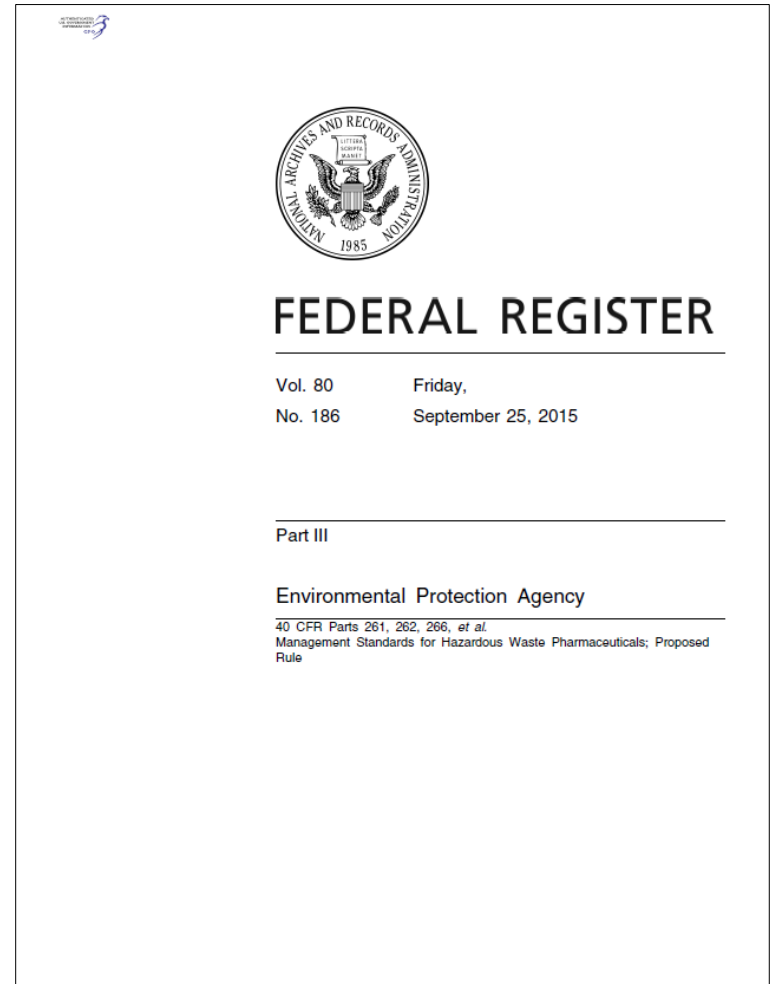


Hazardous Waste Pharmaceuticals Proposed Rule

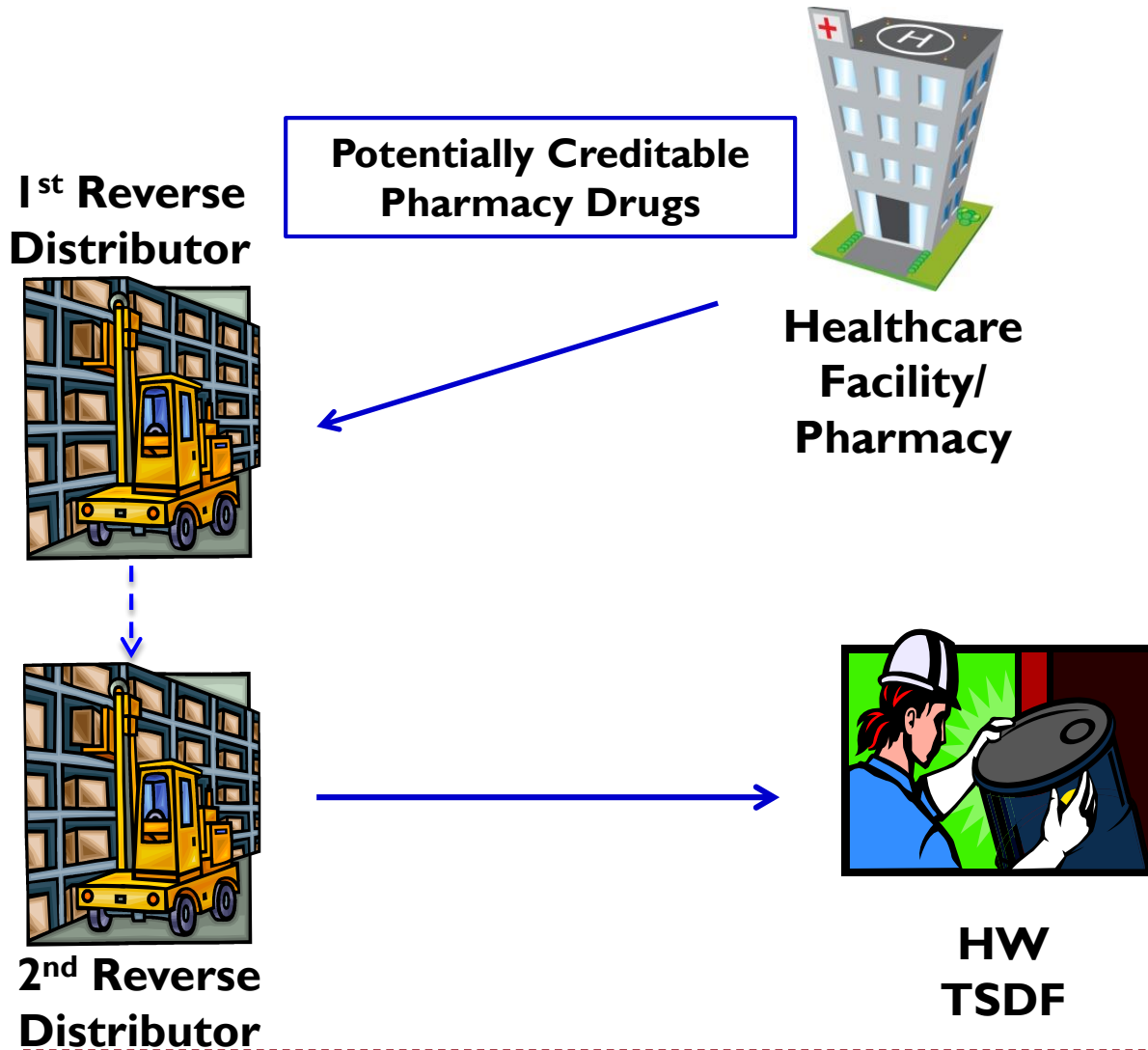
Note that this presentation is an overview of the major provisions of the proposed rule and is not a comprehensive look at every provision of the proposed rule

Outline of Today's Briefing

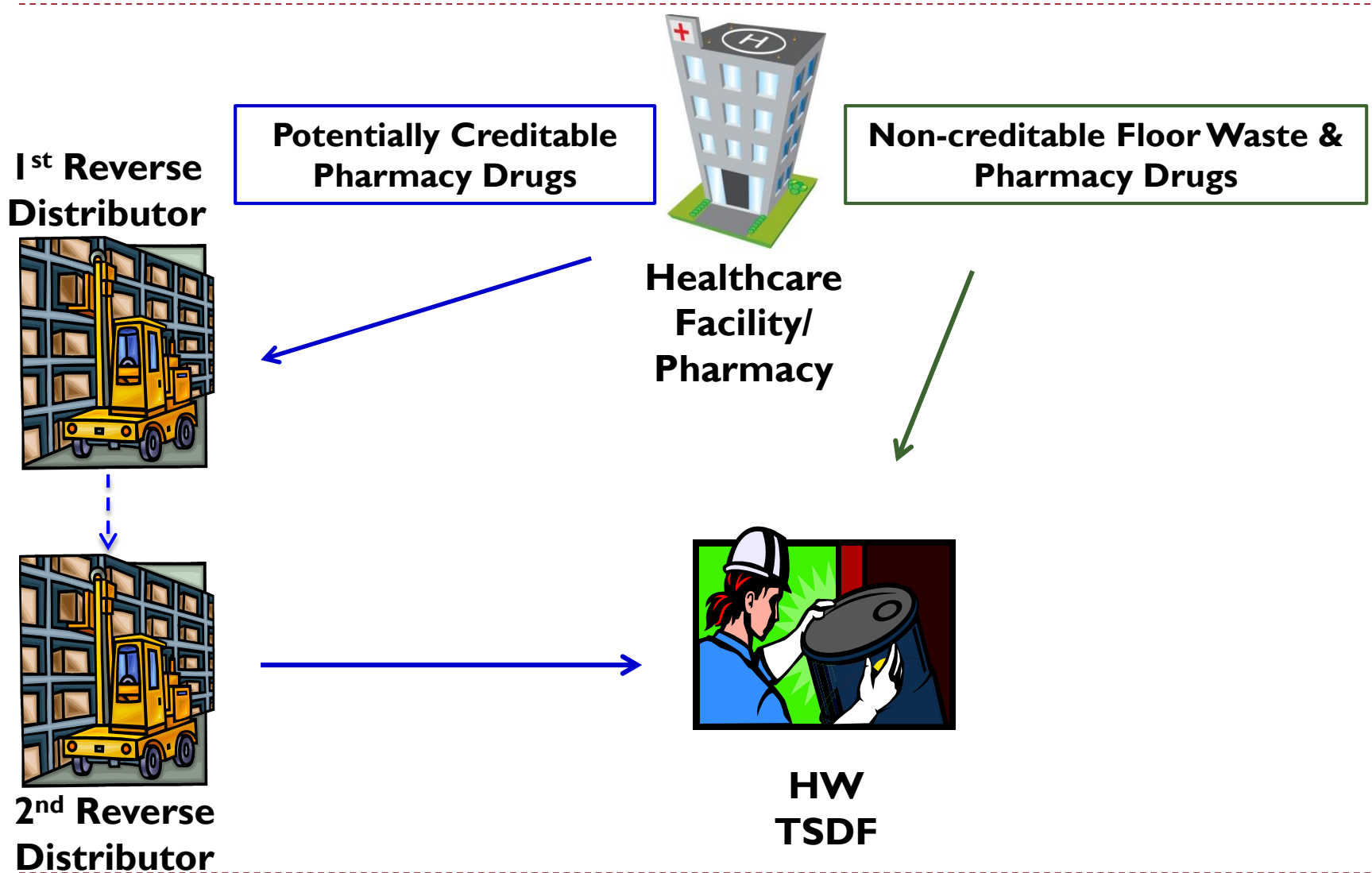
- ▶ **Part I: Background**
 - ▶ Flow of Pharmaceuticals & Problem Areas
- ▶ **Part II: Overview of Major Provisions of Proposal**
 - ▶ Defining Some Key Terms
 - ▶ Standards for Healthcare Facilities
 - ▶ Standards for Pharmaceutical Reverse Distributors
 - ▶ State Adoption
- ▶ **Part III: What's Ahead?**



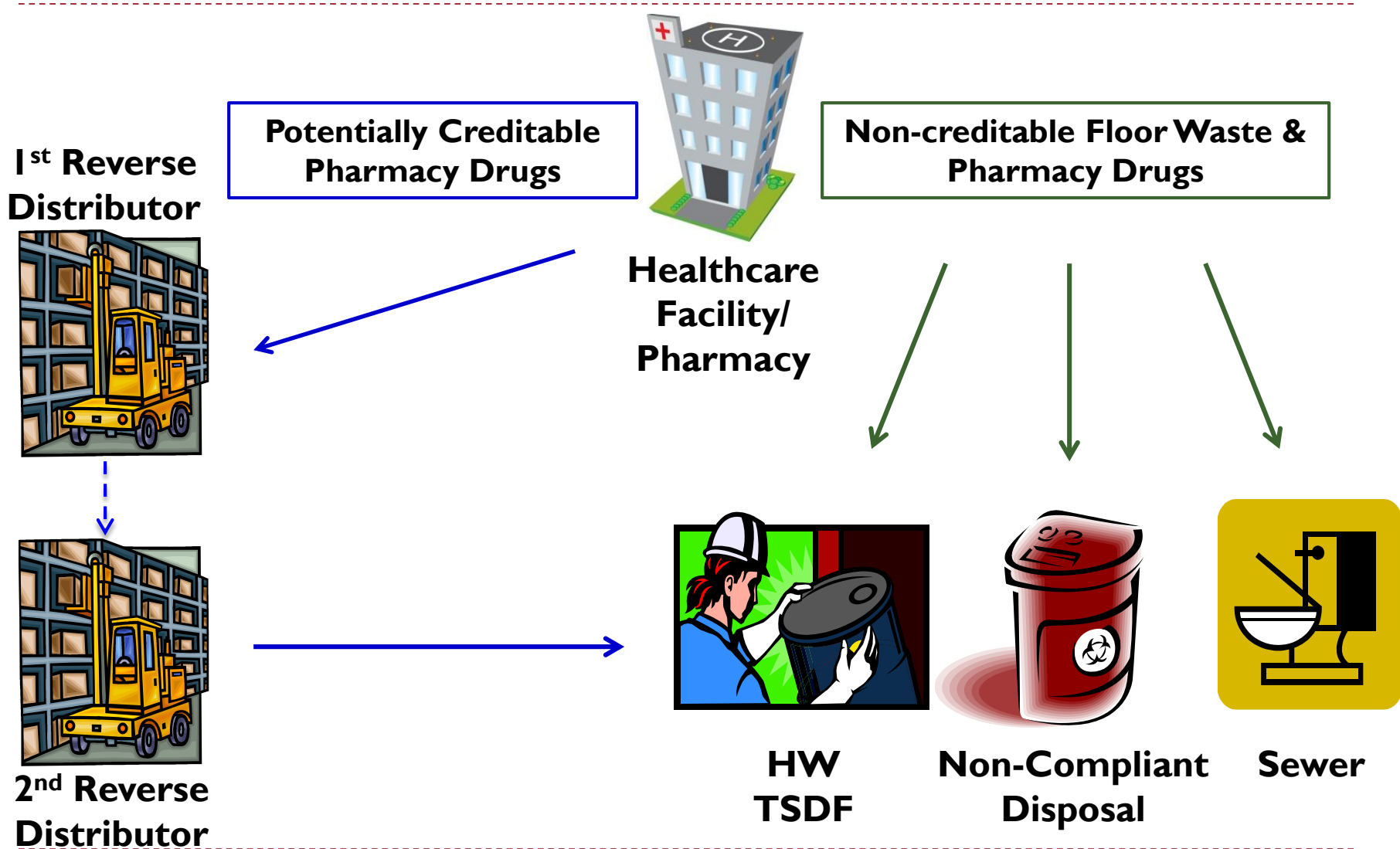
Part I: Flow of HW Pharmaceuticals



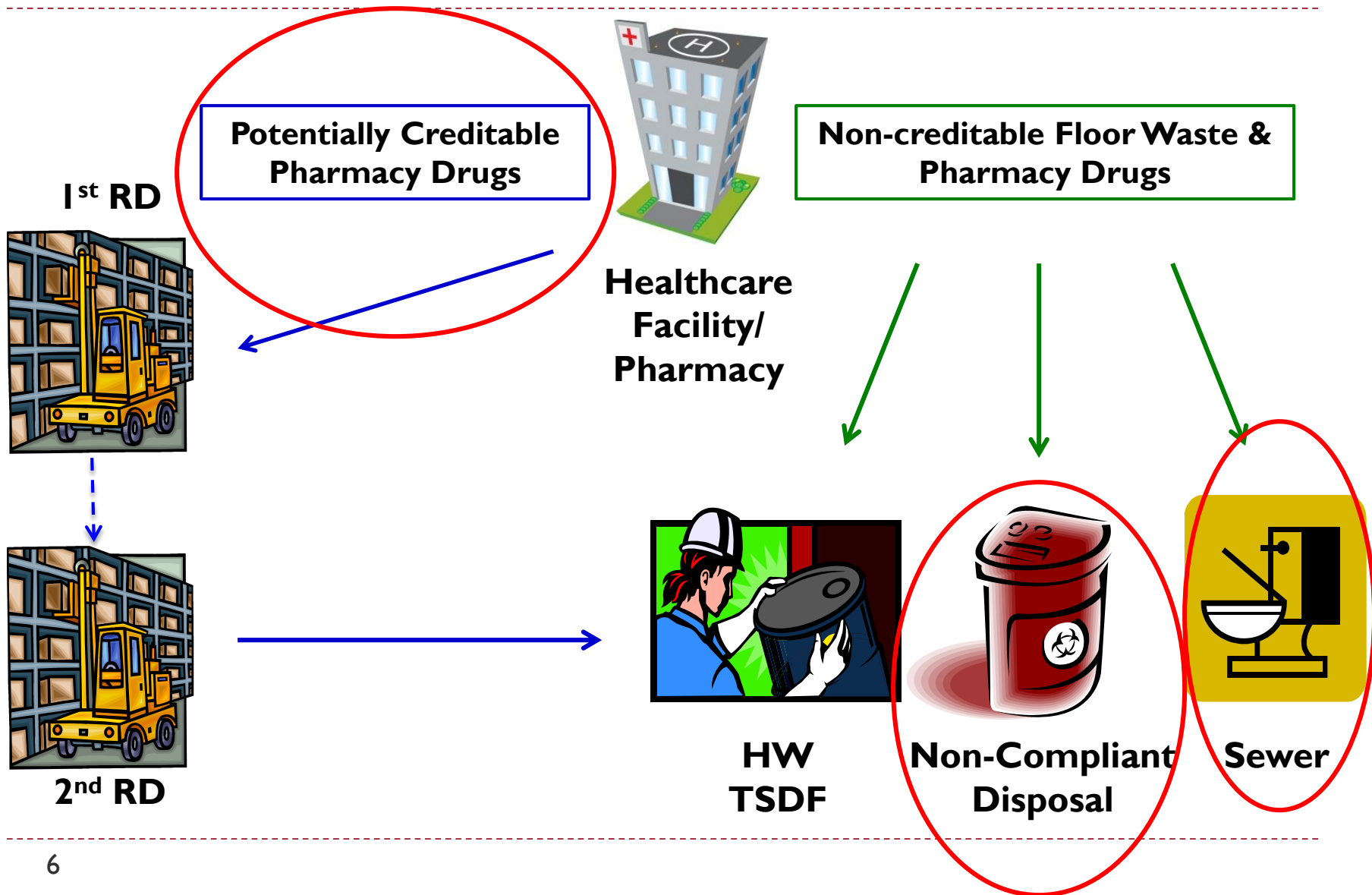
Flow of HW Pharmaceuticals



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 \Rightarrow 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

Clarifying Guidance (chronological order)

1. **Epinephrine salts are not P-listed wastes**
 - ▶ RCRA Online memo #14778; dated October 15, 2007

2. **Residues in partially-used syringes are not listed wastes**
 - ▶ RCRA Online memo #14788; dated April 14, 2008

3. **Nicotine patches, gum, lozenges are P-listed when unused**
 - ▶ RCRA Online memo #14817; dated August 23, 2010

4. **Limited fix for containers with P-listed pharmaceutical residues**
 - ▶ RCRA Online memo #14827; dated November 4, 2011

5. **Phentermine salts are not P-listed wastes**
 - ▶ RCRA Online memo #14831; dated February 17, 2012

Clarifying Guidance (continued)

5. Household pharmaceuticals collected during take-back events should be incinerated

- ▶ RCRA Online memo #14833; dated September 26, 2012



E-cigarettes are P075

- ▶ RCRA Online memo #14850; dated May 8, 2015



Nicotine-containing smoking cessation products are not solid wastes (or HW) when sent for nicotine reclamation

- ▶ RCRA Online memo #14851; dated May 8, 2015



Household pharmaceuticals collected in DEA-authorized collection receptacles are exempt from RCRA as HHW

- ▶ Not on RCRA Online yet; dated October 2, 2015

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 proposing 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 Recover
 - ▶ 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)

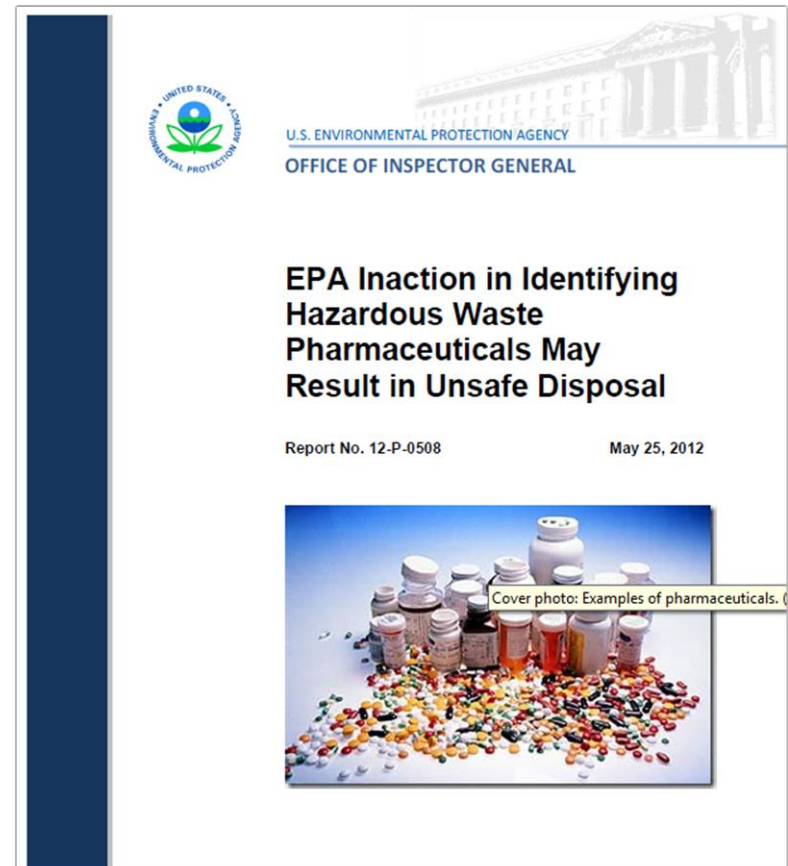
Which Pharmaceuticals Will be Covered?

- ▶ 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?

EPA Inspector General Report:
(May 2012)

EPA Inaction in Identifying Hazardous Waste Pharmaceuticals May Result in Unsafe Disposal



Seek Comment for Possible Future Rules

In response to the 2012 IG Report:

- ▶ Seek comment on expanding what pharmaceuticals are hazardous waste
 - ▶ What's the best way to incorporate new drugs into RCRA?
 - ▶ Are there alternative methods other than the current listings and characteristic approaches?

Seek Comment for Possible Future Rules

In response to the 2014 Retail Notice of Data Availability (NODA):

- ▶ Seek 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

Cartoon Parade



**There's nothing wrong with my eye.
It's a nicotine patch – I'm trying to quit smoking**

Who Will be Covered by the Rule?

- ▶ Healthcare facilities that generate hazardous waste pharmaceuticals
 - ▶ Does not include healthcare facilities that are CESQGs

- ▶ The proposed definition of *Healthcare facility* is: any person that
 - (1) provides 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
 - (2) sells or dispenses over-the-counter or prescription pharmaceuticals.

Who Will be Covered by the Rule?

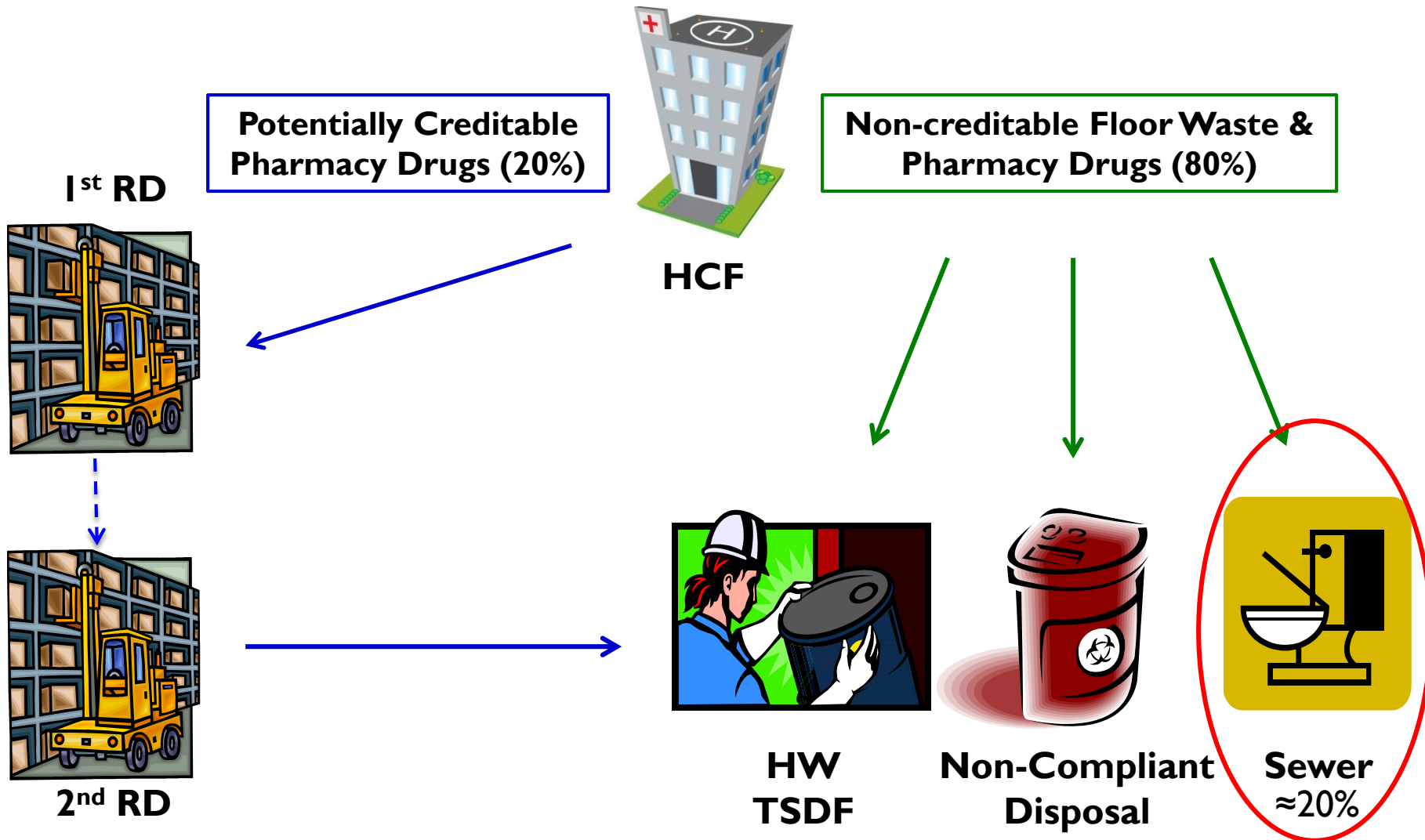
- ▶ **Healthcare facilities – include (but are not limited to):**
 - ▶ Hospitals, including psychiatric hospitals
 - ▶ Pharmacies, including
 - ▶ Long-term care pharmacies
 - ▶ Mail-order pharmacies
 - ▶ Retail stores with pharmacies
 - ▶ Health clinics
 - ▶ Surgical centers
 - ▶ Long-term care facilities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

- ▶ **Drug manufacturers are not considered healthcare facilities**

Who Will be Covered by the Rule?

- ▶ All pharmaceutical reverse distributors - regardless of current generator category
- ▶ The proposed definition of *Pharmaceutical Reverse Distributor* is
 - ▶ Any person that receives and accumulates potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer's credit
 - ▶ Any person, including forward distributors and pharmaceutical manufacturers, that processes pharmaceuticals for the facilitation or verification of manufacturer's credit is considered a pharmaceutical reverse distributor
- ▶ Some drug manufacturers may operate as pharmaceutical reverse distributors

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 and 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”

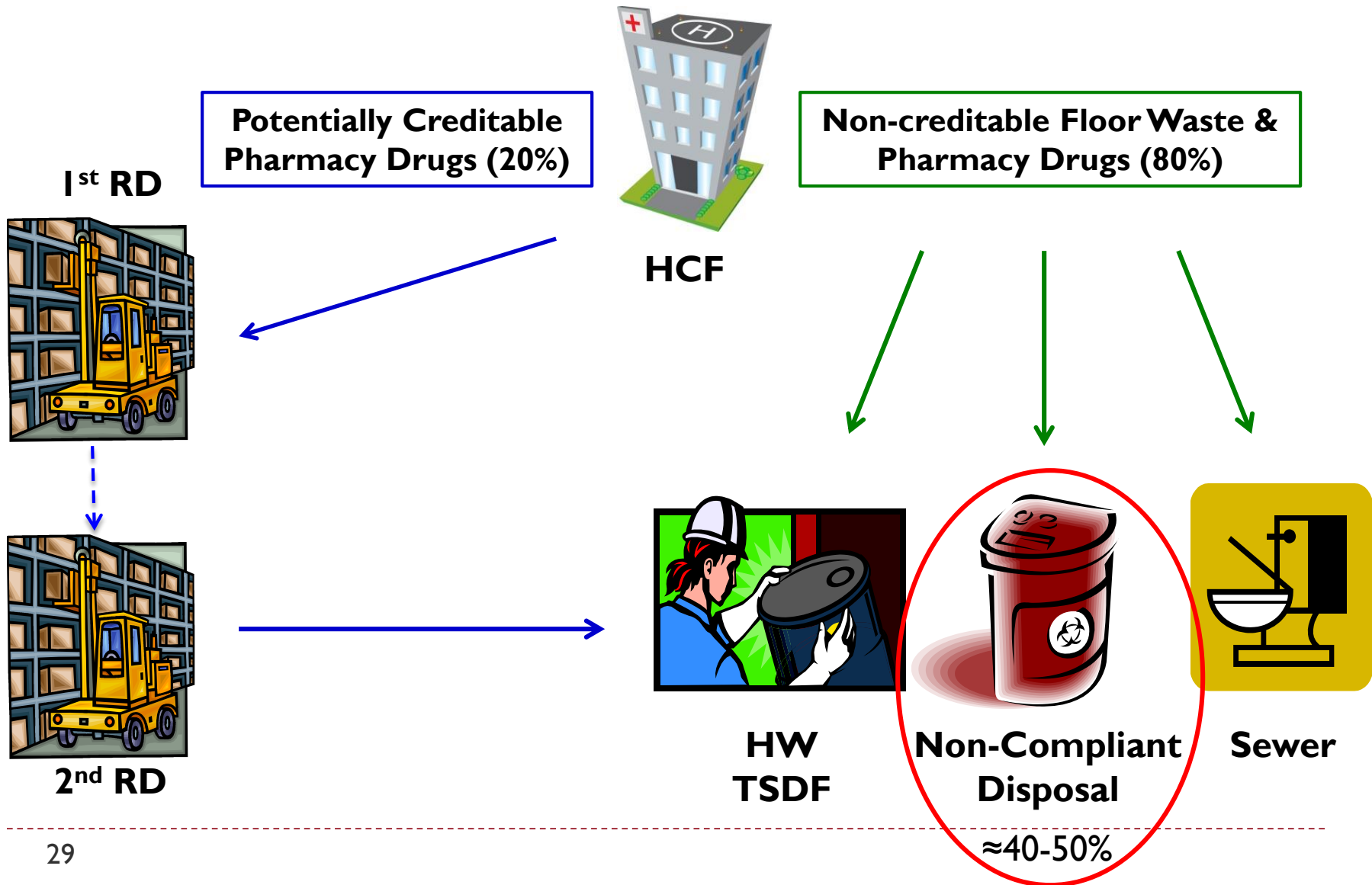
David Sedlak, Director of the Institute for Environmental Science and Engineering at UC Berkeley

#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

Two 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

Two 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

Accumulation on-site at healthcare facility:

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

- ▶ Potentially Creditable HW pharmaceuticals
 - ▶ No specific labeling or accumulation time limits proposed

- ▶ Non-creditable HW pharmaceuticals
 - ▶ Similar to simplified Universal Waste standards
 - ▶ One year accumulation before a permit is required
 - ▶ Closed containers secured to prevent access to contents
 - ▶ Wastes that can't be incinerated must be accumulated separately (e.g., P012)
 - ▶ HW codes are not required on accumulation containers
 - ▶ Label as “Hazardous Waste Pharmaceuticals”

#3: Manufacturing Framework

Proposed Solution

Shipments off-site from a healthcare facility:

- ▶ Potentially Creditable HW pharmaceuticals can go to a Pharmaceutical Reverse Distributor:
 - ▶ Written, advance notice of shipments to RD
 - ▶ Confirmation of receipt of shipment by RD
 - ▶ Recordkeeping of shipments to RD
 - ▶ Common carrier allowed – e.g., US Postal Service, USPS, FedEx, etc.
 - ▶ HW codes not required during shipment

- ▶ Non-creditable HW pharmaceuticals must go to a TSDF
 - ▶ HW transporter required
 - ▶ Manifesting required
 - ▶ HW codes not required on manifest
 - ▶ “Hazardous waste pharmaceuticals” in Box 14 of manifest

#2: LQG Status Due to Acute HW

Problem

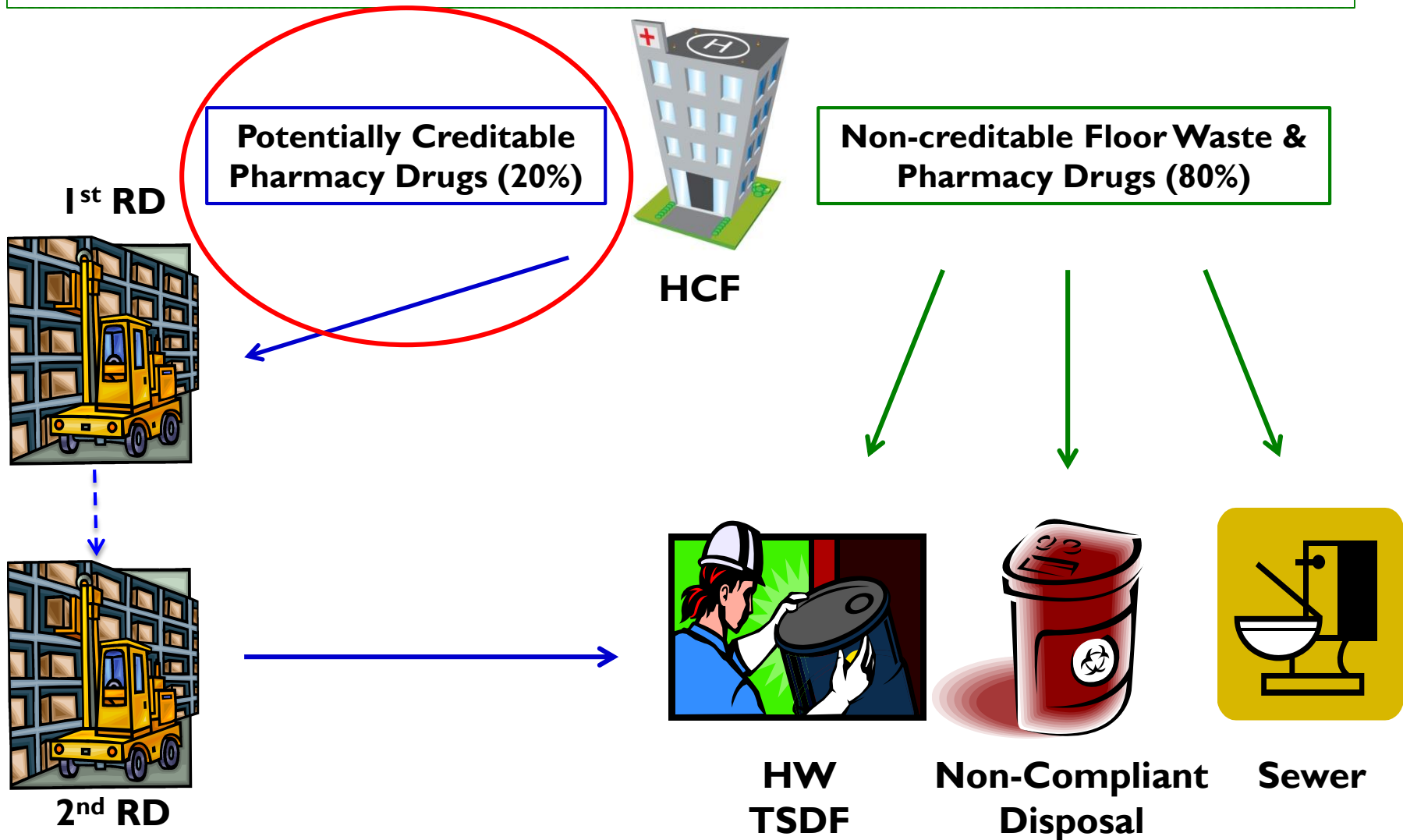
- ▶ LQG status for healthcare facilities & pharmacies due to exceeding 1 kg acute HW/month, which results in:
 - ▶ Shorter accumulation time
 - ▶ Biennial Reporting
 - ▶ More training requirements and documentation
 - ▶ Higher costs for generators
 - ▶ Higher costs for states who must inspect LQGs more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

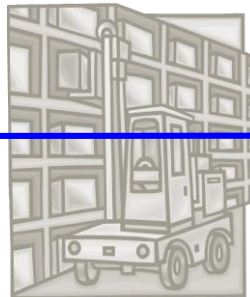


- **Not all steps occur in every case**

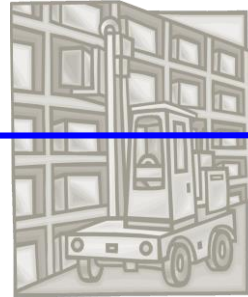
HCF/Pharmacy



**1st RD
can be a
manufacturer**



**2nd RD
can be a
manufacturer**



**3rd RD
must be a
manufacturer**



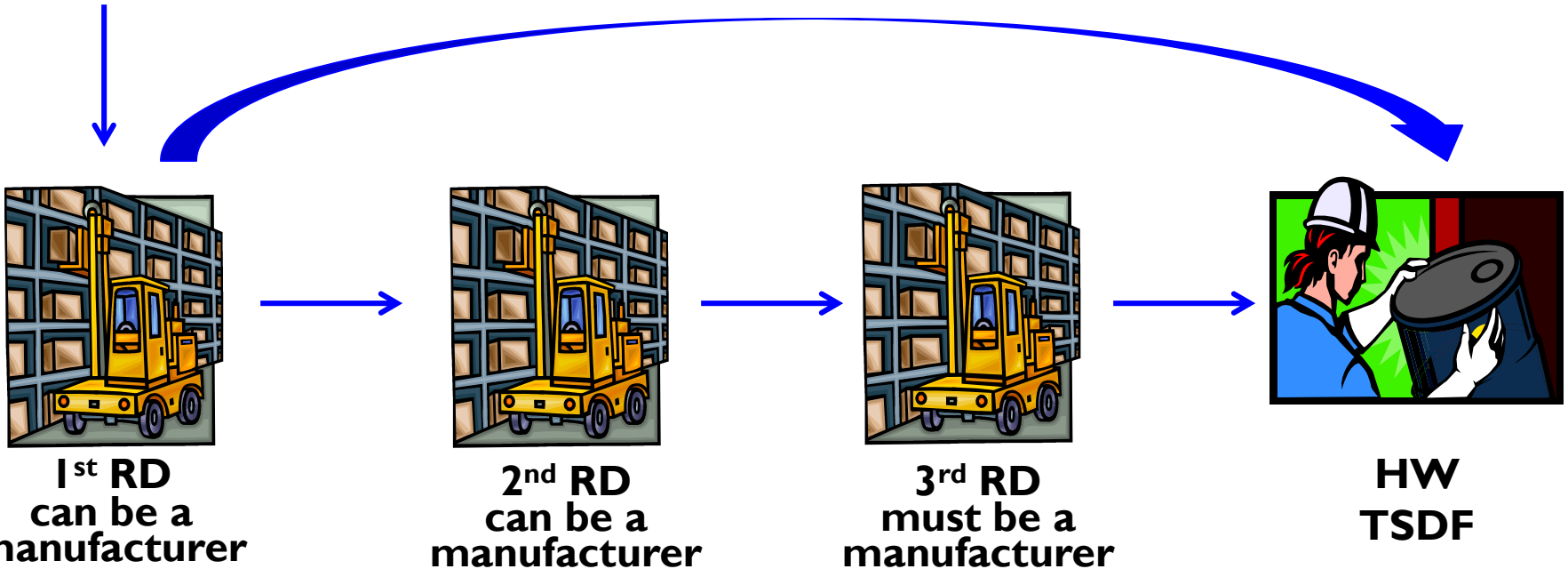
**HW
TSDF**

Flow of HW Pharmaceuticals



- The same steps may not occur in every case

HCF/Pharmacy



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”**



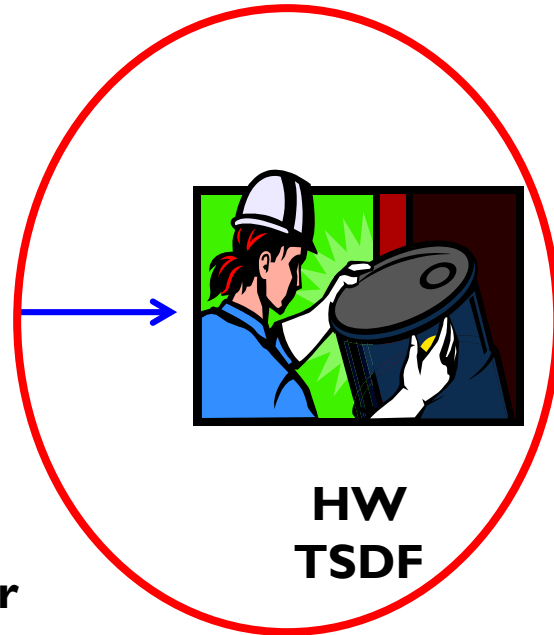
1st RD
can be a
manufacturer



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

Accumulation on-site at reverse distributor:

- ▶ 90 days total accumulation time

- ▶ Potentially Creditable HW pharmaceuticals
 - ▶ No specific labeling or container standards proposed

- ▶ Evaluated HW pharmaceuticals
 - ▶ Must designate an on-site accumulation area and conduct and keep a log of weekly inspections
 - ▶ LQG training for personnel handling evaluated HW pharmaceuticals
 - ▶ Closed containers, if holding liquids or gels
 - ▶ Wastes that can't be incinerated must be accumulated separately (e.g., P012)
 - ▶ HW codes required prior to transport off-site
 - ▶ Label as “Hazardous Waste Pharmaceuticals”
 - ▶ Biennial Report

#1: Status of Creditable Pharmaceuticals

Proposed Solution

Shipments off-site from an reverse distributor:

- ▶ Potentially Creditable HW pharmaceuticals can go to another Pharmaceutical Reverse Distributor:
 - ▶ Written, advance notice of shipments to next RD
 - ▶ Confirmation of receipt of shipment by next RD
 - ▶ Recordkeeping of shipments to RD
 - ▶ Common carrier allowed e.g., US Postal Service, USPS, FedEx, etc.
 - ▶ HW codes not required during shipment

- ▶ Evaluated HW pharmaceuticals must go to a TSDF
 - ▶ HW transporter required
 - ▶ Manifesting required
 - ▶ HW codes required on manifest

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

Part III: What's Ahead?

- ▶ **Publication of proposed rule in Federal Register**
 - ▶ Administrator signed the proposed rule August 31, 2015
 - ▶ Published in FR: September 25, 2015; 80 FR 58014
- ▶ **60-day public comment period**
 - ▶ Public comment period ends Tuesday, November 24, 2015
 - ▶ EPA has received multiple requests for extension
- ▶ **EPA reviews public comments & commences work on final rule**
- ▶ **EPA decides whether to proceed on additional proposed or final rules related to:**
 - ▶ Expanding what pharmaceuticals are hazardous
 - ▶ Nicotine