

HAZARDOUS WASTE PHARMACEUTICALS & AMENDMENT TO THE NICOTINE LISTING (P075) FINAL RULE

NEWMOA CONFERENCE CALL

MAY 14, 2019

20-Minute Introduction to the Pharmaceuticals Rule

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OUTLINE

1. Effective Dates & State Adoption
2. Amendment of the Nicotine Listing
3. Reverse Distribution and Reverse Logistics
4. Part 266 Subpart P Provisions
 - Definitions
 - Applicability
 - Framework



EFFECTIVE DATES & STATE ADOPTION

SECTION II



EFFECTIVE DATES & STATE ADOPTION

- All parts of the rule are effective on August 21, 2019, but only in
 - Non-authorized states (Iowa, Alaska), Indian Country, US Territories (except Guam)
- Sewer prohibition (in Part 266 Subpart P)
 - Effective in **ALL** states on August 21, 2019 (HSWA authority)
 - Applies to **ALL** healthcare facilities and reverse distributors
- The rest of Part 266 Subpart P
 - Not effective in authorized states until state adopts
 - More stringent - all authorized states must adopt
 - Authorized states must adopt by July 1, 2021 or 2022
 - States that require a legislative session get an extra year
- Nicotine Amendment (in Part 261)
 - Not effective in authorized states until state adopts
 - Less stringent – authorized states are not required to adopt
 - No deadline to adopt

FEDERAL
EFFECTIVE DATE

2019

August 21



AMENDMENT OF NICOTINE LISTING

SECTION III



AMENDMENT OF THE NICOTINE LISTING

- The P075 listing for nicotine is being amended such that FDA-approved over-the-counter 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

NICOTINE UNDER THE PHARMACEUTICALS RULE

Forms of nicotine that are **exempt** from P075 listing:

- FDA-approved OTC NRTs (patches, gums & lozenges)

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Forms of P075 nicotine that are **pharmaceuticals** are regulated under Part 266 Subpart P:

- Prescription nicotine (i.e., inhaler, nasal spray)
- E-liquids packaged for retail use in ENDS (e.g., pre-filled liquid cartridges & vials sealed in final packaging that is sold or distributed to consumers)
- Finished product ENDS, including components & parts sealed in final packaging intended for consumer use (e.g., e-cigarettes or vaping pens)

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Forms of P075 nicotine that are **NOT pharmaceuticals** are regulated under Part 262:

- E-liquids used by manufacturers of tobacco products
- E-liquids sold or distributed for further manufacturing, mixing, or packaging into a finished electronic delivery system
- Legacy pesticides containing nicotine
- Nicotine used in research and manufacturing



REVERSE DISTRIBUTION & LOGISTICS

SECTION IV



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 LOGISTICS

NON-RX HW PHARMACEUTICALS & 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 & 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
- The preamble to the final rule reaffirms the same policy for all unsold retail items (other than prescription pharmaceuticals)

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 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



PART 266 SUBPART P

SECTION V



DEFINITION OF PHARMACEUTICAL

Pharmaceutical is a drug for use by humans or other animals and includes, but is not limited to:

- Dietary supplements
- Prescription drugs
- Over-the-counter drugs
- Homeopathic drugs
- Compounded drugs
- Investigational new drugs
- Pharmaceuticals remaining in non-empty containers
- PPE contaminated with pharmaceuticals
- Clean-up material from spills of pharmaceuticals

- Electronic nicotine delivery systems (ENDS) e.g. e-cigarettes, vaping pens
 - Nicotine e-liquid/e-juice packaged for retail sale for use in ENDS e.g. pre-filled cartridges or vials
-

Pharmaceutical does NOT include:

- Dental amalgam
- Sharps
- Medical waste

DEFINITION OF HEALTHCARE FACILITY (CONTINUED)

Healthcare Facility includes, but is not limited to:

- Wholesale distributors
 - Third-party logistics providers (3PLs) that serve as forward distributors
 - Military medical logistics facilities
 - Hospitals
 - Psychiatric hospitals
 - Ambulatory surgical centers
 - Health clinics
 - Physicians' offices
 - Optical and dental providers
 - Chiropractors
 - Long-term care facilities
- Ambulance services
 - Pharmacies
 - Long-term care pharmacies
 - Mail-order pharmacies
 - Retailers of pharmaceuticals (includes vape shops)
 - Veterinary clinics & hospitals
-

Healthcare Facility does NOT include:

- Pharmaceutical manufacturers
- Reverse distributors
- Reverse logistics centers

WASTE SPECIFIC & SECTOR SPECIFIC RULE

	Hazardous Waste Pharmaceuticals	Other Hazardous Wastes
Healthcare facilities & reverse distributors	Part 266 Subpart P	<ul style="list-style-type: none"> • Part 262 (e.g., lab waste) • Part 273 (universal waste) • Part 279 (used oil) • Etc.
Other facilities (e.g., farms/ranches, reverse logistics centers, manufacturers)	Part 262	<ul style="list-style-type: none"> • Part 262 • Part 273 (universal waste) • Part 279 (used oil) • Etc.

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 VSQG amounts of hazardous waste

GENERATOR CATEGORY & PHARMS RULE

Two provisions expected to affect generator category

1. PART 261: Nicotine patches, gums & lozenges are not hazardous waste
 - Some retailers have told us that they are LQGs only because of their nicotine hazardous waste
 - Some healthcare facilities may drop down in generator category now that nicotine patches, gums and lozenges are not considered hazardous waste

2. SUBPART P: Pharmaceuticals managed under Subpart P do not count toward determining a facility's Part 262 generator category
 - Some healthcare facilities that manage their pharmaceuticals under Subpart P may drop down in generator category for their non-pharmaceutical hazardous waste

FRAMEWORK OF PART 266 SUBPART P

	Standards for Healthcare Facilities	Standards for Reverse Distributors
	Potentially Creditable	Potentially Creditable
On-site accumulation	<ul style="list-style-type: none"> • No standards • No time limit 	Evaluate w/in 30 days
Shipping to a reverse distributor	<ul style="list-style-type: none"> • Confirmation of delivery • Common carrier 	<ul style="list-style-type: none"> • Confirmation of delivery • Common carrier
	Non-Creditable	Evaluated
On-site accumulation	<ul style="list-style-type: none"> • UW-like standards • 1 year maximum 	<ul style="list-style-type: none"> • LQG-like standards • 180 days after evaluation
Shipping to a TSDF	<ul style="list-style-type: none"> • Manifest (PHARMS) • HW transporter 	<ul style="list-style-type: none"> • Manifest (waste codes) • HW transporter

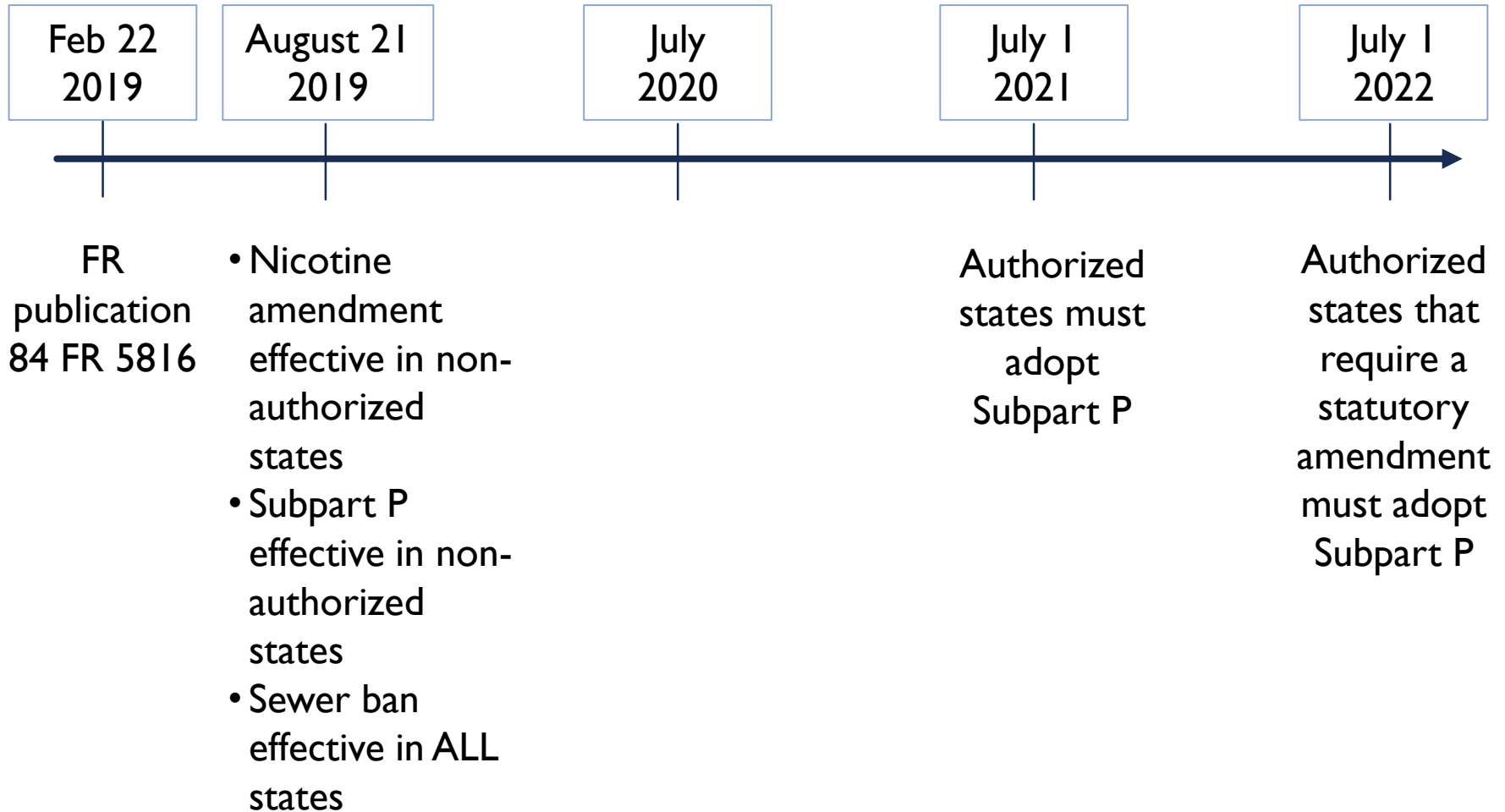


REMINDERS & WRAP-UP

SECTION VI



EFFECTIVE DATES & STATE ADOPTION TIMELINE



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