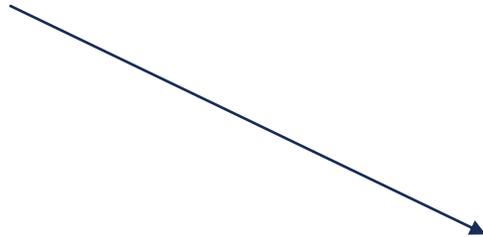
- Non-hazardous
incineration
recommended



UNLIKELY SCENARIO

DEA
Controlled
Substance
(e.g, codeine tablet)

DEA
+
RCRA
(e.g., diazepam)



UNLIKELY SCENARIO

DEA
Controlled
Substance
(e.g, codeine tablet)

DEA
+
RCRA
(e.g., diazepam)

Conditionally exempt
from RCRA. Must be
incinerated

- HW incinerator
- MW combustor
- HMIWI
- CISWI

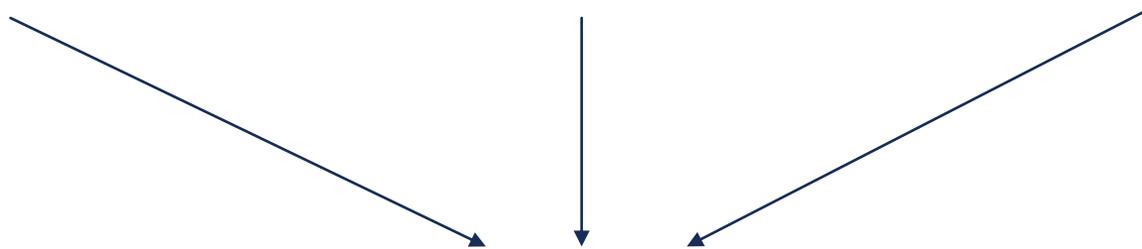


MOST LIKELY SCENARIO

DEA
Controlled
Substance
(e.g, codeine tablet)

DEA
+
RCRA
(e.g., diazepam)

RCRA
Hazardous
Waste
(e.g., warfarin)

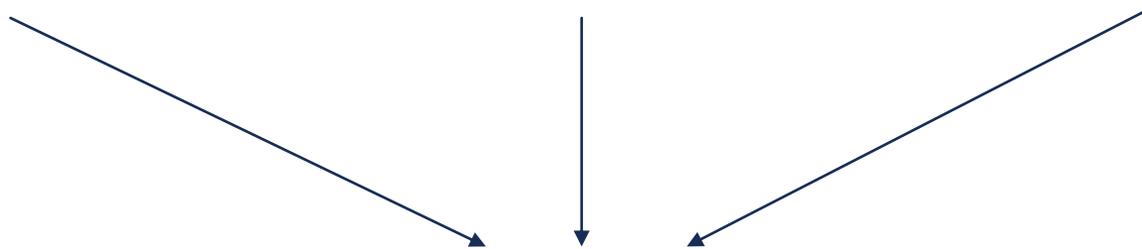


MOST LIKELY SCENARIO

DEA
Controlled
Substance
(e.g. codeine tablet)

DEA
+
RCRA
(e.g., diazepam)

RCRA
Hazardous
Waste
(e.g., warfarin)



Fully regulated hazardous waste

- Hazardous incineration required

DRUG “TREATMENT” SYSTEMS

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QUESTIONS?

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