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Managing Waste Pharmaceuticals: New Obligations on Healthcare Providers, Expanded Definition of Healthcare Facility

WEDNESDAY, JUNE 19, 2019

1pm Eastern | 12pm Central | 11am Mountain | 10am Pacific

Today's faculty features:

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Managing Pharmaceutical Waste under New Resource Conservation and Recovery Act (RCRA) Rule 40 CFR § 266 Subpart P

Strafford June 19, 2019

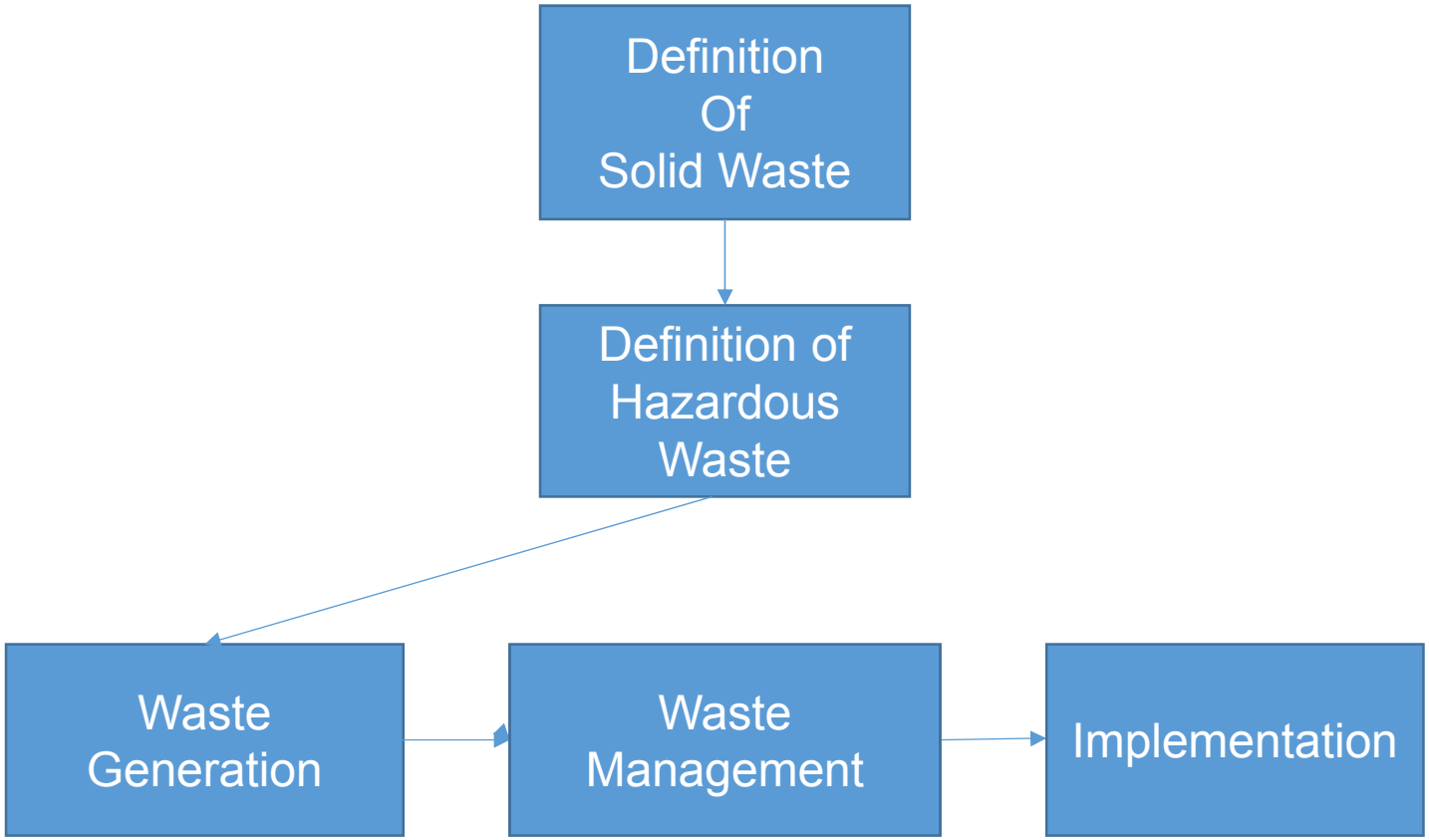
Gwen Keyes Fleming and Marlys Palumbo
Partners, Van Ness Feldman, LLP

NEW OBLIGATIONS FOR HEALTHCARE INDUSTRY

- EPA issued a new rule on February 22, 2019 entitled "Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine," 84 Fed. Reg. 5816
- Our discussion today assumes that those of you listening have a basic understanding of RCRA regulations, particularly the definition of solid waste, and the designation of hazardous wastes, which include many waste pharmaceuticals

MP1

RCRA HAZARDOUS WASTE PROGRAM



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Slide 7

MP1 Marlys Palumbo, 6/5/2019

RCRA BASICS

- Starts with ***Definition of Solid Waste (DSW) as any garbage, refuse, sludge from a waste treatment plant, water supply treatment plant, or air pollution control facility and other discarded material . . . resulting from industrial, commercial, mining, and agricultural operations, and from community activities . . .” RCRA § 1004 (27)***
- When a material is “discarded” and becomes a solid waste is a difficult issue under RCRA, particularly when materials are “recycled” legitimately
- RCRA Regulations in Subtitle C of 40 CFR governs hazardous waste, a subset of “solid waste” – 40 CFR §§ 260-279
- Hazardous wastes (HW) are either: LISTED (by waste code designating the nature and origin of the waste) or CHARACTERISTIC because the waste has one or more of the four characteristics of HW – ignitability, corrosivity, reactivity, or toxicity
- Some HWs are “excluded” because they do not pose a risk to human health or the environment; also household hazardous wastes are excluded from regulation under Subtitle C
- Wastes that are legitimately recycled are generally “excluded” from the definition of solid waste once they are reused, reclaimed, or recycled, and thus excluded from the definition of HW

HW CHARATERIZATION

- Generators are required to characterize all waste at point of generation (40 CFR 262.11) each month of waste generation
- Is any waste “excluded” under 40 CFR § 261.4?
- If “no” – is generated waste on one of the lists in 40 CFR § 261 subpart D? if “yes” the waste is HW
- Does the waste exhibit one or more of the four “characteristics” that make the waste hazardous? If yes, the waste is HW
- Is the waste an “acute HW”? If yes, must consider both volume and toxicity in determining status of generator as very small quantity generator (VSQG), small quantity generator (SQG), or large quantity generator (LQG)

GOALS OF REGULATION

- Create regulations better suited for the healthcare sector's management of hazardous waste pharmaceuticals
- Eliminate intentional sewering of hazardous waste pharmaceuticals
- Reduce overlapping regulations with DEA & FDA
- Provide regulatory clarity and national consistency on how RCRA applies to reverse distribution and reverse logistics
- Reevaluate regulatory status of certain common FDA approved over-the-counter (OTC) nicotine replacement therapies – lozenges, patches, gums currently treated as P075 acute listed waste

AMENDMENT OF P075 NICOTINE LISTING

- **BACKGROUND:** Nicotine preparations when discarded are listed waste under waste code P075 in 40 CFR § 261.33 as an acute hazardous waste
- The P075 listing is amended so that FDA approved OTC nicotine replacement therapies are excluded
  - EPA concluded that patches, gums, and lozenges do not meet the regulatory criteria for hazardous waste
  - These materials now discarded as non-hazardous solid waste

AMENDMENT OF P075 NICOTINE LISTING

- **Nicotine is still listed as P075**
  - Many unused formulations of nicotine are still P075 when discarded including:
    - E-liquids in e-cigarettes, cartridges, or vials
    - Prescription nicotine (e.g., nasal spray, inhaler)
    - Legacy pesticides containing nicotine
    - Nicotine used in research and manufacturing

OTHER KEY TAKE AWAYS

- **New Definitions and Standards**
  - Healthcare Facility (HCF)
  - Reverse Distributor (RD)
  - Pharmaceutical & Hazardous Waste (HW) Pharmaceutical
  - Non-Creditable HW Pharmaceutical
  - Potentially Creditable HW Pharmaceutical
  - Evaluated HW Pharmaceutical
- **New Empty Container Standards**
- **Conditional Exemptions under RCRA for certain DEA controlled substances**
- **Sewering Ban**

NEW DEFINITIONS: HEALTHCARE FACILITY

HEALTHCARE FACILITY is any person 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**

(2) Distribute, sell, or dispense pharmaceuticals, including OTC pharmaceuticals, dietary supplements, homeopathic drugs, or prescription pharmaceuticals

NEW DEFINITIONS: HEALTHCARE FACILITY

HEALTHCARE FACILITY includes but is not limited to:

- Wholesale distributors
- Third-party logistics providers that serve as forward distributors
- Military medical logistics facilities
- Hospitals
- Psychiatric hospitals
- Ambulatory surgical centers
- Health clinics
- **LONG TERM CARE FACILITIES**
- Physician's offices
- Optical and dental providers
- Chiropractors
- Ambulance services
- Pharmacies
- Mail order pharmacies
- Retailers of pharmaceuticals
- Veterinary clinics & hospitals
- **LONG-TERM CARE PHARMACIES**

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NEW DEFINITIONS: HEALTHCARE FACILITY

HEALTHCARE FACILITY DOES NOT INCLUDE:

- Pharmaceutical Manufacturers
- Reverse Distributors
- Reverse Logistics Centers

NEW DEFINITIONS: LONG TERM CARE FACILITY

- **LONG TERM CARE FACILITIES (LTCF) means**

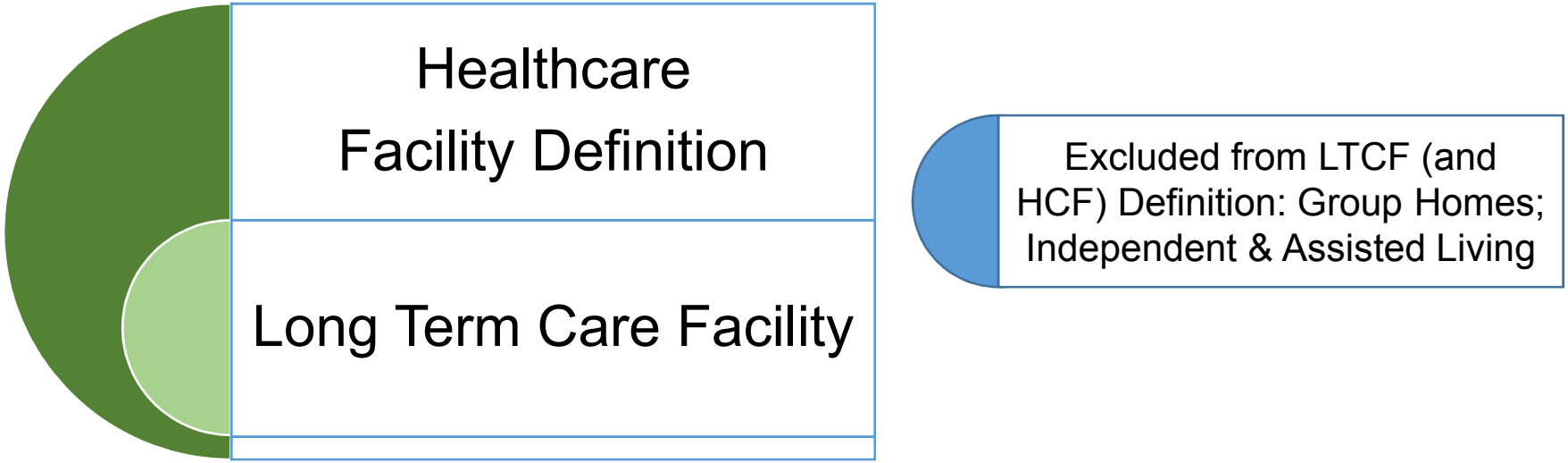
A licensed entity that provides assistance with activities of daily living, including managing and administering pharmaceuticals to one or more individuals at the facility

- **LTCF includes, but is not limited to:**
  - Hospice facilities
  - Nursing facilities
  - Skilled nursing facilities

NEW DEFINITIONS: LONG TERM CARE FACILITY

LTCF does not include:

- Group homes
- Independent living communities
- Assisted living facilities
- The independent and assisted living portions of continuing care retirement communities.



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NEW DEFINITIONS: PHARMACEUTICAL

- **PHARMACEUTICAL means**
  - Any drug or dietary supplement for humans or animals
  - Any electronic nicotine delivery system
  - Any liquid nicotine packaged for retails sale for use in the above
- **DOES NOT INCLUDE MEDICAL WASTE, DENTAL AMALGAM, OR SHARPS**

NEW DEFINITIONS: PHARMACEUTICAL

PHARMACEUTICAL includes:

- Prescription drugs
- OTC drugs
- Homeopathic drugs
- Compounded Drugs
- Investigational new drugs
- Pharmaceuticals remaining in non-empty containers
- Personal protective equipment (PPE) contaminated with pharmaceuticals
- Clean up material from spills of pharmaceuticals

NEW DEFINITIONS: HAZARDOUS WASTE PHARMACEUTICAL

- **HAZARDOUS WASTE (HW) PHARMACEUTICAL means a pharmaceutical that**

  (1) is a solid waste per § 261.2; and

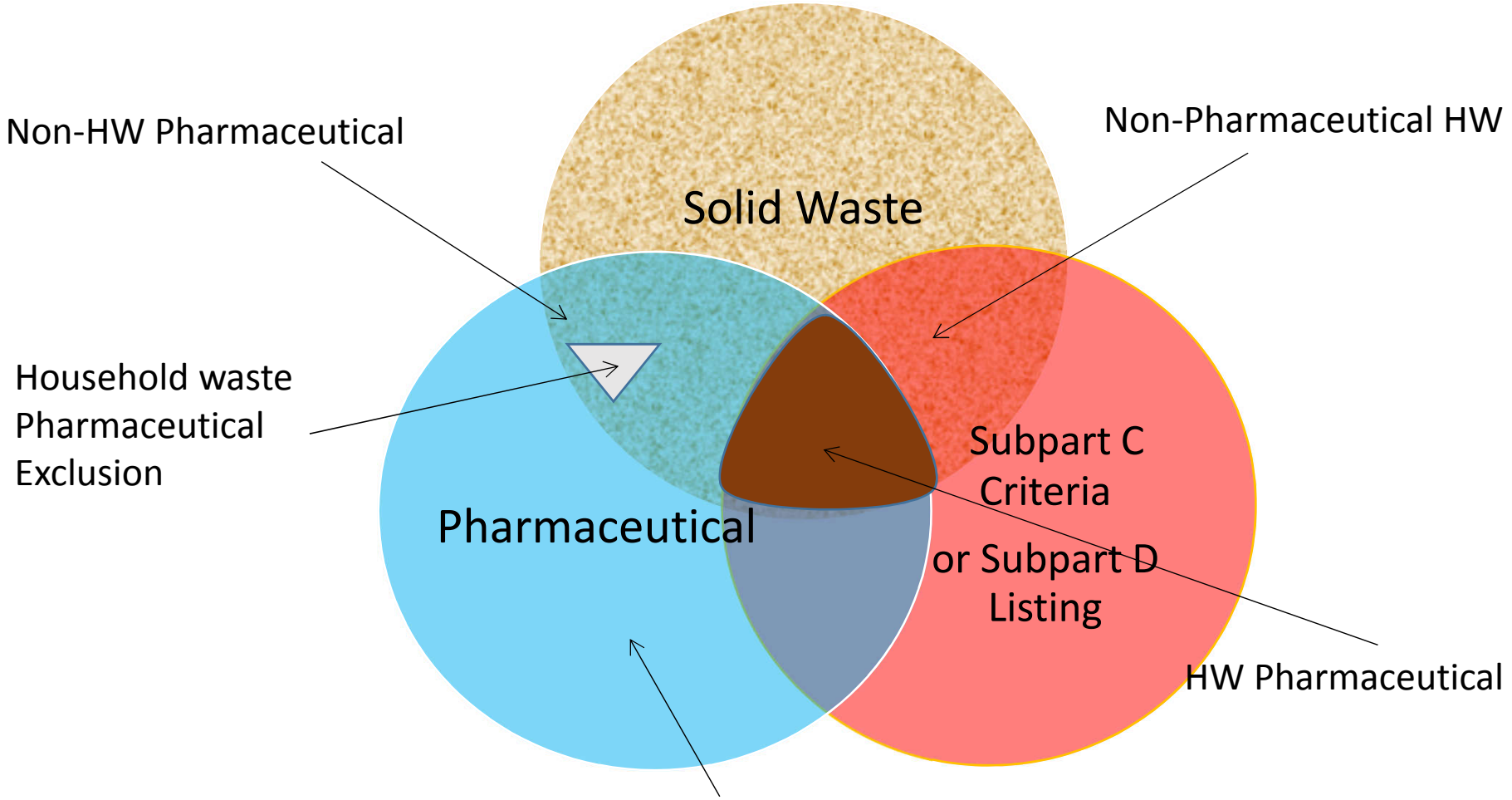
  (2) exhibits ≥ 1 characteristic in Part 261 C or listed in Part 261 D

- **A pharmaceutical is not a solid waste (and therefore not a HW pharmaceutical) if**

  (1) it is legitimately used/reused; or

  (2) reclaimed

PHARMACEUTICALS



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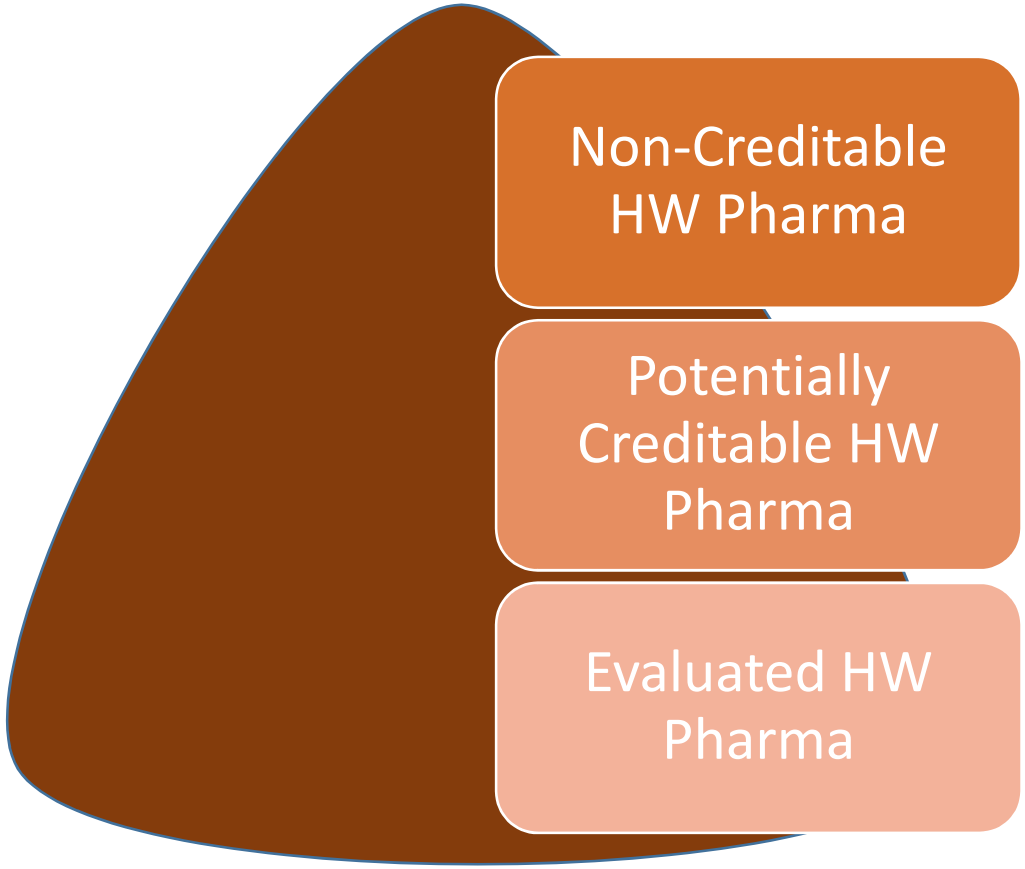
NEW DEFINITIONS WITHIN HW PHARMACEUTICALS



The regulations addresses 3 subsets of PRESCRIPTION HW PHARMACEUTICALS

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NEW DEFINITIONS WITHIN HW PHARMACEUTICALS

Non-Creditable HW Pharma	• Prescription (Rx) HW pharma that ≠ have a reasonable expectation to be eligible for manufacturer credit; or • Non-prescription HW pharma that ≠ reasonable expectation to be legitimately used or reclaimed
Potentially Creditable HW Pharma	• Rx HW pharma that has a reasonable expectation to be eligible for manufacturer credit; AND is 1) in original packaging (except recall); 2) Undispensed; AND 3) Unexpired or < 1 yr past expiration. DOES NOT INCLUDE NON-Rx.
Evaluated HW Pharma	• Rx HW pharma that has been evaluated by an reverse distributor in accordance with § 266.510(a)(3) and will not be sent to another reverse distributor for further evaluation or verification of manufacturer credit.

NEW DEFINITIONS: REVERSE DISTRIBUTOR

- **REVERSE DISTRIBUTOR (RD) means**

  Any person that receives and accumulates prescription pharmaceuticals that are potentially creditable HW pharmaceuticals for the purpose of facilitating or verifying manufacturer credit

- **RD includes:**
  - Forward distributors;
  - Third-party logistics providers; and
  - Pharmaceutical manufacturers that process prescription pharmaceuticals for facilitation/verification of manufacturer credit

NEW DEFINITIONS: REVERSE DISTRIBUTOR vs. REVERSE LOGISTICS

Reverse Distribution

- Receive shipments of unused/expired prescription pharmaceuticals to facilitate crediting process
- Prescription pharmaceuticals are not reused, resold and are discarded

vs.

Reverse Logistics

- Designed to evaluate unsold retail items; analyze secondary markets and assess for suitability of reuse
- Non-prescription pharmaceuticals (e.g., OTCs, supplements, etc.)
- All other unsold retail items

NEW DEFINITIONS: REVERSE DISTRIBUTOR vs. REVERSE LOGISTICS

Reverse Distribution

- EPA maintains position in proposed rule that prescription pharmaceuticals are wastes at the HCF
- Distinguishes between creditable and non-creditable pharmaceuticals

vs.

Reverse Logistics

- Final Rule reaffirms and codified EPA's long standing policy that non-prescription pharmaceuticals are not wastes at the HCF if they have a reasonable expectation of being lawfully used/reused for their intended purpose or reclaimed
- Same policy for all unsold retail items as well

FLOW OF NON-Rx PHARMACEUTICALS & UNSOLD RETAIL ITEMS

HCF

Is there a reasonable expectation of Use/Reuse or Reclamation?

NO

TSDF

YES

Reverse Logistics Center

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Sources: https://www.alicowasteexperts.com/images/waste-disposal.jpg
https://clipartion.com/wp-content/uploads/2015/11/free-to-use-amp-public-domain-hospital-clip-art2.png
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§ 266.500

SUBPART P APPLICABILITY

- **Part 266 Subpart P is both sector specific and waste-specific**
  - Applies to
    - ALL HCFs that generate above VSQG amounts (all SQGs, LQGs)
    - VSQGs can “opt-in” to some or all of Subpart P
    - ALL reverse distributors
  - Does not apply to
    - Management of hazardous pharmaceutical waste by facilities other than HCF and reverse distributors
    - LTCF ≤ 20 beds (rebuttable presumption of VSQG status)
    - HCF management of non-pharmaceutical hazardous waste regulated under other RCRA regulations

SUBPART P APPLICABILITY

- **Does not apply to**
  - Pharmaceuticals that are not solid waste because they are legitimately used/reused or reclaimed
  - OTC pharmaceuticals, dietary supplements, or homeopathic drugs because they have a reasonable expectation of being redistributed (used/reused) or reclaimed
  - Pharmaceuticals under a recall approved by the FDA Pharmaceuticals managed by recall corrective action plan accepted by CPSC
  - Pharmaceuticals stored according to a preservation order in an investigative/judicial proceeding
  - Investigational new drugs
  - Household waste pharmaceuticals including Drug Take Back programs approved by the DEA

SUBPART P APPLICABILITY

HCF VSQGs

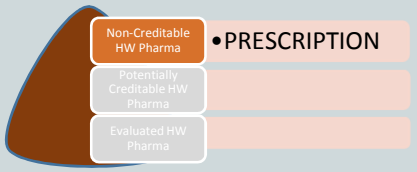
- An HCF that is still a VSQG after counting both HW pharmaceuticals and non-pharmaceutical HW
  - Subject to generator standards in § 262.14 and not Subpart P, but subject to sewering ban and empty container requirements
  - Can opt into § 266.504 standards for managing potentially creditable HW pharmaceuticals headed to an RD and use conditional off site collection provisions at other HCFs
  - Can also use § 266.501(d) to opt into provisions relating to
    - § 266.502, Standards for managing non-creditable HW pharmaceuticals
    - Standards for managing potentially creditable HW pharmaceuticals headed another HCF & NOT headed to an RD
    - § 266.503, Standards for potentially creditable HW pharmaceuticals that are Rx pharmaceuticals headed to an RD

SUBPART P APPLICABILITY cont.

LTCF VSQGs

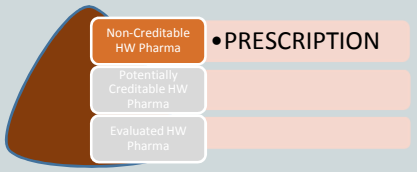
- **A LTCF that is still a VSQG after counting both HW pharmaceuticals and non-pharmaceutical HW**
  - May dispose of HW pharmaceuticals (except PPE or clean up materials) in an onsite collection receptacle of a DEA-defined and registered authorized collector
  - **PROVIDED** that HW materials are collected, stored, transported, destroyed, and disposed of in compliance with DEA regulations
- **LTCF w/ ≤ 20 beds is presumed to be VSQG and not subject to Subpart P except for sewering ban & empty container provisions**

HEALTHCARE FACILITY MANAGEMENT STANDARDS



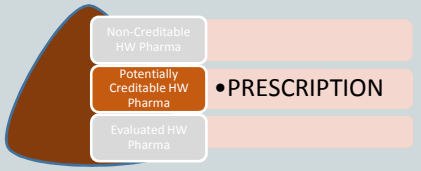
- **For non-creditable hazardous waste pharmaceuticals**
  - *Notification and Withdrawal*
    - Next Biennial Report or within 60 days of effective/applicability date
  - *Training of Personnel*
  - *Container Standards*
    - Must be structurally sound and compatible with contents; contents must be compatible
  - *Labeling*
    - Accumulation containers must be labeled with the words “Hazardous Waste Pharmaceuticals”
    - No hazardous waste codes or other labeling requirements
  - *Accumulation Time*
    - One year without permit; must be able to demonstrate accumulation time
    - Conditional additional 90 days for rejected shipments

HEALTHCARE FACILITY MANAGEMENT STANDARDS



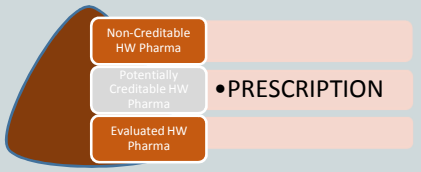
- **For non-creditable hazardous waste pharmaceuticals (cont.)**
  - *Land Disposal Restrictions*
    - Must comply with § 268.7(a) requirements except waste code
  - *HW Determinations*
  - *Recordkeeping*
    - Not required if manage non-creditable non-HW pharmaceuticals the same as non-creditable HW pharmaceuticals
  - *No biennial reporting under § 262.41*
  - *Response to Spills*
  - *Accepting from Off-site VSQG HCF*

HEALTHCARE FACILITY MANAGEMENT STANDARDS



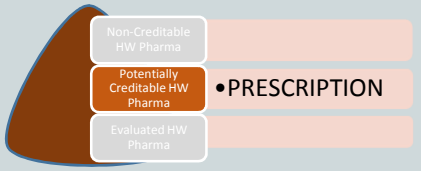
- **For potentially creditable hazardous waste pharmaceuticals**
  - HW Determination
  - Accepting from off-site VSQG HCF
  - Can only send to a Reverse Distributor
  - No biennial reporting
  - Recordkeeping
    - Keep confirmation of delivery and shipping papers per 49 CFR 172 for 3 years
  - No labeling or container or accumulation time standards

SHIPPING STANDARDS



- **Non-creditable HW pharmaceuticals shipped by HCF & Evaluated HW pharmaceuticals shipped by an RD must comply with:**
  - Pre-transport packaging, labeling, markings, and placarding per DOT regulations
  - Manifest requirements of 40 CFR § 262 except that when shipped by a HCF use “PHARMS” on manifest instead of waste codes
  - RD must use hazardous waste codes on manifest for Evaluated HW Pharmaceuticals
  - HW must ultimately be sent to a transfer, storage, and disposal facility (TSDF)
  - Import and Export regulations apply

SHIPPING STANDARDS



- **Potentially creditable HW pharmaceuticals from HCF to RD or RD to RD**
  - Manifest and hazardous waste transporter are not required; can use common carrier
  - Shipper must receive delivery confirmation from RD; electronic tracking is sufficient
  - Export regulations apply except the manifest requirements
  - For imports: Subpart P applies in lieu of 40 CFR § 262, Subpart H

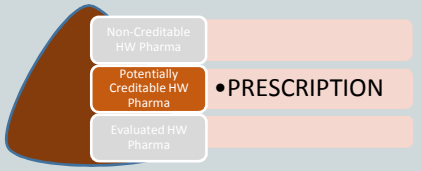
EMPTY CONTAINER STANDARDS

- **New standards apply to**
  - Containers with both acute & non-acute HW pharmaceuticals
  - HCF & RD subject to Part 266 Subpart P; and
  - Anyone else with containers of hazardous waste pharmaceuticals
- **Residues remaining in "RCRA empty" containers are not regulated as hazardous waste**
- **Can be used to determine if HCF is subject to Subpart P**
- **Triple rinsing of containers with acute hazardous waste is not required**

EMPTY CONTAINER STANDARDS

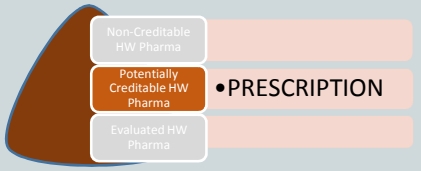
RCRA EMPTY DETERMINATIONS	Considered RCRA empty and not considered hazardous waste if
Stock dispensing (<1 liter or 10K pills) and unit does containers	Contents have been removed
Syringes	Contents have been removed by fully depressing plunger
IV bags	ACUTE: Contents have been fully administered to patient or NON-ACUTE: meets § 261.7
Other containers	ACUTE: cannot be RCRA empty NON-ACUTE: meets § 261.7(b)(1) or (2)

REVERSE DISTRIBUTOR STANDARDS



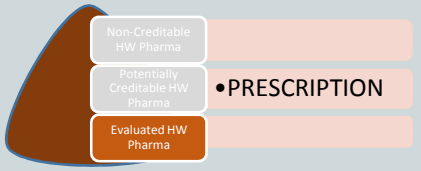
- **Standards for RD <u>accepting</u> potentially creditable HW pharmaceuticals**
  - Notification
  - Inventory
  - Evaluation
    - Differs if RD is also a manufacturer or not
  - Accumulation Times
  - Security
  - Contingency Planning
  - Closure Requirements
  - Unauthorized Waste Reports
  - General Recordkeeping

REVERSE DISTRIBUTOR STANDARDS



- **Additional Standards for <u>RD sending</u> potentially creditable HW pharmaceutical waste <u>to another RD</u>:**
  - Standards for Accepting Plus
    - RD receiving from HCF must send to another RD within 180 days
    - RD receiving from RD must send to an RD that is a pharmaceutical manufacturer within 180 days
    - Must follow shipping requirements
    - Recordkeeping Requirements

REVERSE DISTRIBUTOR STANDARDS



- **Additional Standards for RD sending <u>evaluated</u> HW pharmaceutical waste to a TSDF:**
  - Standards for Accepting Plus
    - Accumulation Area
    - Weekly Inspections
    - Personnel Training
    - Labeling and Management of Containers
    - Hazardous Waste Codes
    - Shipping Per § 266.508(a) or (b)
    - Rejected Shipment Requirements
      - May accumulate for 90 days in designated area provided follow § 266.510(a) & (c)
    - Land Disposal Restrictions
    - Reporting Requirements
    - Recordkeeping
      - Inspections; Manifests; Reports & Training

REVERSE DISTRIBUTOR STANDARDS

- No RCRA permit required
- No generator categories
- All RDs are regulated the same

Permit is required if

1. RD does not meet conditions of the regulation;
2. Accepts manifested HW from off site; OR
3. Treats or disposed of HW pharmaceuticals on site

REVERSE DISTRIBUTION OF HW PHARMACEUTICALS

HCF → 1st RD → 2nd RD

NON-CREDITABLE HW PHARMACEUTICAL

POTENTIALLY CREDITABLE HW PHARMACEUTICAL

EVALUATED HW PHARMACEUTICAL

TSDF ← 3rd RD

Must be a Manufacturer

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Sources: https://www.alicowasteexperts.com/images/waste-disposal.jpg
https://clipartion.com/wp-content/uploads/2015/11/free-to-use-amp-public-domain-hospital-clip-art2.png
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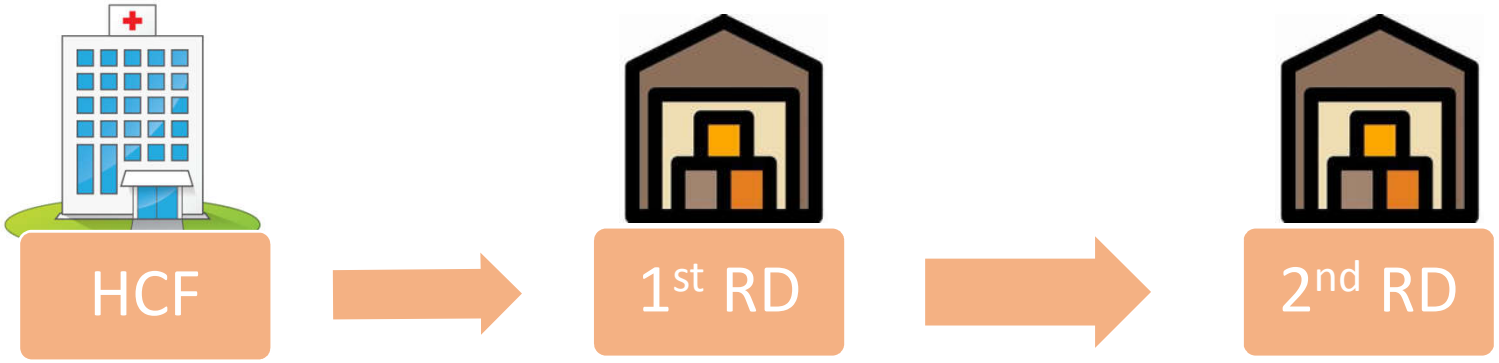
§ 266.500

REVERSE DISTRIBUTION OF HW PHARMACEUTICALS



TIME FRAMES

30 Days Evaluation
\+ 180 Days Accumulation
= 210 Days Total per RD

Must be a Manufacturer

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Sources: https://www.alicowasteexperts.com/images/waste-disposal.jpg
https://clipartion.com/wp-content/uploads/2015/11/free-to-use-amp-public-domain-hospital-clip-art2.png
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REVERSE DISTRIBUTION OF HW PHARMACEUTICALS

HCF

§ 266.509

1st RD

§ 266.510(a) & (b)

§ 266.509

2nd RD

§ 266.510(a) & (b)

§ 266.509

3rd RD

Must be a Manufacturer

§ 266.510(a) & (c)

§ 266.508

TSDF

SHIPPING STANDARDS

MANAGEMENT STANDARDS

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THE GOOD NEWS

There are no generator categories under Part 266 Subpart P

Triple rinsing of containers with acute HW pharmaceuticals is not required anymore

THE GOOD NEWS

HCFs and RDs operating under Subpart P do not have to:

1. Keep track of how much HW pharmaceuticals they generate per month
2. Segregate the acute and non-acute HW pharmaceuticals

CONDITIONAL EXEMPTIONS; DEA CONTROLLED SUBSTANCES

- **HW pharmaceuticals that are also listed as DEA controlled substances and household waste pharmaceuticals collected in a take-back program are exempt from 40 CFR § 262 if they are**
  - Not sewered
  - Collected, stored, transported, and disposed of in compliance with DEA regulations
  - Destroyed by a method DEA publicly deemed in writing to meet non-retrievable standards at either
    - A permitted large or small municipal waste combustor or
    - A permitted hospital, medical, and infectious waste incinerator
    - A permitted commercial and industrial SW incinerator or
    - A permitted HW combustor

SEWERING BAN

- **Applies to**
  - All HCFs, including VSQGs
  - All RDs
  - Hazardous wastes that are DEA controlled substances
- **Effective in ALL states six months after publication – August 21, 2019**
- For violations of RCRA Subtitle C regulations, the maximum civil penalty is now **$74,552 per day, per violation***

*EPA promulgated the inflation adjustment rule on February 6, 2019 – see 84 Fed. Reg. 2056

EFFECTIVE DATES

- **Effective Dates & State Adoption Deadlines**
  - *August 21, 2019* – Nicotine Amendment & Subpart P in non-authorized states; Sewer ban in ALL states
  - *July 1, 2021* – Authorized states must adopt Subpart P
  - *July 1, 2022* – Authorized states that require a statutory amendment must adopt Subpart P

STATE AUTHORIZATION

- **Part 266 Subpart P is considered more stringent and therefore not optional**

NOTE: the nicotine exemption is considered LESS STRINGENT and therefore adoption by states is not required

THINGS TO REMEMBER

- **HCF and reverse distributors are still subject to**
  - Part 262 for the management of non-pharmaceutical hazardous waste
  - Part 273 for the management of universal waste
  - Other parts as applicable

THINGS TO REMEMBER

- **The following are not subject to RCRA regulation**
  - Pharmaceuticals that are not solid waste because they are legitimately used/reused or reclaimed
  - OTC pharmaceuticals, dietary supplements, or homeopathic drugs that are not solid waste because they have a reasonable expectation of being legitimately used/reused or reclaimed
  - Household waste pharmaceuticals

THINGS TO REMEMBER

- **The following are not subject to RCRA regulation unless & until the decision to discard is made**
  - Recalled pharmaceuticals
  - Pharmaceuticals under preservation order or during an investigation or judicial proceeding
  - Investigational new drugs

These become subject to Subpart P when the decision to discard is made

QUESTIONS

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- Gwen Keyes Fleming has more than twenty years of public sector experience, having served as both an elected and appointed official at the state and local levels, as well as in various branches of the federal government. Most recently, she served as the Principal Legal Advisor (General Counsel) for Immigration & Customs Enforcement (ICE) in the U.S. Department of Homeland Security (DHS), and as Chief of Staff to the Environmental Protection Agency (EPA) during the second term of the Obama Administration. In addition to her time at the DHS and EPA, Gwen served as the EPA Region 4 (Southeastern Region) Regional Administrator, where she was responsible for establishing and implementing environmental policy for eight southeastern states and six federally recognized tribes. Gwen was twice elected District Attorney for the Stone Mountain Judicial Circuit in DeKalb County, Georgia; the first African-American and first woman to hold that office.
- Gwen's practice at Van Ness Feldman focuses on environmental policy, enforcement defense litigation, and special investigations for private as well as municipal clients. She also provides strategic advice and counsel on national security matters related to the protection of environmental and energy infrastructure from cyber and physical threats, including compliance planning, incident response and subsequent enforcement or litigation matters. She is a member of the firm's Environmental Practice Group and coordinates the firm's practice in the area of Cybersecurity. She is the co-author of Van Ness Feldman's Reports entitled *"Critical Infrastructure: 2017 Cybersecurity Review and What to Expect in 2018,"* *"Federal Government Takes Steps to Shape Rules for Automated Vehicles"* and *"D.C. Circuit Decision Loosens Restrictions on Solid Waste."* She has also served as a speaker on the issues relating to critical infrastructure cybersecurity and policy development in the environmental space.
- Gwen's strength in building relationships, managing complex matters, and in depth knowledge of the EPA, DHS and other branches of the federal government, helps clients achieve their business imperatives.

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- Marlys' practice focuses on matters arising under major federal and state environmental, energy, and natural resources statutes. Drawing on a comprehensive understanding of science and policy underlying the Resource Conservation and Recovery Act (RCRA); Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA); Clean Air Act; Clean Water Act; Model Toxics Control Act; renewable portfolio standards; and other regulatory schemes, Marlys advises clients in assessing, managing, and mitigating environmental liabilities and compliance obligations. In addition to her environmental regulatory practice, Marlys has extensive substantive experience in corporate and real estate transactions involving contaminated properties, facility auditing, due diligence investigations, and drafting and negotiating complex transaction agreements. She combines her significant experience in corporate and regulatory transactional projects with an in-depth knowledge of business considerations to advise clients in complex project development, facility acquisitions and divestitures, and other transactional matters.
- Marlys brings a business sensibility to advising clients in all phases of industrial property and plant acquisitions, from letters of intent, to the negotiation and drafting of transaction documents. She also guides clients through various regulatory approval processes and in the planning and implementation of post-closing integration activities. Marlys is adept at guiding transactional teams that include colleagues with expertise in other practice areas – including energy facility development, transmission regulation, federal government licensing, permitting, real estate disposition, and land use regulation – to ensure an integrated approach to achieving the client's legal and business objectives.
- Prior to joining Van Ness Feldman, Marlys was the Senior Vice President and U.S. General Counsel for Philip Services Corporation, a $2 billion company with over 10,000 employees providing integrated hazardous waste management and industrial services to clients in North America and Europe. She was also General Counsel of Sabey Corporation, a pre-eminent Pacific Northwest industrial real estate development company. Her initial legal experience was as a litigation associate in a major Seattle law firm.