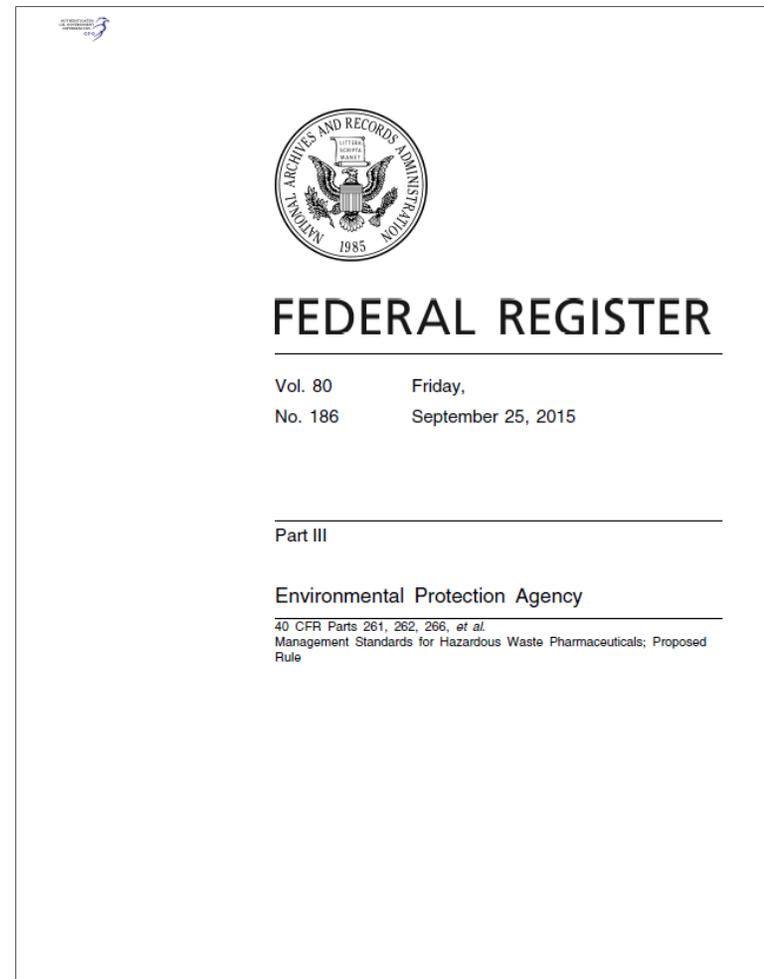


Hazardous Waste Pharmaceuticals Proposed Rule

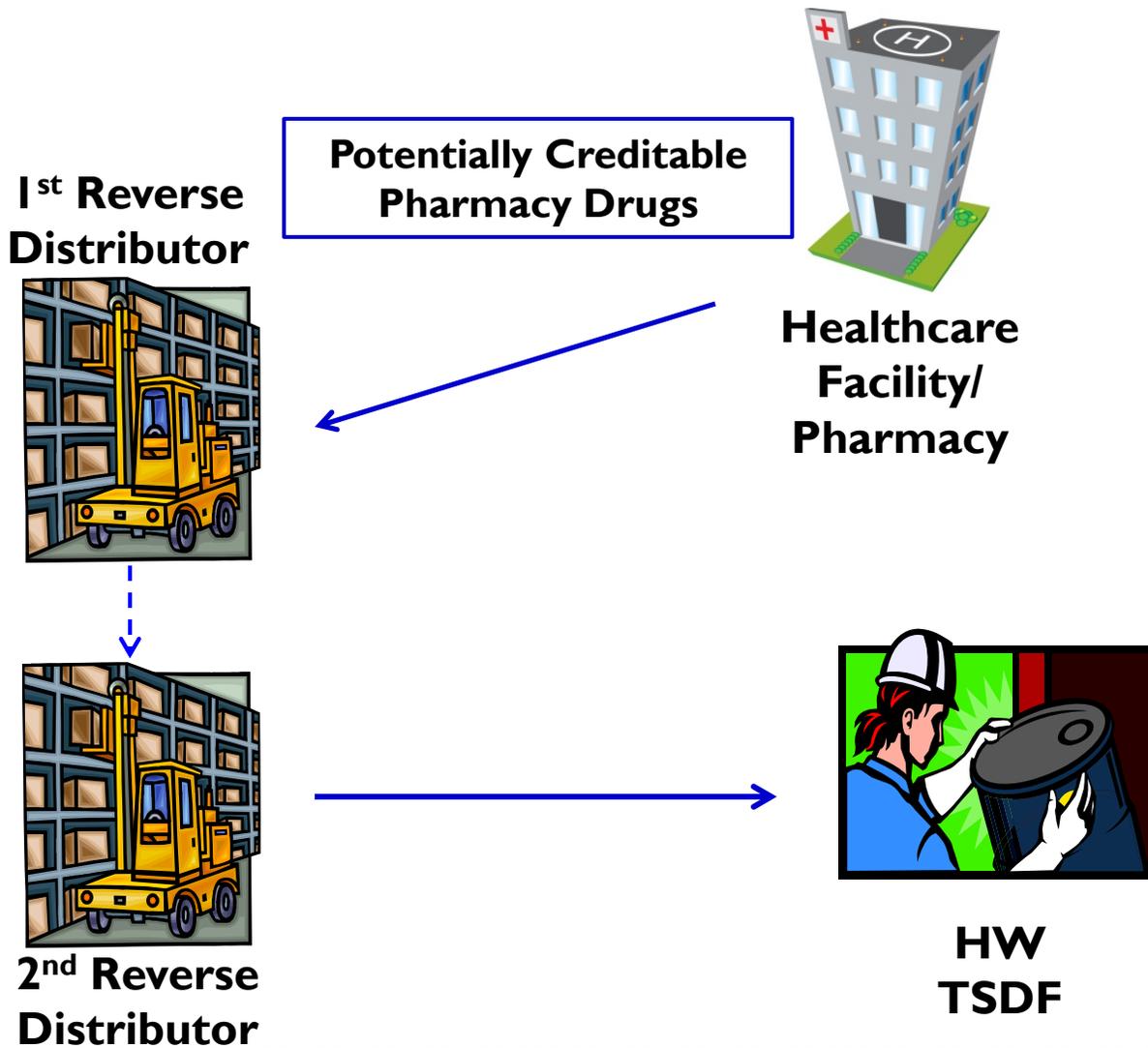
Retail Waste Workgroup Webcast
Thursday, May 26, 2016

Outline of Today's Briefing

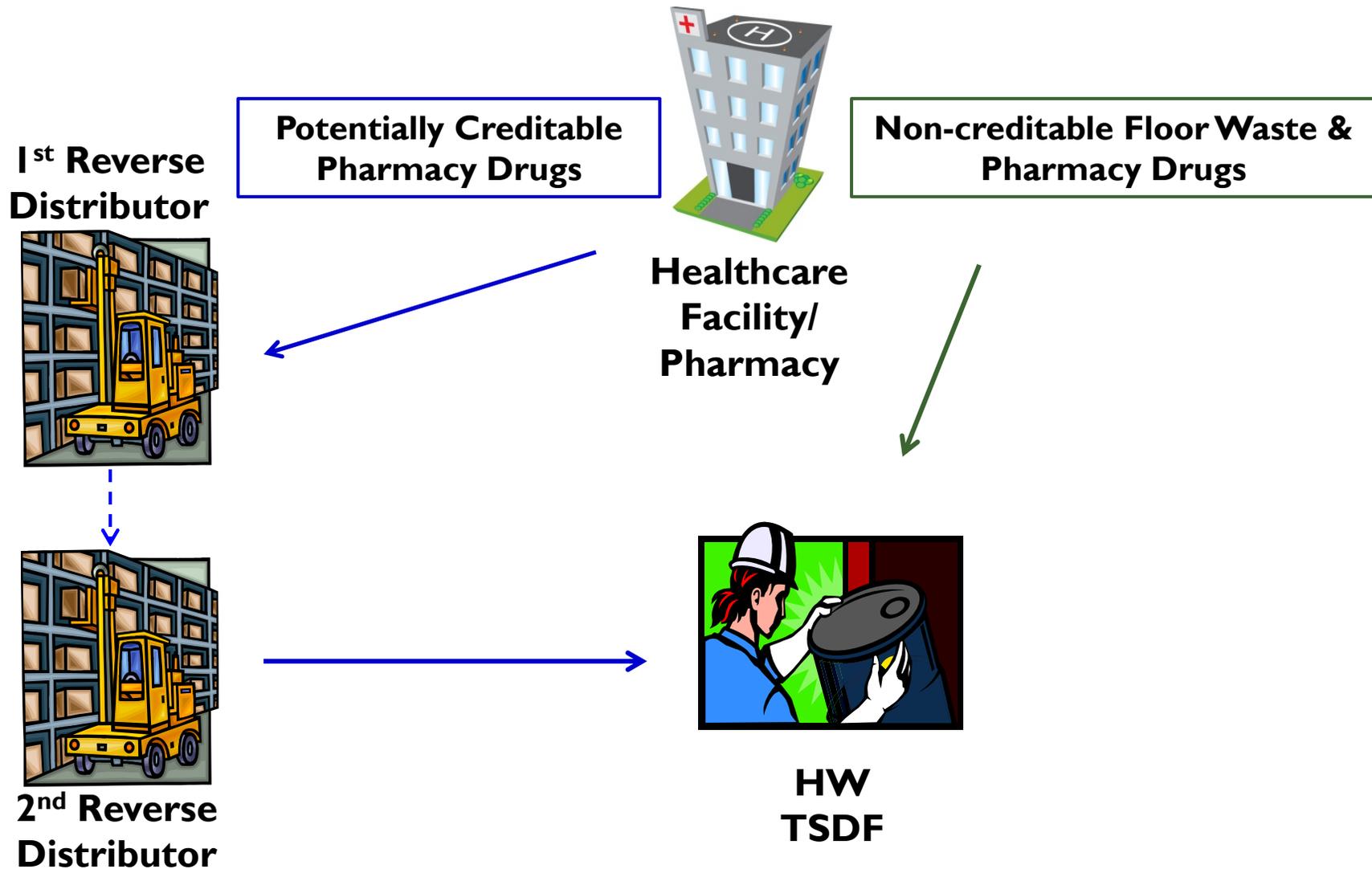
- ▶ **Part I: Background**
 - ▶ Flow of Pharmaceuticals & Problem Areas
- ▶ **Part II: Overview of Major Provisions of Proposal**
 - ▶ Defining Some Key Terms
 - ▶ Standards for Healthcare Facilities
 - ▶ Standards for Reverse Distributors
- ▶ **Part III: What's Ahead?**
 - ▶ State Adoption



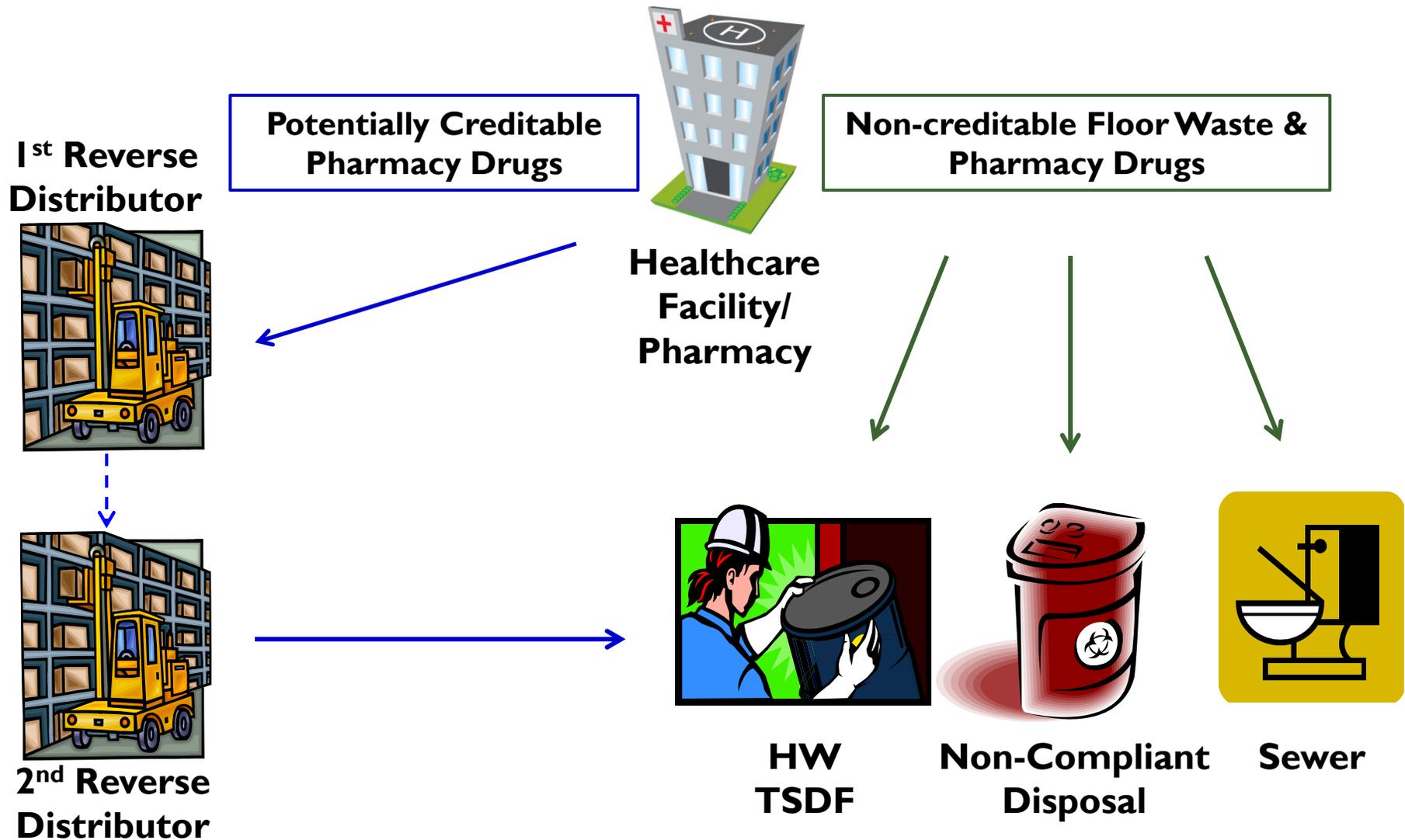
Part I: Flow of HW Pharmaceuticals



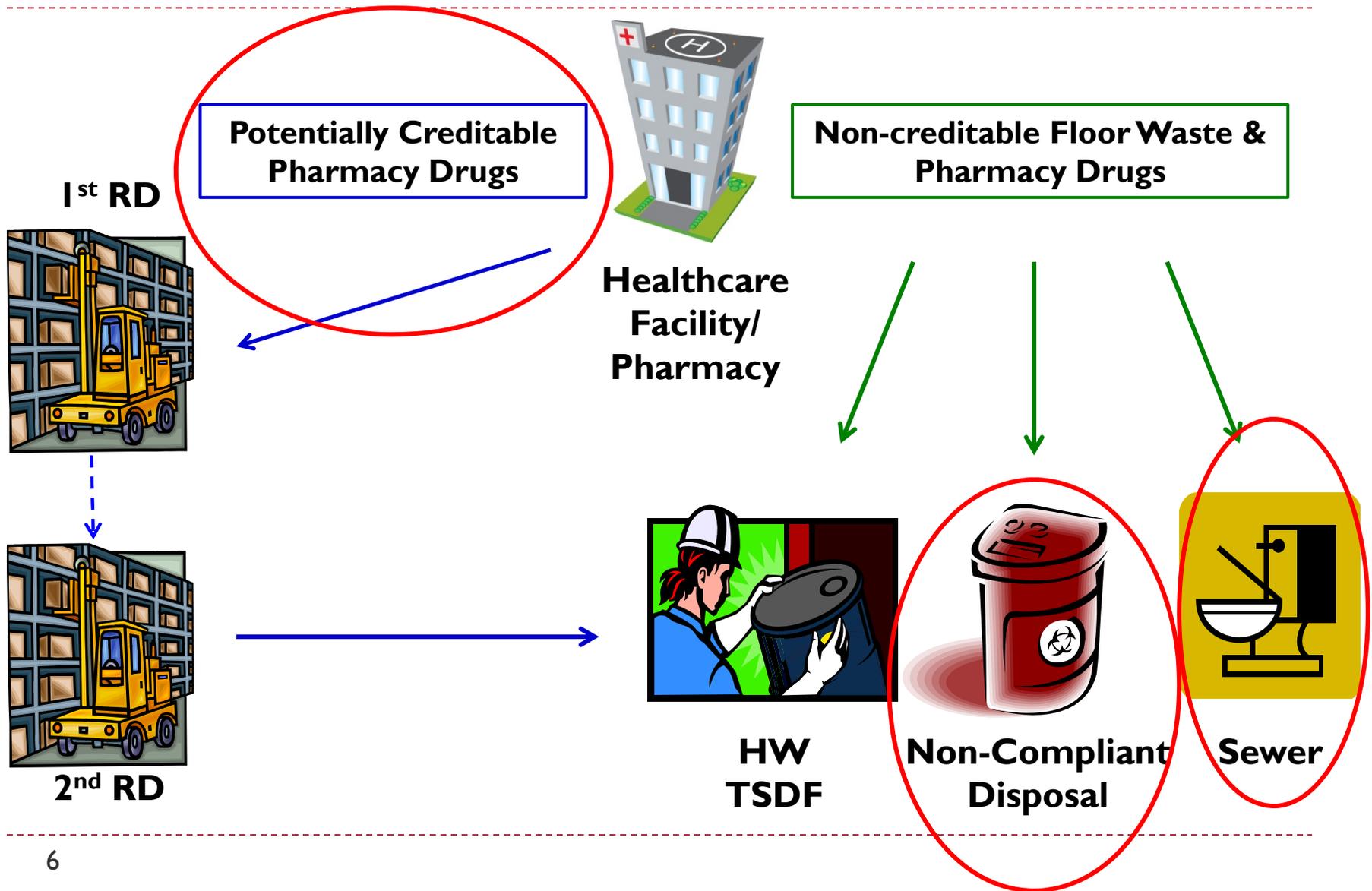
Flow of HW Pharmaceuticals



Flow of HW Pharmaceuticals



3 Problem Areas to Address in Rule



How RCRA Applies to Healthcare Facilities

- ▶ Currently, healthcare facilities that generate hazardous waste are regulated the same as any industrial facility that generates hazardous waste
 - ▶ The level of regulation increases with the amount of hazardous waste that is generated (CESQG < SQG < LQG)
 - ▶ If a facility generates >1 kg acute HW/month \implies LQG
 - ▶ Many healthcare facilities/pharmacies are LQGs due to discarded nicotine or warfarin

Why a Pharmaceuticals Rulemaking?

- ▶ We have issued clarifying guidance where possible and within the confines of the current regulations
- ▶ Remaining issues require regulatory fixes via rulemaking

6 Main Remaining Issues for Rulemaking

1. Regulatory status of creditable pharmaceuticals
2. LQG status due to P-listed hazardous waste
 - ▶ e.g., warfarin & nicotine
3. Manufacturing-oriented framework of the generator regulations
4. Intersection of EPA & DEA regulations
5. Containers with P-listed pharmaceutical residues
6. Pharmaceuticals being flushed/sewered

Part II: Overview of Proposed Rule

- ▶ Proposed to add hazardous waste pharmaceuticals to the Universal Waste program (2008)
 - ▶ Commenters felt UW was inadequate for pharmaceuticals
 - ▶ Could not address negative comments on proposal without re-proposing
- ▶ New approach has been to build on the 2008 Universal Waste (UW) proposal by:
 - ▶ Keeping the aspects of the UW proposal that commenters liked
 - ▶ Addressing commenters' concerns about the UW proposal
 - ▶ Addressing new areas that the UW proposal did not
 - ▶ Coordinating with other federal agencies (e.g., DEA, FDA)
 - ▶ Promoting national consistency

Overview of Proposed Rule

- ▶ We are not proposing to change WHO is regulated by RCRA, but rather HOW they would be regulated

- ▶ We proposed sector-specific standards for the management of hazardous waste pharmaceuticals for:
 - ▶ Healthcare facilities/pharmacies, and
 - ▶ Pharmaceutical reverse distributors

- ▶ The two flows of hazardous waste pharmaceuticals are addressed differently by the rule:
 1. Creditable hazardous waste pharmaceuticals that go through reverse distribution to obtain manufacturer's credit
 2. Non-creditable hazardous waste pharmaceuticals that do not and should not go through reverse distribution

Where are the New Regulations?

- ▶ Part 266 – Standards for the Management of Specific Hazardous Wastes and Specific Types of Hazardous Waste Management Facilities
- ▶ Current hazardous wastes under Part 266
 - ▶ Subpart F – Precious Metals Recovery
 - ▶ Subpart G – Spent Lead Acid Batteries Being Reclaimed
 - ▶ Subpart M – Military Munitions



Part 266 Subpart P - Management Standards for Hazardous Waste Pharmaceuticals

What Is a Pharmaceutical?

- ▶ The proposed definition of *Pharmaceutical* is
 - ▶ Any chemical or biological product that is intended for use in the diagnosis, cure, mitigation, care, treatment, or prevention of disease or injury of a human or other animal; or
 - ▶ Any chemical or biological product that is intended to affect the structure or function of the body of a human or other animal.
 - ▶ This definition includes, but is not limited to:
 - ▶ Dietary supplements as defined by the FD&C Act
 - ▶ Prescription drugs
 - ▶ Over-the-counter drugs (OTCs)
 - ▶ Residues of pharmaceuticals remaining in containers
 - ▶ Personal protective equipment contaminated with pharmaceuticals, and
 - ▶ Clean-up material from spills of pharmaceuticals (e.g., floor sweepings)

What is a Pharmaceutical?

- ▶ The proposed definition of *Pharmaceutical*
 - ▶ Includes all dose forms including tablets, capsules, gums, lozenges, liquids, ointments, lotions, IVs, antiseptics, patches, etc.
 - ▶ At commenters' request, it is broader than it was in the Universal Waste proposal
 - ▶ Borrows heavily from the FDA's definition of "drug"
 - ▶ A rule of thumb for OTCs: If FDA requires a "Drug Facts" label, it would be considered a pharmaceutical under this proposed rule
 - ▶ Does not include sharps (e.g., needles)

Which Pharmaceuticals Will be Covered?

- ▶ Only those pharmaceuticals that are already considered hazardous waste will be covered by the new rule
- ▶ This rule does NOT propose to expand the number of pharmaceuticals that are considered hazardous waste
 - ▶ This rule proposes to change HOW the hazardous waste pharmaceuticals must be managed
- ▶ **We encourage healthcare facilities to manage all waste pharmaceuticals under the new rule**

Which Pharmaceuticals Will be Covered?

- ▶ In response comments to the 2014 Retail (NODA), we sought comment on 2 Options for addressing low-concentration nicotine smoking cessation products
 1. Exemption from P075 Listing for FDA-Approved Over-the-Counter Nicotine-Containing Smoking Cessation Products
 2. Concentration-Based Exemption from P075 Listing for Low-Concentration Nicotine-Containing Products

- ▶ Both of these options require data on nicotine toxicity to evaluate against the acute listing criteria

Who Will be Covered by the Rule?

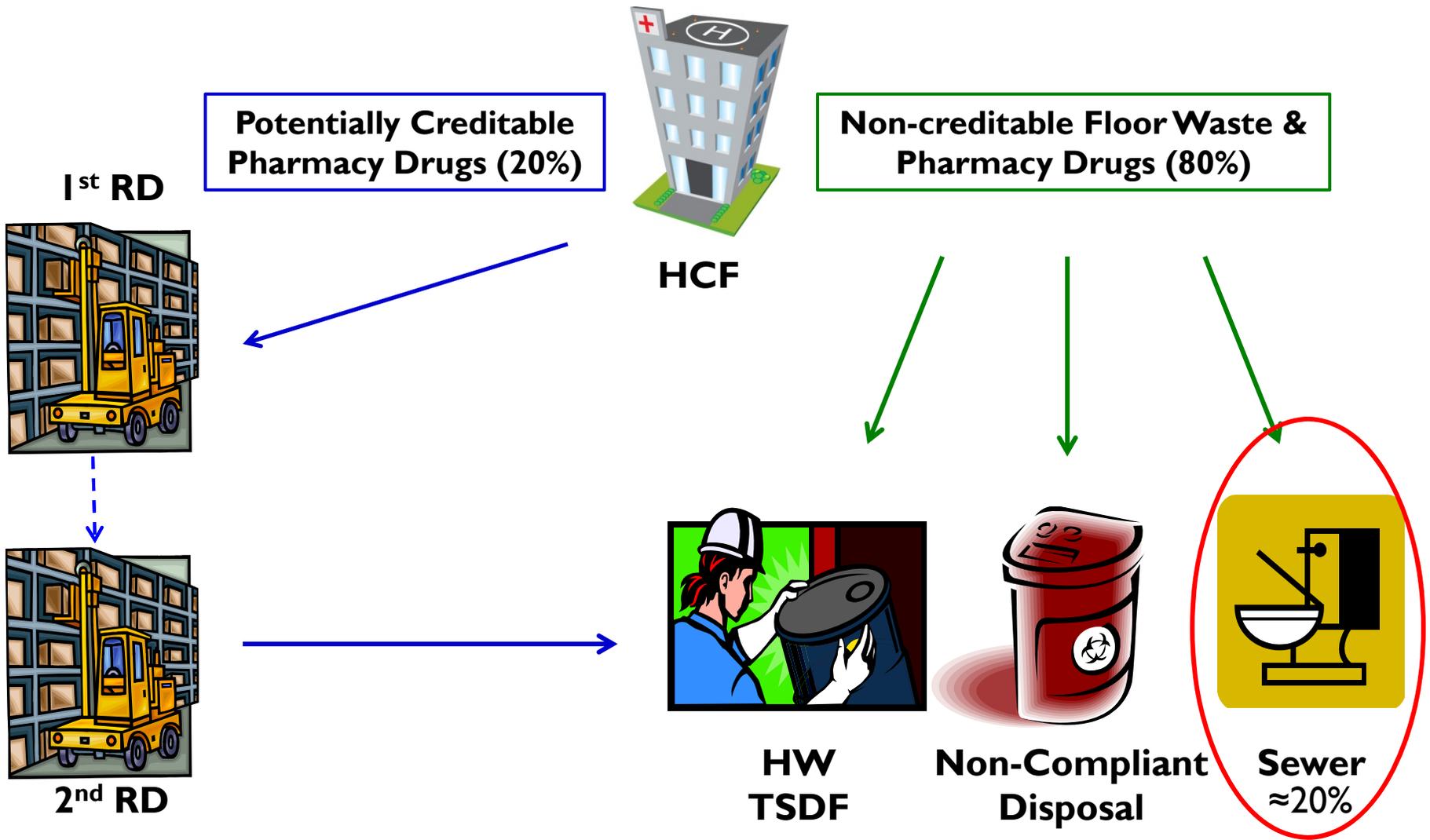
- ▶ Healthcare facilities that generate hazardous waste pharmaceuticals
 - ▶ Does not include healthcare facilities that are CESQGs
 - ▶ Does not include pharmaceutical manufacturers
- ▶ All pharmaceutical reverse distributors – regardless of current RCRA generator category
 - ▶ May include pharmaceutical manufacturers when they operate as reverse distributors

Who Will be Covered by the Rule?

- ▶ **Healthcare facilities – include (but are not limited to):**
 - ▶ Hospitals, including psychiatric hospitals
 - ▶ Pharmacies, including
 - ▶ Long-term care pharmacies
 - ▶ Mail-order pharmacies
 - ▶ Retail stores with pharmacies
 - ▶ Health clinics
 - ▶ Surgical centers
 - ▶ Long-term care facilities
 - ▶ Physicians offices, including dental, optical, & chiropractors
 - ▶ Veterinary clinics and hospitals
 - ▶ Drug compounding facilities
 - ▶ Coroners & medical examiners

- ▶ **Wholesale distributors want to be considered healthcare facilities**

Problem Area #1



6 Main Remaining Issues for Rulemaking

1. Regulatory status of creditable pharmaceuticals
2. LQG status due to P-listed hazardous waste
 - ▶ Warfarin & nicotine
3. Manufacturing-oriented framework of the generator regulations
4. Intersection of EPA & DEA regulations
5. Containers with P-listed pharmaceutical residues
6. Pharmaceuticals being flushed/sewered

#6: Sewering Pharmaceuticals

Problem

- ▶ Flushing of pharmaceuticals has become a commonly used disposal method by healthcare facilities which
 - ▶ Contributes to pharmaceuticals in surface and drinking water,
 - ▶ Has demonstrated risks to the environment
 - ▶ Has the potential to present risks to human health
 - ▶ Are not being treated for by POTWs, except incidentally
 - ▶ Flushing is allowed by current RCRA regulation
-

“There’s not some sort of magic process that can remove everything we put down the drain”

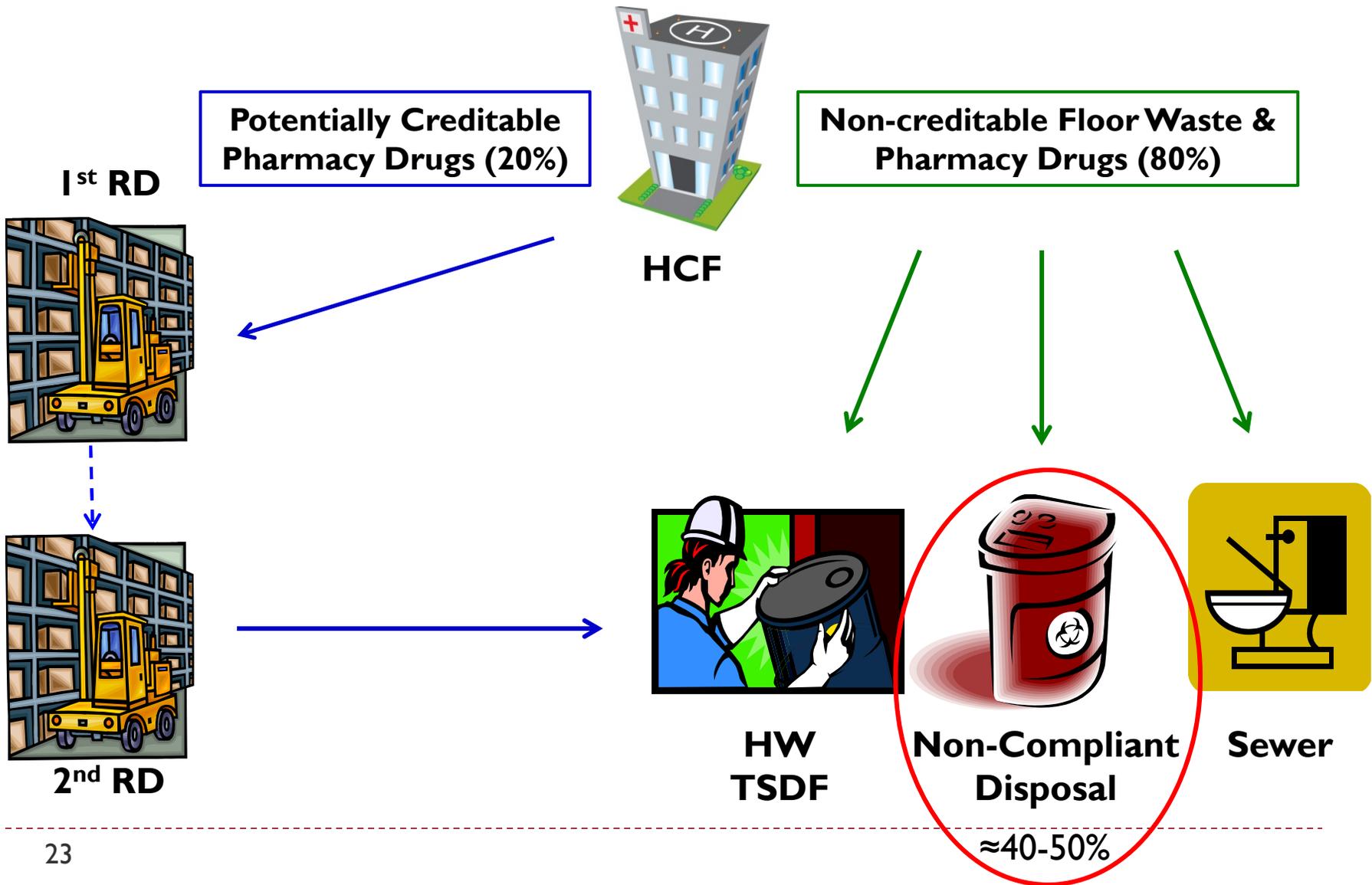
David Sedlak, Director of the Institute for Environmental Science and Engineering at UC Berkeley

#6: Sewering Pharmaceuticals

Proposed Solution

- ▶ **Rule bans the sewerage of HW pharmaceuticals**
 - ▶ Sewer ban applies to all healthcare facilities & RDs, including CESQGs
 - ▶ Otherwise CESQG healthcare facilities are not subject to the proposal
 - ▶ Prevents 6400 TONS of hazardous waste pharmaceuticals from contaminating the water per year
 - ▶ Sewer ban reinforces and highlights EPA's policy against flushing pharmaceuticals
 - ▶ At EPA's urging, DEA no longer allows sewerage as a means of destroying controlled substances
 - ▶ Several federal agencies, including EPA, have been coordinating to educate consumers to stop flushing pharmaceuticals
 - ▶ EPA would join other jurisdictions with sewer bans for pharmaceuticals, including IL, NJ, DC, WA and CT (proposed)

Problem Area #2



6 Main Remaining Issues for Rulemaking

1. Regulatory status of creditable pharmaceuticals
2. LQG status due to P-listed hazardous waste
 - ▶ Warfarin & nicotine
3. Manufacturing-oriented framework of the generator regulations
4. Intersection of EPA & DEA regulations
5. Containers with P-listed pharmaceutical residues
6. Pharmaceuticals being flushed/sewered

#5: Containers with Residues

Problem

- ▶ If residues are acute/P-listed HW, then to be considered “RCRA empty,” containers must be:
 - ▶ Triple-rinsed, or
 - ▶ Cleaned by another method shown in the scientific literature or by tests by generator, to achieve equivalent removal

- ▶ Current RCRA empty container rules apply to residues in very small containers used in healthcare setting, including:
 - ▶ Vials
 - ▶ Dixie cups
 - ▶ Soufflé cups
 - ▶ Blister packs, etc.

#5: Containers with Residues

Proposed Solution

- ▶ Residues in unit-dose containers and dispensing bottles/vials would be exempt from RCRA
 - ▶ Unit-dose containers (e.g., packets, cups, wrappers, blister packs and unit-dose delivery devices) and
 - ▶ Dispensing bottles and vials up to 1 liter or 1000 pills
- ▶ If all contents are removed (fully dispensed), it will be equivalent to rendering the container “RCRA empty”
 - ▶ Data from 4 studies show only very small amounts of residue remain
- ▶ Container may be disposed of as non-hazardous waste
- ▶ Original pharmaceutical packaging, including dispensing vials & bottles, must be destroyed to prevent diversion (e.g., crushed)

#5: Containers with Residues

Proposed Solution

- ▶ Dispensed syringes would be exempt from RCRA provided:
 - ▶ The syringe has been used to administer the pharmaceutical to a patient, and
 - ▶ The syringe is placed in a sharps containers that is managed appropriately

- ▶ Needed to minimize potential exposures to healthcare workers

- ▶ We seek comment on the need to place a limit on the:
 - ▶ Volume of the syringe
 - ▶ Volume of residue remaining in syringe

#5: Containers with Residues

Proposed Solution

- ▶ All other containers, including delivery devices, that once held listed or characteristic pharmaceuticals, must be managed as hazardous waste, including:
 - ▶ IV bags and tubing
 - ▶ Inhalers
 - ▶ Aerosols
 - ▶ Nebulizers
 - ▶ Tubes of ointment, gels or creams

#4: Intersection of DEA & EPA Rules

Problem

- ▶ There are a few RCRA hazardous wastes that are also DEA controlled substances
 - ▶ Chloral hydrate (U034)
 - ▶ Fentanyl sublingual spray (D001)
 - ▶ Phenobarbital (D001)
 - ▶ Testosterone gels (D001)
 - ▶ Valium injectable (D001)

- ▶ These are dually regulated by EPA and DEA – must comply with both sets of regulations

#4: Intersection of DEA & EPA Rules

Proposed Solution

2 Conditional Exemptions:

- I. Hazardous waste pharmaceuticals that are also DEA controlled substances would be exempt from RCRA regulation
-
- ▶ Conditions for exemption:
 - ▶ Must be managed in accordance with all DEA regulations
 - ▶ Must be combusted at a permitted/interim status:
 - ▶ municipal solid waste combustor or
 - ▶ hazardous waste combustor

#4: Intersection of DEA & EPA Rules

Proposed Solution

2 Conditional Exemptions (continued):

2. Authorized collectors of DEA controlled substances that co-mingle them with pharmaceuticals that are exempt household hazardous waste (HHW) would be exempt from RCRA regulation
- ▶ Conditions for exemption:
 - ▶ Must be managed in accordance with all DEA regulations
 - ▶ Must be combusted at a permitted/interim status:
 - ▶ municipal solid waste combustor or
 - ▶ hazardous waste combustor

#3: Manufacturing Framework

Problem

- ▶ Healthcare facilities that generate hazardous waste are currently regulated the same as any industrial facility that generates hazardous waste

- ▶ Healthcare facilities differ from industry
 - ▶ Healthcare workers and pharmacists have little expertise with RCRA yet are critical in getting the hazardous wastes directed to proper waste management
 - ▶ Thousands of drugs in their formularies, which vary over time
 - ▶ Lots of healthcare workers involved in generation of waste in lots of locations throughout facility

- ▶ Hazardous waste pharmaceuticals are unique among hazardous wastes:
 - ▶ Street value
 - ▶ Potential for diversion/theft

#3: Manufacturing Framework

Proposed Solution

- ▶ **Replace Part 262 generator regulations with Part 266 Subpart P regulations**
 - ▶ Sector-specific management standards for the management of hazardous waste pharmaceuticals at healthcare facilities and pharmaceutical reverse distributors

- ▶ **Part 262 generator regulations do NOT apply to hazardous waste pharmaceuticals, including:**
 - ▶ SQG and LQG generator categories
 - ▶ Satellite accumulation area (SAA) regulations
 - ▶ Central accumulation area (CAA) regulations

#3: Manufacturing Framework

Proposed Solution

Basic requirements for healthcare facilities:

- ▶ One-time notification as HCF (as opposed to as a generator)
- ▶ Performance-based training for healthcare workers
- ▶ No Biennial Report for hazardous waste pharmaceuticals
- ▶ Different standards for:
 - ▶ Creditable hazardous waste pharmaceuticals
 - ▶ Non-creditable hazardous waste pharmaceuticals

#3: Manufacturing Framework

Proposed Solution

	Standards for Healthcare Facilities “UW Plus”	Standards for Reverse Distributors “LQG Plus”
	Potentially Creditable	
On-site accumulation	No proposed standards	
Shipping to a reverse distributor	<ul style="list-style-type: none"> • Advance notice • Confirmation of receipt • Common carrier 	
	Non-Creditable	
On-site accumulation	UW-like standards	
Shipping to a TSDF	<ul style="list-style-type: none"> • Manifest • HW transporter 	

#2: LQG Status Due to Acute HW

Problem

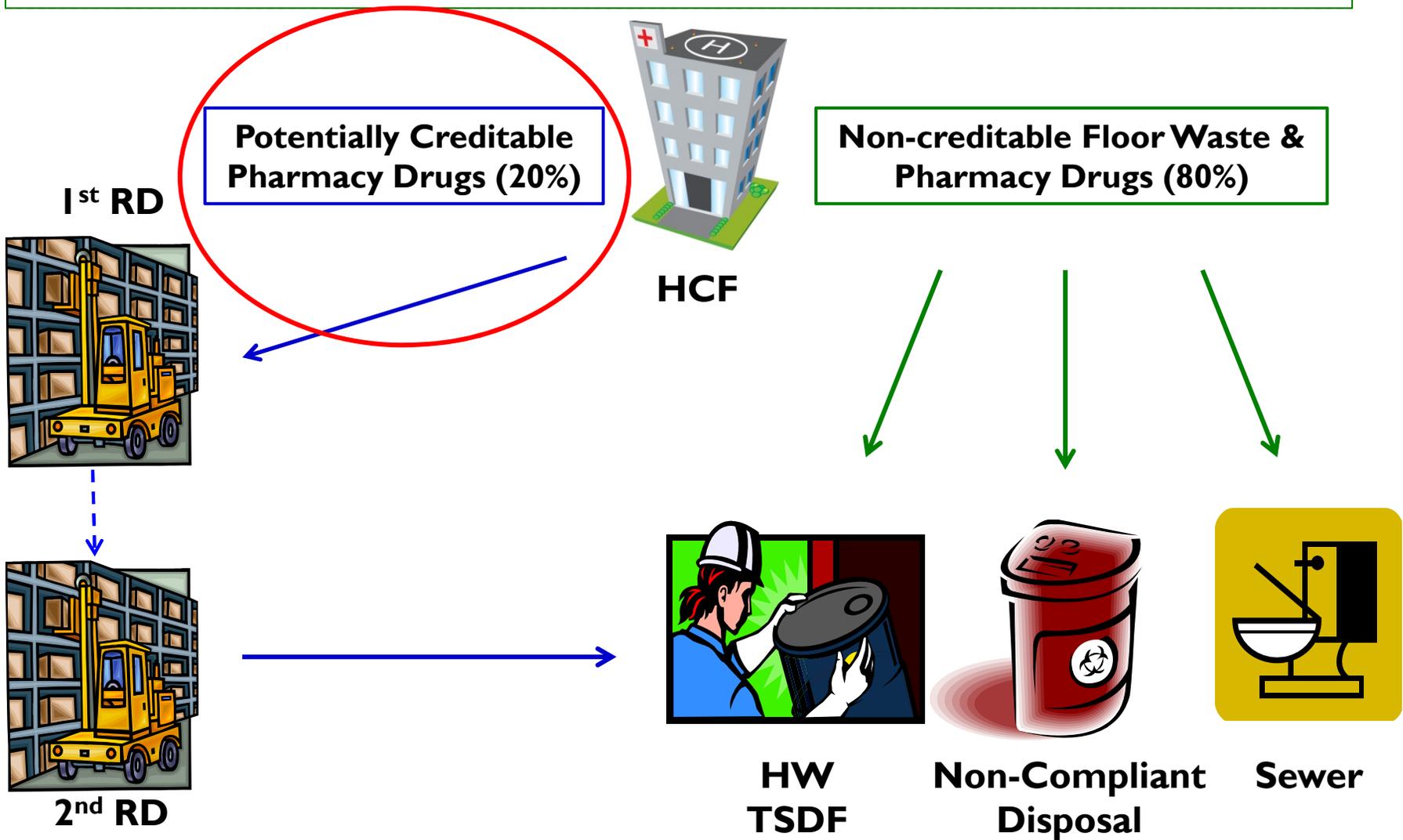
- ▶ LQG status for healthcare facilities & pharmacies due to exceeding 1 kg acute HW/month, which results in:
 - ▶ Shorter accumulation time
 - ▶ Biennial Reporting
 - ▶ More training requirements and documentation
 - ▶ Higher costs for generators
 - ▶ Higher costs for states who must inspect LQGs more frequently

#2: LQG Status Due to Acute HW

Proposed Solution

- ▶ HW pharmaceuticals do not have to be counted toward the healthcare facility's generator status when they are managed under Part 266 Subpart P
 - ▶ No SQG or LQG status for HW pharmaceuticals
 - ▶ All HW pharmaceuticals are managed the same
 - ▶ Don't have to keep track of monthly generation for hazardous waste pharmaceuticals
 - ▶ Don't have to accumulate acutes and non-acutes separately
 - ▶ Reduces incidences of episodic generation
 - ▶ Removes regulatory disincentive for managing non-hazardous pharmaceuticals as hazardous pharmaceuticals

Problem Area #3



6 Main Remaining Issues for Rulemaking

1. Regulatory status of creditable pharmaceuticals
2. LQG status due to P-listed hazardous waste
 - ▶ Warfarin & nicotine
3. Manufacturing-oriented framework of the generator regulations
4. Intersection of EPA & DEA regulations
5. Containers with P-listed pharmaceutical residues
6. Pharmaceuticals being flushed/sewered

#1: Status of Creditable Pharmaceuticals

Problem

- ▶ **Current guidance allows point of generation of creditable pharmaceuticals to be at reverse distributor, based on the assumption that some pharmaceuticals will be redistributed**
 - ▶ Creditable pharmaceuticals are not regulated as wastes even though they are being discarded after manufacturer's credit is processed by reverse distributor
 - ▶ Current guidance creates concern about lack of tracking and the potential for diversion (theft)

- ▶ **Some states are questioning our interpretation**
 - ▶ Regulatory uncertainty exists for reverse distributors and the healthcare facilities that use them

#1: Status of Creditable Pharmaceuticals

Proposed Solution

- ▶ EPA now understands that little to no redistribution of pharmaceuticals is actually occurring during reverse distribution and we are proposing to revise our interpretation such that
 - ▶ The point of generation for pharmaceuticals sent to a reverse distributor is at the healthcare facility, not the reverse distributor
 - ▶ Allows better tracking of shipments of creditable HW pharmaceuticals to reverse distributors
 - ▶ Allows better oversight of reverse distributors through notification
- ▶ If a pharmaceutical product is redistributed for reuse or legitimately recycled, then it is not considered a solid waste or hazardous waste and is not covered by this proposed rule

#1: Status of Creditable Pharmaceuticals

Proposed Solution

- ▶ A Pharmaceutical Reverse Distributor would be considered a new type of hazardous waste management facility
 - ▶ Can only accept “potentially creditable hazardous waste pharmaceuticals”
 - ▶ No RCRA storage permit required
 - ▶ All RDs are regulated the same for hazardous waste pharmaceuticals
 - ▶ No CESQG, SQG or LQG categories for hazardous waste pharmaceuticals
 - ▶ Standards similar to LQGs, with additions:
 - ▶ One-time notification as RD (as opposed to as a generator or TSDF)
 - ▶ Inventory of HW pharmaceuticals
 - ▶ Facility security

What is “Potentially Creditable”?

- ▶ The proposed definition of *Potentially Creditable Hazardous Waste Pharmaceutical* is:

A hazardous waste pharmaceutical that has the potential to receive manufacturer’s credit and is:

1. Unused or un-administered; and
2. Unexpired or less than one year past expiration date
3. The term does not include:
 - ▶ Evaluated hazardous waste pharmaceuticals
 - ▶ Residues of pharmaceuticals remaining in containers
 - ▶ Contaminated personal protective equipment, and
 - ▶ Clean-up material from the spills of pharmaceuticals

What is NOT “Potentially Creditable”?

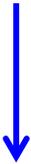
- ▶ Since manufacturers set the policies of when a pharmaceutical receives credit, a healthcare facility does not always know when credit will be given
- ▶ However, if there is no reasonable expectation of credit, the hazardous waste pharmaceutical can not go to an RD, for example if the pharmaceutical:
 - ▶ Is a sample
 - ▶ Is a generic
 - ▶ Is more than 1 year past expiration
 - ▶ Has been removed from original container and re-packaged for dispensing
 - ▶ Was generated during patient care, or refused by a patient

Flow of HW Pharmaceuticals



HCF/Pharmacy

- Diagram shows maximum number of transfers allowed
- 90-days maximum allowed at each RD



**1st RD
can be a
manufacturer**



**2nd RD
can be a
manufacturer**



**3rd RD
must be a
manufacturer**



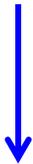
**HW
TSDF**

Flow of HW Pharmaceuticals

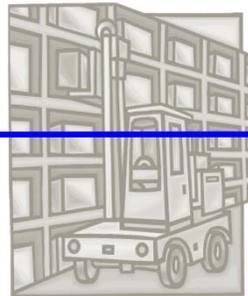


HCF/Pharmacy

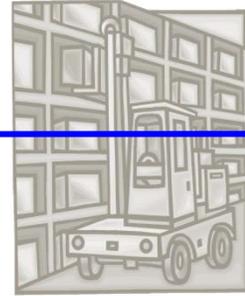
- **Not all steps occur in every case**



**1st RD
can be a
manufacturer**



**2nd RD
can be a
manufacturer**



**3rd RD
must be a
manufacturer**



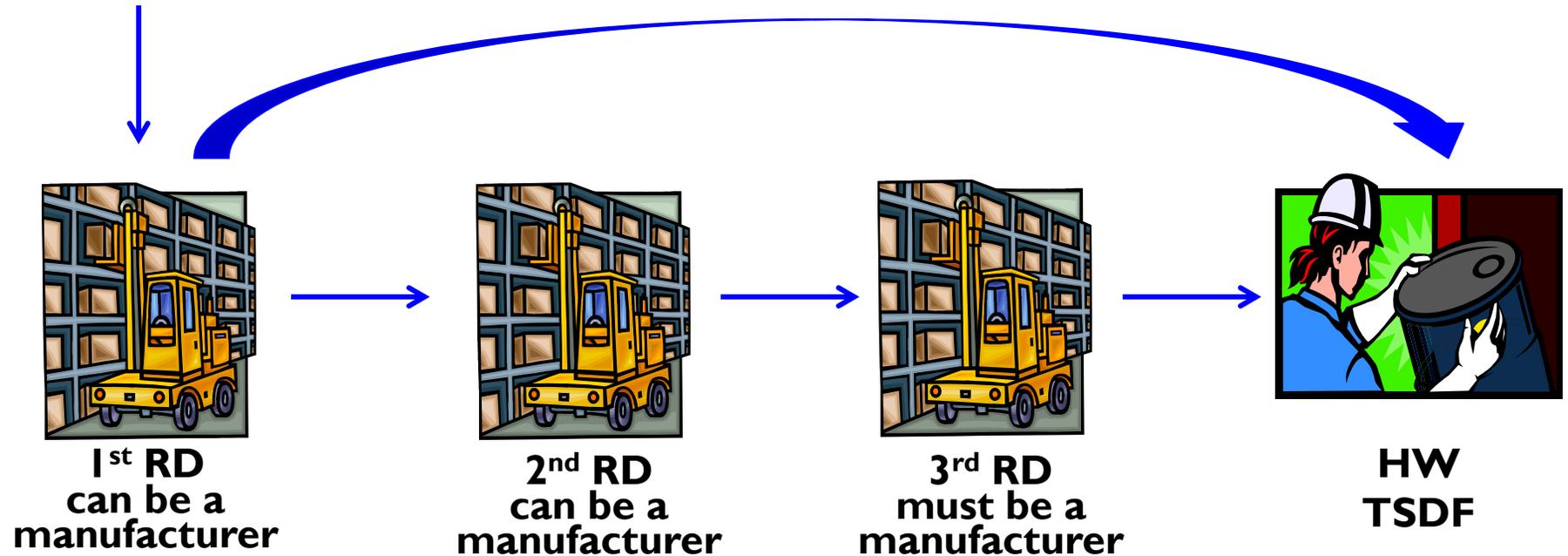
**HW
TSDF**

Flow of HW Pharmaceuticals



HCF/Pharmacy

- The same steps may not occur in every case



Flow of HW Pharmaceuticals



HCF/Pharmacy

As long as manufacturer's credit is being determined/verified, and pharmaceuticals are destined for an RD, they are still considered **“Potentially Creditable HW Pharmaceuticals”**



1st RD
can be a
manufacturer



2nd RD
can be a
manufacturer



3rd RD
must be a
manufacturer



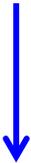
HW
TSDF

Flow of HW Pharmaceuticals



HCF/Pharmacy

Once manufacturer's credit has been determined/verified, and pharmaceuticals are destined for a TSDF, they are considered **“Evaluated HW Pharmaceuticals”**



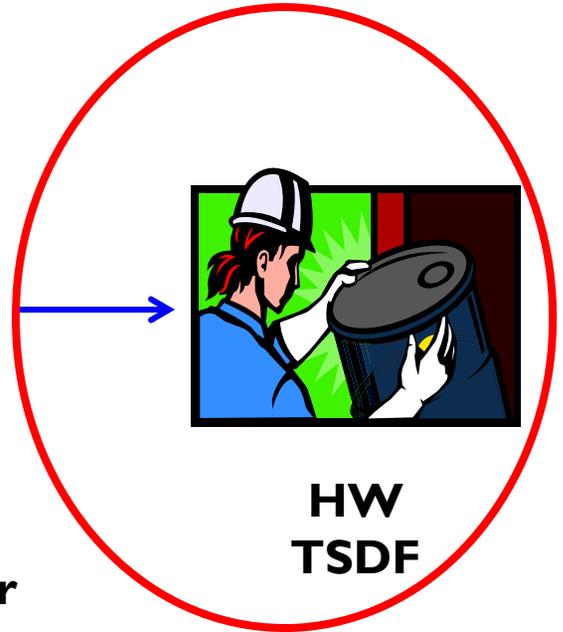
1st RD
can be a
manufacturer



2nd RD
can be a
manufacturer



3rd RD
must be a
manufacturer



HW
TSDF

#1: Status of Creditable Pharmaceuticals

Proposed Solution

- ▶ An RD must evaluate each potentially creditable hazardous waste pharmaceutical within 21 calendar days of arrival to determine whether it is destined for:
 - ▶ Another pharmaceutical reverse distributor for further evaluation/verification of manufacturer's credit, or
 - ▶ A permitted/interim status TSDF

- ▶ If an RD receives hazardous waste, other than potentially creditable hazardous waste pharmaceuticals, it must:
 - ▶ Prepare an "unauthorized waste report" and send it to the shipper and to EPA
 - ▶ Manage the waste appropriately

#1: Status of Creditable Pharmaceuticals

Proposed Solution

	Standards for Healthcare Facilities “UW Plus”	Standards for Reverse Distributors “LQG Plus”
	Potentially Creditable	Potentially Creditable
On-site accumulation	No proposed standards	Evaluate w/in 21 days
Shipping to a reverse distributor	<ul style="list-style-type: none"> • Advance notice • Confirmation of receipt • Common carrier 	<ul style="list-style-type: none"> • Advance notice • Confirmation of receipt • Common carrier
	Non-Creditable	Evaluated
On-site accumulation	UW-like standards	LQG-like standards
Shipping to a TSDF	<ul style="list-style-type: none"> • Manifest • HW transporter 	<ul style="list-style-type: none"> • Manifest • HW transporter

Part III: What's Ahead?

- ▶ EPA reviewing public comments & working on final rule
- ▶ EPA deciding whether to proceed on additional proposed or final rules related to:
 - ▶ Expanding what pharmaceuticals are hazardous
 - ▶ Nicotine

State Adoption

- ▶ On the whole, the proposed rule is considered more stringent than current policy and regulation
 - ▶ States will be required to adopt the final rule
 - ▶ Regulated entities will be required to use the final rule
- ▶ The sewer ban is considered a HSWA provision
 - ▶ It will be effective in all states upon the effective date for the rule, even before the state adopts it
- ▶ Universal Waste is not considered protective enough for pharmaceuticals
 - ▶ FL & MI will have to replace their UW programs with this one

Contact Information

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- ▶ **Resources**

- <http://www2.epa.gov/hwgenerators/proposed-rule-management-standards-hazardous-waste-pharmaceuticals>

- <http://hwpharms.wikispaces.com>