HAZARDOUS WASTE PHARMACEUTICALS

ASTSWMO JOINT HAZARDOUS WASTE AND MATERIALS MANAGEMENT MEETING

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A Brief Introduction to the Pharmaceuticals Final Rule and Take-Backs

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OUTLINE

- Part I: Hazardous Waste Pharmaceuticals Final Rule
- Part II: Pharmaceutical Take-Backs

PART I: PHARMACEUTICALS FINAL RULE

The Hazardous Waste Pharmaceuticals Final Rule has three components:

1. Amendment of the Nicotine Listing
2. Reverse Distribution and Reverse Logistics Policy
3. Part 266 Subpart P

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 are not newly applying RCRA regulations to hazardous waste pharmaceuticals at healthcare facilities and reverse distributors
- We are changing HOW they are regulated under RCRA moving forward
  - GOAL: to create regulations that are a better fit for the management of hazardous waste pharmaceuticals at healthcare facilities and reverse distributors

PART II: PHARMACEUTICAL TAKE-BACKS

EPA's role in pharmaceutical take-backs

- Because collected household pharmaceuticals are wastes, EPA has been involved:
  - RCRA and Clean Air Act
- EPA strongly encourages participation in take-backs
- EPA has taken an active role by coordinating the federal agencies that govern various aspects of pharmaceutical take-backs
  - EPA's Office of Resource Conservation and Recovery, and Office of Air
  - Drug Enforcement Administration (DEA)
  - Department of Transportation (DOT)
  - US Postal Service (USPS)

1. PHARMACEUTICALS FINAL RULE

1. AMENDMENT OF NICOTINE LISTING

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- The P075 listing for nicotine is being amended such that FDA-approved over-the-counter (OTC) nicotine replacement therapies will no longer be included under the P075 listing for hazardous waste
  - EPA has concluded that nicotine patches, gums and lozenges do not meet the regulatory criteria for acute hazardous waste
  - Nicotine patches, gums and lozenges can be discarded as non-hazardous waste

≠ P075

NICOTINE IS STILL LISTED AS P075

- Nicotine continues to be a listed, acute hazardous waste with the hazardous waste code P075
- Other unused formulations of nicotine will still be considered P075 when discarded, including
  - E-liquids/e-juices in e-cigarettes, cartridges, or vials
  - Prescription nicotine (e.g., nasal spray, inhaler)
  - Legacy pesticides containing nicotine
  - Nicotine used in research and manufacturing

= P075

1. PHARMACEUTICALS FINAL RULE

2. REVERSE DISTRIBUTION & REVERSE LOGISTICS

REVERSE DISTRIBUTION vs REVERSE LOGISTICS

We have adopted the terminology suggested by a significant number of commenters that distinguishes between:

- **REVERSE DISTRIBUTION** of
  - Prescription (Rx) pharmaceuticals and

- **REVERSE LOGISTICS** of
  - Nonprescription pharmaceuticals (e.g., OTCs, supplements, etc.)
  - All other unsold retail items

REVERSE DISTRIBUTION
Rx HW PHARMACEUTICALS

- Commenters confirmed that
  - reverse distributors receive shipments of unused/expired prescription pharmaceuticals from healthcare facilities and, on behalf of manufacturers, facilitate the process of crediting healthcare facilities for these unused pharmaceuticals
  - prescription pharmaceuticals at RDs are not reused, nor resold, and are discarded
- The final rule maintains the position from the proposed rule that
  - prescription pharmaceuticals moving through reverse distribution are wastes at the healthcare facility
- The fact that the hazardous waste pharmaceuticals going through reverse distribution have value in the form of manufacturer credit has allowed us to take a tailored and more flexible regulatory approach
- EPA developed a regulatory system that is designed with existing business practices in mind for unused/expired prescription pharmaceuticals that are sent through reverse distribution

REVERSE LOGISTICS
NON-RX HW PHARMACEUTICALS AND OTHER UNSOLD RETAIL ITEMS

- Commenters noted that reverse logistics centers are designed to
  - evaluate unsold retail items including nonprescription pharmaceuticals
  - analyze secondary markets, and
  - assess the suitability of the unsold retail items for reuse in those secondary markets
- The final rule reaffirms and codifies EPA's long-standing policy that nonprescription pharmaceuticals (e.g., OTCs) that are sent through reverse logistics are not wastes at the healthcare or retail facility **IF** they have a reasonable expectation of being lawfully used/reused for their intended purpose or reclaimed
- Reverse Logistics Policy: the preamble to the final rule reaffirms the same policy for all unsold retail items (other than prescription pharmaceuticals)

1. PHARMACEUTICALS FINAL RULE

3. PART 266 SUBPART P

§ 266.501

PART 266 SUBPART P APPLICABILITY

- Part 266 Subpart P is considered more stringent, and therefore is NOT optional for
  - States to adopt
  - Healthcare facilities and reverse distributors
- Hazardous waste pharmaceuticals must be managed under Part 266 Subpart P by:
  - All reverse distributors
  - All healthcare facilities that generate above very small quantity generator (VSQG) amounts of hazardous waste
    - VSQG healthcare facilities may elect to opt into Subpart

MANAGE ALL PHARMACEUTICALS UNDER SUBPART P

- EPA encourages managing all waste pharmaceuticals under Subpart P
- Benefits of managing all waste pharmaceuticals under Subpart P
  - Less training: do not have to make individual hazardous waste determinations on each pharmaceutical
  - Fewer accumulation containers: can commingle hazardous and non-hazardous pharmaceuticals
  - Do not have to worry about bumping up in generator category: there are no generator categories under Subpart P

FRAMEWORK OF PART 266 SUBPART P

How the hazardous waste pharmaceuticals are regulated under Part 266 Subpart P depends on two things:

1. Who is managing the hazardous waste pharmaceuticals
   - Healthcare facility
   - Reverse distributor
2. Where the hazardous waste pharmaceuticals are headed
   - Directly to a TSDF
   - Indirectly to a TSDF, via a reverse distributor to obtain manufacturer credit

OTHER PROVISIONS OF SUBPART P

- Sewer prohibition for hazardous waste pharmaceuticals
  - Only Subpart P provision that applies to VSQGs
  - Only Hazardous and Solid Waste Amendments (HSWA) provision - effective in ALL states on August 21, 2019
- Two new conditional exemptions
  1. RCRA hazardous waste pharmaceuticals that are also Drug Enforcement Administration (DEA) controlled substances
  2. Household waste pharmaceuticals collected in DEA authorized collection receptacles (kiosks)
- New standards for "RCRA empty" for types of containers in healthcare settings
  - Includes standards for syringes, IV bags, etc.

II. PHARMACEUTICAL TAKE-BACKS

WHY PHARMACEUTICAL TAKE-BACK PROGRAMS

- Protects human health
  - Pharmaceutical take-back programs get drugs out of the house and unavailable for theft, misuse or abuse
- Protects the environment
  - Reduces pharmaceuticals entering surface water through flushing or pouring down the drain

TWO TYPES OF PHARMACEUTICAL TAKE-BACK PROGRAMS

1. DEA's National Prescription Take-Back Days
   - 2x/year: last Saturday in April and October

2. 2014 DEA regulations created alternative mechanisms with the goal of creating more regular take-backs
   - Mail-back envelopes
   - Take-back receptacles (kiosks)
   - Local take-back events

See DEA's website for more information about both types of take-backs

https://takebackday.dea.gov/

DEA NATIONAL DRUG TAKE-BACK DAYS

- Law enforcement agencies are encouraged to participate in the DEA sponsored national drug take-back events each April and October
- DEA pays for the transportation and destruction of pharmaceuticals collected during these events
- Last DEA national take-back day (April 27, 2019):
  - Almost 1 million pounds collected
  - >6000 sites nationwide participated

DEA REGULATIONS FOR TAKE-BACKS

- Secure and Responsible Drug Disposal Act of 2010
- Directed DEA to develop regulations for take-backs options so that they do not have to include law enforcement
- September 2014, DEA finalized their regulations for take-backs
- It took time for the industry to work through the logistics of implementing the new DEA regulations and is operational now
- Law enforcement may also choose to use these more permanent mechanisms for take-backs in addition to the 2x/year national drug take-back days

DEA REGULATIONS FOR TAKE-BACKS

- Methods allowed by DEA for participating in take-backs
  - Mail-back envelopes
  - Collection receptacles/kiosks
  - Take-back events

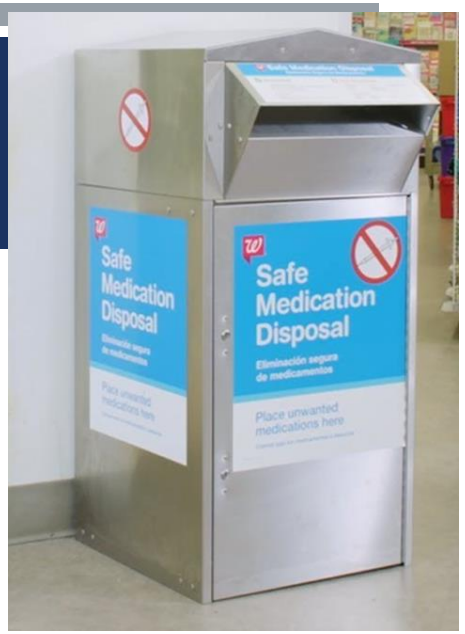
- DEA requirements for all methods
  - All take-back programs/events can only collect pharmaceuticals from "ultimate users" (i.e., households)
  - All collected household pharmaceuticals must be destroyed to meet DEA's non-retrievable standard (i.e., incineration)

MAIL BACK ENVELOPES

- Where to get Mail-Back Envelopes
  - Community organizations or law enforcement can purchase DEA approved mail-back envelopes to hand out to communities
  - Veterans Administration and one national chain provide free mail-back envelopes to any customer that fills a prescription for an opioid
  - Individuals can purchase mail-back envelopes at pharmacies
- Customers put their unwanted pharmaceuticals in the mail-back envelope and mail it to the pre-addressed recipient at no additional cost
- Mail-back envelopes go directly to permitted incinerators for destruction

COLLECTION RECEPTACLES (KIOSKS)

- Who can have a collection receptacle?
  - Law enforcement
  - DEA registrants that are either retail pharmacies or hospitals with pharmacies, can amend their DEA registration to become collectors
- Collection receptacles are permanent locations for pharmaceutical drop-off
- Collection receptacles have liners inside that are removed, sealed and shipped to a DEA registered reverse distributor



TAKE-BACK EVENTS

- Take-back events are temporary, short-term events
- Law enforcement must be present at take-back events
  - Community groups can partner with law enforcement to conduct take-back events
- Law enforcement has multiple options for getting the collected household pharmaceuticals to a DEA registered reverse distributor
  - Drive the collected pharmaceuticals to a DEA registered reverse distributor
  - Drive the collected pharmaceuticals to a permitted incinerator that is not a DEA registrant and witness the destruction
  - Ship collected pharmaceuticals to a DEA registered reverse distributor, like the retail pharmacies do

DEA REGISTERED REVERSE DISTRIBUTORS

- There are approximately 35 DEA registered reverse distributors authorized to accept shipments of liners of collected household pharmaceuticals

- For an up-to-date list of DEA reverse distributors, contact ODLP@dea.usdoj.gov

HOW TO DESTROY COLLECTED PHARMACEUTICALS?

- Because collected take-back pharmaceuticals are solid wastes legally, if going into a combustion unit they must be burned in a:
  - Hazardous Waste Incinerator, or
  - Unit regulated under § 129 of Clean Air Act (CAA) which includes
    - large and small municipal waste combustors (MWCs)
    - hospital, medical, and infectious waste incinerators (HMIWIs)
    - commercial and industrial solid waste incinerators (CISWIs)
- The pharmaceuticals final rule codified that collected household pharmaceuticals must be destroyed by:
  - A method deemed in writing by the DEA to meet the non-retrievable standard or
  - Combusted at one of the above types of units allowed by the CAA

HOW TO DESTROY COLLECTED PHARMACEUTICALS?

- Methods of destroying the collected pharmaceuticals that do **NOT** comply with the DEA destruction standard of non-retrievable
  - Landfilling
  - Flushing
  - Mixing with kitty litter, coffee grounds
  - Drug Disposal Units (e.g., Cactus Sink, Rx Destroyer, etc.)

LAW ENFORCEMENT SHOULD NOT USE BURN BARRELS

- EPA strongly recommends against law enforcement using burn barrels - see memo dated September 11, 2018; RCRA Online #14906
- "Contraband or prohibited goods" may be burned in unpermitted units (burn barrel)
  - Exemption under the Clean Air Act regulations
  - Unpermitted burn units must be owned or operated by law enforcement
  - EPA has lost litigation and taken a remand on this and other non-statutory exemptions
  - Unpermitted units must burn only contraband
- Take-back pharmaceuticals are not contraband
  - Unpermitted units, like burn barrels, should not be used to burn pharmaceuticals from collection programs/take-back events

HEALTH AND SAFETY WHEN USING BURN BARRELS

- When take-back pharmaceuticals are burned they are burned along with the packaging (plastic, foils, glass, cardboard)
- Burn barrels do not reach temperatures of permitted incineration
- Dioxin and furans are products of incomplete combustion which can occur in these burn barrels at low temperatures
- Police typically operate these units in their parking lots without any PPE

MOBILE BURN BARRELS WITH FANS

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Would this meet DEA's standard of non-retrievable?

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Final rule webpage: https://www.epa.gov/hwgenerators/final-rule-management-standards-hazardous-waste-pharmaceuticals-and-amendment-p075