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
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.
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)
I. 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 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
I. PHARMACEUTICALS FINAL RULE

2. REVERSE DISTRIBUTION & 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
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.
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)
I. PHARMACEUTICALS FINAL RULE

3. PART 266 SUBPART P
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
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
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
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.)
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
MOBILE BURN BARRELS WITH FANS
Would this meet DEA’s standard of non-retrievable?
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