HAZARDOUS WASTE PHARMACEUTICALS RULE

NICOTINE AMENDMENT & SUBPART P

NJDEP COMPLIANCE SEMINAR
MAY 30, 2024

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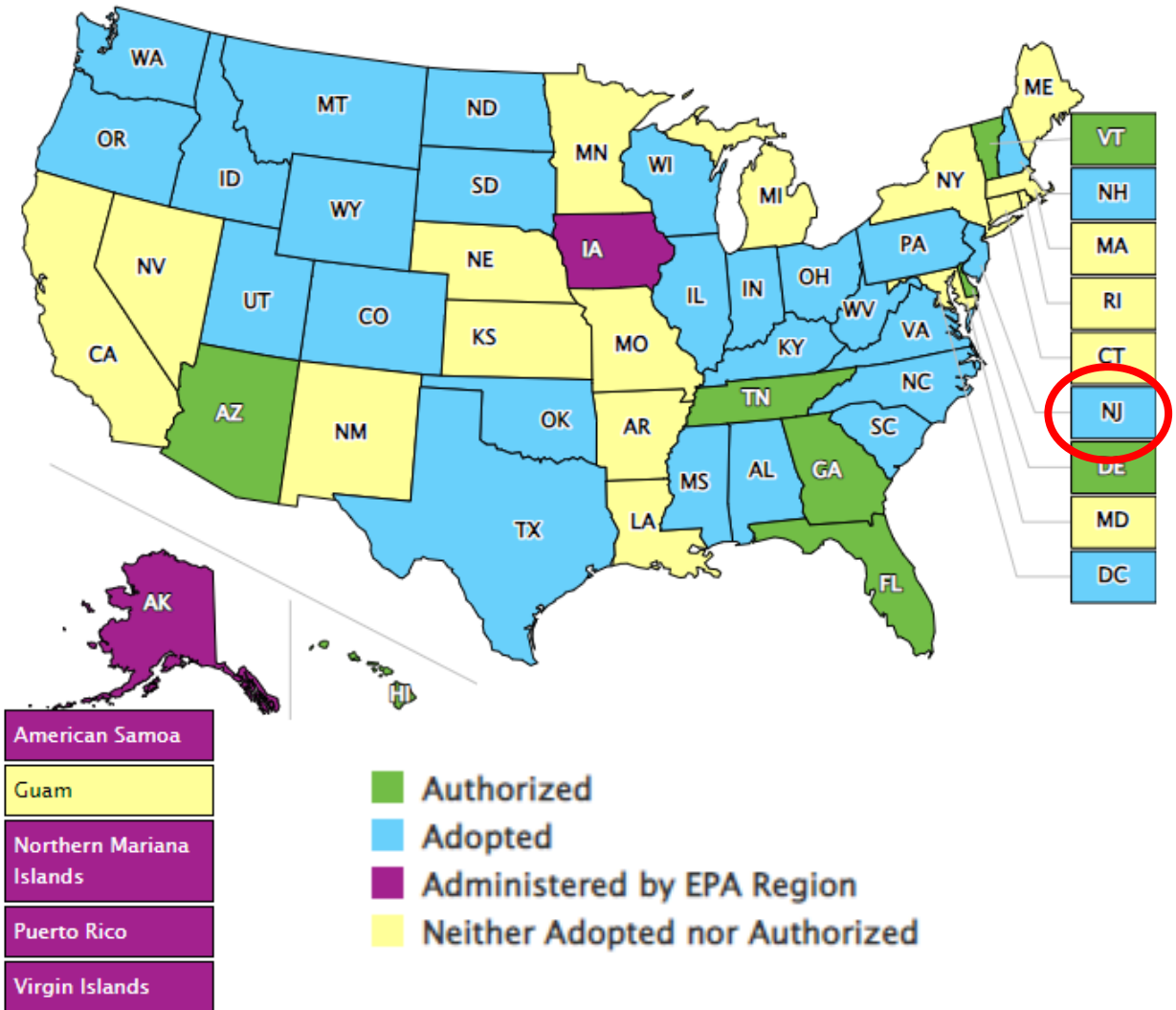
OUTLINE OF OVERVIEW

1. State Adoptions
2. 3 Elements of the HW Pharmaceuticals Rule
    1. Amendment of the Nicotine Listing in Part 261
    2. Reverse Distribution vs Reverse Logistics Policy
    3. Part 266 Subpart P

STATE ADOPTION OF PART 266 SUBPART P

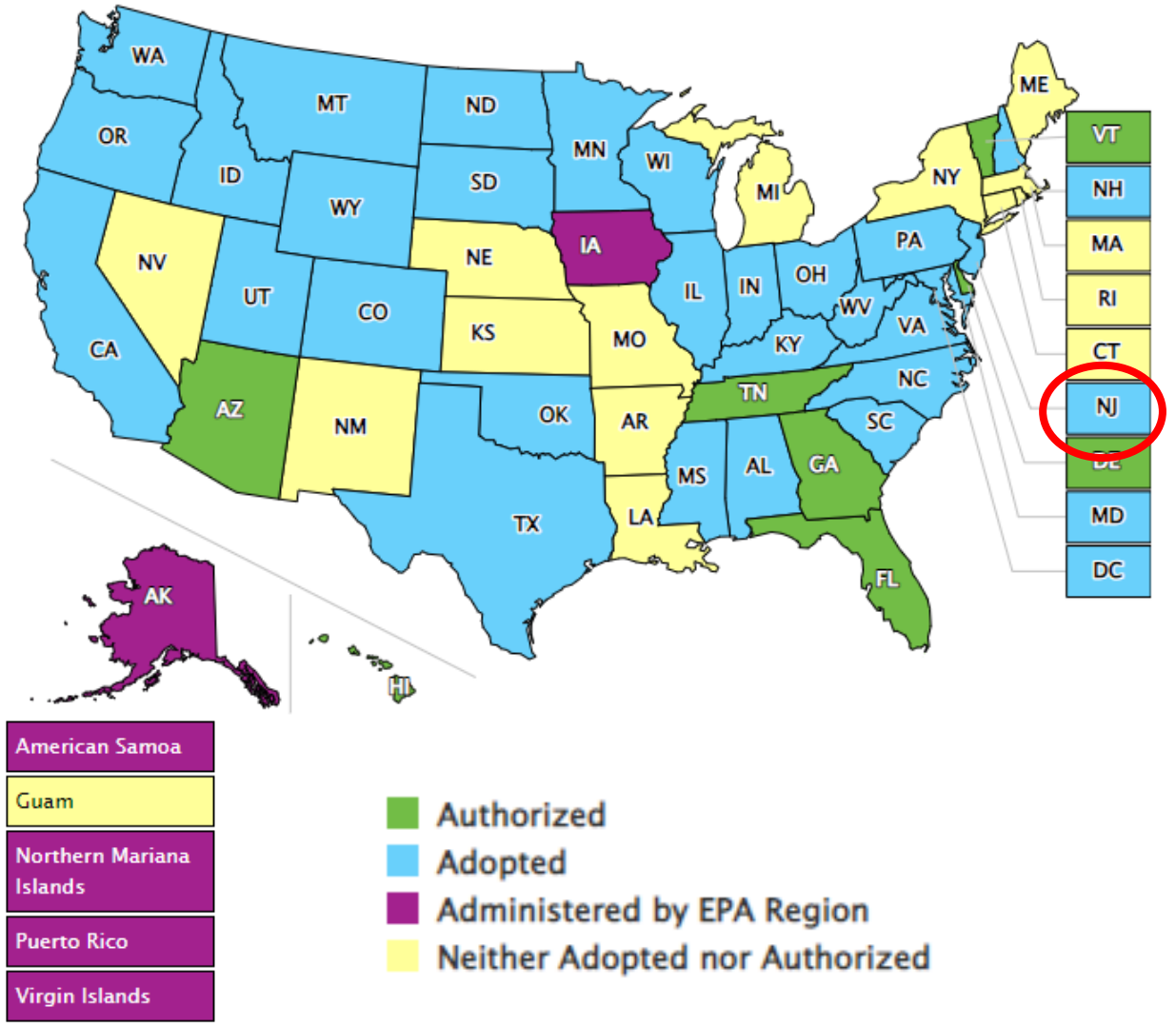
Effective in:
Indian country
4 Territories
35 States
(count includes DC)



As of Nov 14, 2023

STATE ADOPTION OF NICOTINE AMENDMENT

Effective in:
Indian country
4 Territories
38 States
(count includes DC)



As of Nov 14, 2023

AMENDMENT OF NICOTINE LISTING

SECTION II

AMENDMENT OF THE NICOTINE LISTING IN 261

- The P075 listing for nicotine was 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 <u>patches, gums and lozenges</u> 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

3 NICOTINE FAQS

Q1: Does the nicotine exemption for OTC NRTs apply to OTC NRT manufacturers?

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3 NICOTINE FAQS

Q1: Does the nicotine exemption for OTC NRTs apply to OTC NRT manufacturers?

A: Yes. The nicotine exemption for OTC NRTs applies to any generator of the discarded items in final dosage form. The listing for P075 under Part 261 has been amended. Therefore, the nicotine exemption for OTC NRTs applies to all generators, not just healthcare facilities and reverse distributors operating under Subpart P.

3 NICOTINE FAQS

Q2: Do OTC nicotine replacement therapies (i.e., patches, gums & lozenges) kept behind the pharmacy counter qualify for the nicotine exemption?

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3 NICOTINE FAQS

Q2: Do OTC nicotine replacement therapies (i.e., patches, gums & lozenges) kept behind the pharmacy counter qualify for the nicotine exemption?

A: Yes. The nicotine exemption applies to all FDA-approved OTC nicotine patches, gums & lozenges, regardless of where they are located within a healthcare facility, or if they are prescribed.

3 NICOTINE FAQS

Q3: Do VSQG healthcare facilities have to opt into subpart P to take advantage of the nicotine amendment?

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3 NICOTINE FAQS

Q3: Do VSQG healthcare facilities have to opt into subpart P to take advantage of the nicotine amendment?

A: No. The nicotine amendment was finalized at the same time as subpart P, but it is not part of subpart P. The nicotine exemption is available to all generators of FDA-approved OTC nicotine replacement therapy waste, not just healthcare facilities and reverse distributors.

REVERSE DISTRIBUTION & LOGISTICS

SECTION III

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

- Prescription pharmaceuticals at RDs are
  - Discarded and
  - Not reused, nor resold
- 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
- Subpart P is a regulatory system that is designed with existing business practices in mind for unused/expired prescription pharmaceuticals that are sent through reverse distribution

Reverse Distribution of Rx HW Pharmaceuticals

Reasonable Expectation of Receiving Manufacturer Credit

Healthcare Facility

1st Reverse Distributor

2nd Reverse Distributor

HW TSDF

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

- 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
- 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 Logistics of Unsold Retail Items & Non-Rx Pharms

Reasonable Expectation of Use/Reuse or Reclamation

Healthcare Facility

Reverse Logistics Center

Donate

Sell

Recycle

Repair

HW TSDF

PART 266 SUBPART P

SECTION IV

PRIOR TO SUBPART P

- The following terms did not appear in the RCRA regulations
  - Healthcare facility
  - Pharmaceutical
  - Reverse distributor
- Healthcare facilities and reverse distributors were regulated as hazardous waste generators under Part 262
  - Generator categories
  - Satellite accumulations areas
  - Central accumulation areas
- RCRA was a poor fit for the operations of this sector

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 a better fit for the management of hazardous waste pharmaceuticals at healthcare facilities and reverse distributors

WASTE SPECIFIC & SECTOR SPECIFIC RULE

	Hazardous Waste Pharmaceuticals	Other Hazardous Wastes
Healthcare facilities & reverse distributors	Part 266 Subpart P	• 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	• Part 262 • Part 273 (universal waste) • Part 279 (used oil) • Etc.

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PART 266 SUBPART P APPLICABILITY

- Part 266 Subpart P is considered more stringent, and therefore is NOT optional for
  - Authorized 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
    - IF healthcare facility generates above VSQG amounts of hazardous waste
    - We estimate that ≈ 80% of healthcare facilities are VSQGs

DOES SUBPART P APPLY TO MY RD?

Ask yourself a series of questions:

WHO You Are:

- Is my facility a reverse distributor?

WHAT You Have:

- Does my facility have pharmaceuticals?
- When discarded, are they hazardous waste pharmaceuticals?
  - Listed
  - Characteristic
  - NIOSH

DOES SUBPART P APPLY TO MY HCF?

Ask yourself a series of questions:

WHO You Are:

- Is my facility a healthcare facility?

WHAT You Have:

- Does my healthcare facility have pharmaceuticals?
- When discarded, are they hazardous waste pharmaceuticals?
  - Listed
  - Characteristic
  - NIOSH

HOW MUCH

- Does my healthcare facility generate more than VSQG amounts of hazardous waste per month?

BENEFITS OF OPTING INTO SUBPART P?

- Once operating under Part 266 Subpart P
  - There are NO generator categories under Part 266 Subpart P
  - All healthcare facilities are regulated the same for their hazardous waste pharmaceuticals
  - Healthcare facilities operating under Subpart P do not have to count their hazardous waste pharmaceuticals when determining generator category

BENEFITS OF OPTING INTO SUBPART P?

- What does this mean on a practical level?
  - Provides an incentive to over-manage non-hazardous pharmaceuticals as hazardous, without having to worry about bumping up generator category & incurring additional regulations
  - Do not have to keep track of how much hazardous waste pharmaceuticals you generate on a monthly basis
  - Do not have to segregate your P-listed hazardous waste pharmaceuticals from other hazardous waste pharmaceuticals
  - Same training at every facility
  - Could reduce your generator category for non-pharmaceutical hazardous waste

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TYPES OF HAZ WASTE PHARMACEUTICALS

There are 3 types of *Hazardous Waste Pharmaceuticals:*

1. Non-creditable hazardous waste pharmaceutical
2. Potentially creditable hazardous waste pharmaceutical
3. Evaluated hazardous waste pharmaceutical

3 Types of HW Pharmaceuticals

2. Potentially Creditable HW Pharmaceuticals

1. Non-creditable HW Pharmaceuticals

1st Reverse Distributor

Healthcare Facility

3. Evaluated HW Pharmaceuticals

2nd Reverse Distributor

HW TSDF

3 Types of HW Pharmaceuticals

Healthcare Facility

1. Non-creditable HW Pharmaceuticals

- Broken or leaking
- Repackaged
- Dispensed
- Expired >1 yr
- Investigational new drugs
- Contaminated PPE
- Floor sweepings
- Clean-up material

HW TSDF

3 Types of HW Pharmaceuticals

1st Reverse Distributor

2. Potentially Creditable HW Pharmaceuticals

- Original manufacturer packaging (except recalls)
- Undispensed
- Unexpired or less than 1-yr past expiration
- Reasonable expectation of receiving manufacturer credit

Healthcare Facility

1. Non-creditable HW Pharmaceuticals

2. Potentially Creditable

2nd Reverse Distributor

HW TSDF

3 Types of HW Pharmaceuticals

1st Reverse Distributor

2. Potentially Creditable HW Pharmaceuticals

Healthcare Facility

1. Non-creditable HW Pharmaceuticals

2. Potentially Creditable

2nd Reverse Distributor

3. Evaluated HW Pharmaceuticals

No further evaluation or verification of manufacturer credit is necessary

HW TSDF

3 Types of HW Pharmaceuticals

1st Reverse Distributor

2. Potentially Creditable

Healthcare Facility

1. Non-Creditable

"Universal Waste Plus"

2. Potentially Creditable

2nd Reverse Distributor

3. Evaluated

HW TSDF

3 Types of HW Pharmaceuticals

1st Reverse Distributor

2. Potentially Creditable

Tracking of Shipments Required

Healthcare Facility

1. Non-Creditable

"Universal Waste Plus"

2. Potentially Creditable

Tracking of Shipments Required

2nd Reverse Distributor

3. Evaluated

HW TSDF

3 Types of HW Pharmaceuticals

1st Reverse Distributor

2. Potentially Creditable

Tracking of Shipments Required

Healthcare Facility

1. Non-Creditable

"Universal Waste Plus"

2. Potentially Creditable

Tracking of Shipments Required

2nd Reverse Distributor

3. Evaluated

"LQG Plus"

HW TSDF

HEALTHCARE FACILITY STANDARDS

- Standards that apply to the healthcare facility
  - One-time notification as a healthcare facility
  - Training of healthcare personnel
  - Hazardous waste determinations
- Other standards apply to the waste and differ depending on the type of hazardous waste pharmaceuticals
  - Non-creditable hazardous waste pharmaceuticals
  - Potentially creditable hazardous waste pharmaceuticals

Healthcare Facility Standards

	Non-creditable HW Pharms	Potentially creditable HW Pharms
Container Standards	• Security • Compatibility	None
Labeling	• "Hazardous Waste Pharmaceuticals" • Hazardous waste codes allowed but not required	None
Maximum Accumulation Time	One year	None
Over-managing non-hazardous pharmaceuticals & commingling with hazardous pharmaceuticals	Allowed	Allowed
Include hazardous waste pharmaceuticals on BR	No	No

Shipments of HW Pharmaceuticals

1st Reverse Distributor

2. Potentially Creditable

Healthcare Facility

2. Potentially Creditable

- Common carrier
- Delivery confirmation

1. Non-Creditable

- HW Transporter
- Manifest
- PHRM/PHARMS code

2nd Reverse Distributor

3. Evaluated

- HW Transporter
- Manifest
- HW codes

HW TSDF

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ROLE OF REVERSE DISTRIBUTOR

- Reverse distributors are middlemen that provide manufacturer credit to healthcare facilities for unsold pharmaceuticals
- Under Subpart P, a reverse distributor is a new type of hazardous waste management facility that can accept hazardous waste from off-site
  - Can accept only hazardous waste that is "potentially creditable hazardous waste pharmaceutical" that has a reasonable expectation of receiving manufacturer credit
  - Can not accept other hazardous waste, including other types of hazardous waste pharmaceuticals
  - No RCRA storage permit required
  - Must comply with new regulations that are similar to LQG regulations, with some additions
  - All reverse distributors are regulated the same for hazardous waste pharmaceuticals (no VSQG, SQG, LQG categories)

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REVERSE DISTRIBUTOR STANDARDS

- Standards that apply to the reverse distributor
  - One-time notification as a reverse distributor
  - Inventory of hazardous waste pharmaceuticals
  - Security requirements
  - Contingency plan
  - Closure
- Other standards apply to the waste and differ depending on the type of hazardous waste pharmaceuticals
  - Potentially creditable hazardous waste pharmaceuticals
  - Evaluated hazardous waste pharmaceuticals

FLOW OF HW PHARMACEUTICALS

HCF/Pharmacy

- 30 days to evaluate after arrival at each RD
- 180 days after evaluation allowed at each RD
- 210 days total allowed at each RD

1st RD can be a manufacturer

2nd RD can be a manufacturer

3rd RD must be a manufacturer

HW TSDF

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REVERSE DISTRIBUTOR STANDARDS

	Potentially Creditable HW Pharms	Evaluated HW Pharms
Training	None	• LQG personnel training
Labeling	None	• Hazardous waste pharmaceutical • Hazardous waste codes required prior to shipment off-site
Container Standards	None	• Good condition • Prevent leaks
Accumulation Area	None	• Conduct weekly inspections of accumulation area
Maximum Evaluation or Accumulation Time	30 days for evaluation	• 180 days for accumulation
Include hazardous waste pharmaceuticals on BR	No	Yes

QUESTIONS?

SIX TOPICS

1. What is a pharmaceutical?
2. What is a healthcare facility?
3. What can go to a reverse distributor
4. Sewer Ban
5. Sequestration devices
6. 10-Step Blueprint

WHAT IS A PHARMACEUTICAL

TOPIC #1

OUTLINE

- Definition of a pharmaceutical
- NIOSH hazardous drugs

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DEFINITION OF PHARMACEUTICAL

Pharmaceutical includes, but is not limited to:

- Dietary supplements, includes vitamins
- 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

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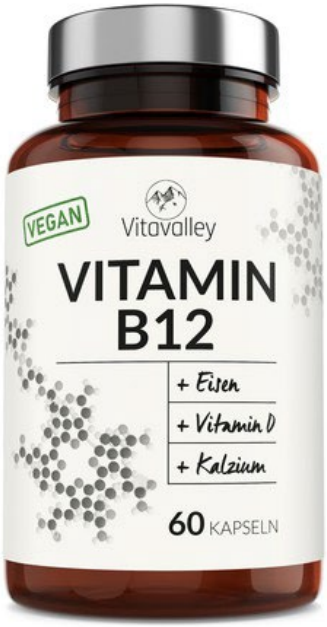
IS THIS A PHARMACEUTICAL?



Supplement Facts

Serving Size 1 Tablet

Amount Per Serving		% Daily Value for Children Under 4 Years of Age	% Daily Value for Adults and Children 4 or more Years of Age
Calories	5		
Total Carbohydrate	1 g	†	< 1%*
Sugars	1 g	†	†
Vitamin A (50% as beta-carotene)	2500 IU	100%	50%
Vitamin C	40 mg	100%	67%
Vitamin D	400 IU	100%	100%
Vitamin E	15 IU	150%	50%
Thiamin	1.1 mg	157%	73%
Riboflavin	1.2 mg	150%	71%
Niacin	14 mg	156%	70%
Vitamin B_6	1.1 mg	157%	55%
Folate	300 mcg	150%	75%
Vitamin B_{12}	5 mcg	167%	83%

* Percent Daily Values are based on a 2,000 calorie diet.
† Daily Value not established.

Other ingredients: Sucrose, sodium ascorbate, stearic acid, gelatin, maltodextrins, artificial flavors, dl-alpha tocopheryl acetate, niacinamide, magnesium stearate, Yellow 6, artificial colors, stearic acid, palmitic acid, pyridoxine hydrochloride, thiamin mononitrate, vitamin A acetate, beta-carotene, folic acid, cholecalciferol, and cyanocobalamin.

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IS THIS A PHARMACEUTICAL?

§ 266.500

IS THIS A PHARMACEUTICAL?

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IS THIS A PHARMACEUTICAL?

Purell®

Professional
Advanced Hand Sanitizer Gel

Drug Facts

Active ingredient — **Purpose**
Ethyl alcohol 70% v/v ..... Antimicrobial

Use Hand sanitizer to help reduce bacteria on the skin

Warnings **Flammable. Keep away from fire or flame.**

For external use only

When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash appears and lasts

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

US Patent # 8,402,393 DSP-DH-36
Kills 99.99% of most common germs

Drug Facts (continued)

Directions
• Place product on hands • Rub until dry

Inactive ingredients
Water (Aqua), Isopropyl Alcohol, Caprylyl Glycol, Glycerin, Isopropyl Myristate, Tocopheryl Acetate, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aminomethyl Propanol, Fragrance (Parfum)

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IS THIS A PHARMACEUTICAL?

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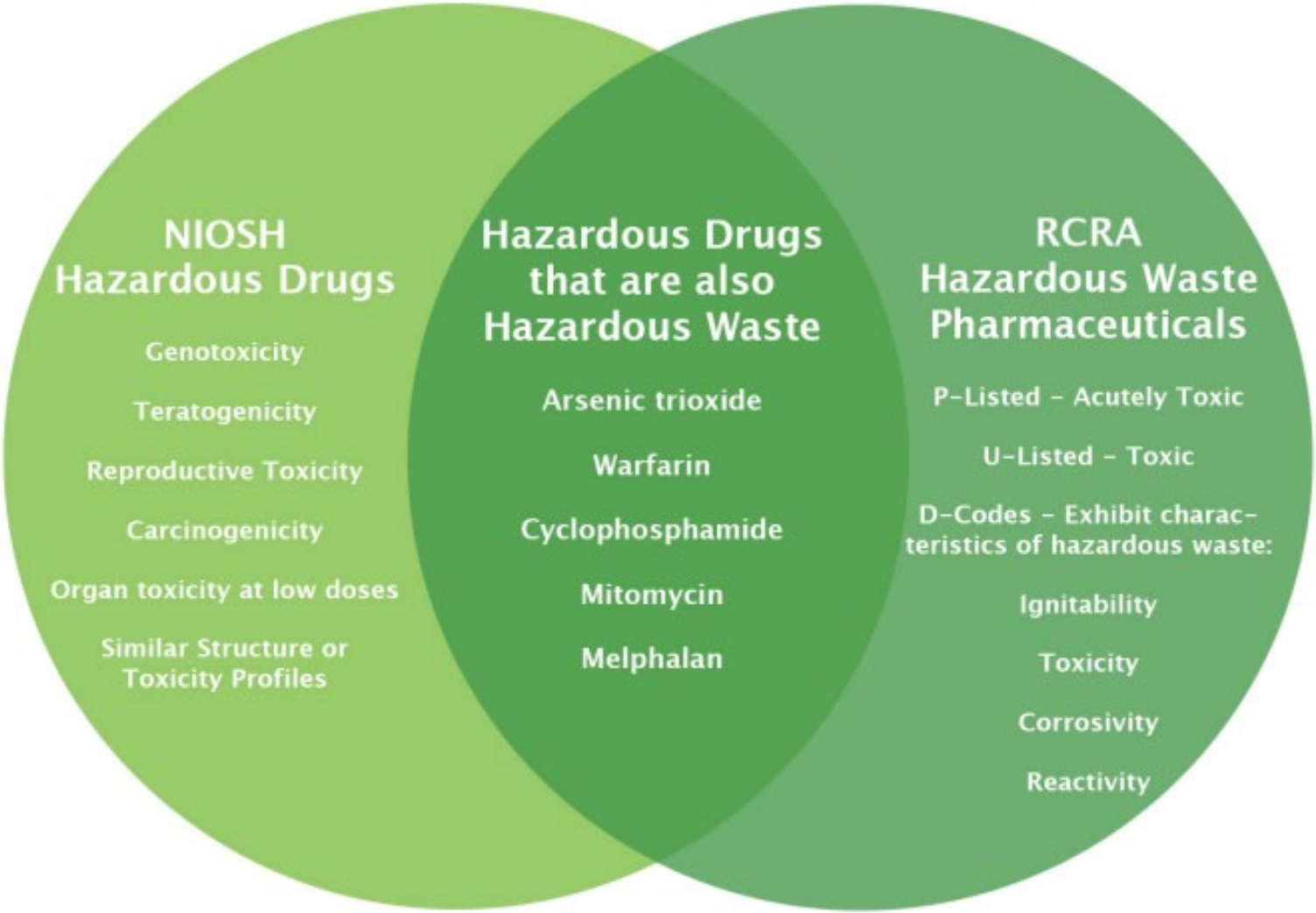
IS THIS A PHARMACEUTICAL?

FAQ re: diagnostic kits:
https://www.epa.gov/hwgenerators/frequent-questions-about-management-standards-hazardous-waste-pharmaceuticals-and#b14

HAZARDOUS DRUG VS HAZARDOUS WASTE

- National Institute of Occupational Safety & Health (NIOSH) is part of the Center for Disease Control (CDC)
- NIOSH developed/update a list of "hazardous drugs"
- NIOSH is not a regulatory body
- The hazardous drugs list get incorporated into regulations and standards of other organizations
  - OSHA Guidelines for Occupational Exposure to Handling Hazardous Drugs
  - US Pharmacopeia Chapter <800> Handling of Hazardous Drugs

HAZARDOUS DRUG VS HAZARDOUS WASTE



HAZARDOUS DRUG VS HAZARDOUS WASTE

- 2016 NIOSH hazardous drug list
  - Table 1 lists >100 antineoplastic/chemo drugs
  - Table 2 lists > 50 non-antineoplastic drugs
  - Table 3 lists >50 drugs with reproductive hazards
- RCRA hazardous wastes on NIOSH Table 1
  - 7 P- and U-listed older chemo drugs
  - 1 chemo drug that is TC for mercury (D009)
  - 9 chemo drugs that are ignitable (D001)
- EPA recommends managing as RCRA hazardous waste all the antineoplastic/chemo drugs on NIOSH hazardous drugs on Table 1
- 2020 NIOSH hazardous drug draft list is still pending

CHEMO & TRACE CHEMO

- Trace chemo refers to the paraphernalia associated with antineoplastic chemo drugs, such as
  - Empty vials
  - Empty syringes
  - Empty IV bags
  - Wipes
  - PPE, such as gloves and gowns
- EPA recommends managing trace chemo in yellow bins which is incinerated at a hospital, medical and infectious waste incinerator (HMIWI)

WHAT IS A HEALTHCARE FACILITY?

TOPIC #2

§ 266.500

DEFINITION OF HEALTHCARE FACILITY

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
- Co-located healthcare facilities (e.g. clinic at a manufacturer)

Healthcare Facility does NOT include:

- Pharmaceutical manufacturers
- Reverse distributors
- Reverse logistics centers

3 HEALTHCARE FACILITY FAQS

Q1: Is a vape shop a healthcare facility under Subpart P?

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3 HEALTHCARE FACILITY FAQS

Q1: Is a vape shop a healthcare facility under Subpart P?

A: Yes. A retailer selling pharmaceuticals is a healthcare facility. And the definition of pharmaceutical includes:

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

3 HEALTHCARE FACILITY FAQS

Q2: My healthcare facility is a VSQG. Am I required to operate under Subpart P?

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3 HEALTHCARE FACILITY FAQS

Q2: My healthcare facility is a VSQG. Am I required to operate under Subpart P?

A: No. All healthcare facilities generating more than VSQG amounts of hazardous waste must operate under Subpart P. But VSQG healthcare facilities have the choice of opting into Subpart P.

3 HEALTHCARE FACILITY FAQS

Q3: Is a clinic at a school or manufacturer a healthcare facility?

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3 HEALTHCARE FACILITY FAQS

Q3: Is a clinic that is at a school or manufacturer considered a healthcare facility?

A: Yes. We refer to this type of healthcare facility as a "co-located" healthcare facility.

If the entire facility generates above VSQG amounts of hazardous waste, then the healthcare facility must operate under Subpart P for the management of its hazardous waste pharmaceuticals.

WHAT CAN GO TO A REVERSE DISTRIBUTOR?

TOPIC #3

WHAT PHARMACEUTICALS CAN GO TO AN RD?

- Potentially creditable hazardous waste pharmaceuticals
  - Reasonable expectation of receiving manufacturer credit
  - In original manufacture packaging
  - Not dispensed to a patient
  - Unexpired or < 1year past expiration
- Examples that might surprise you
  - Generics can sometimes get manufacturer credit
  - Partials can sometimes get manufacturer credit

WHY RELY ON MANUFACTURER CREDIT?

- Manufacturers determine which pharmaceuticals get credit and which do not
  - Manufacturer policies can vary between customers
  - Manufacturer policies can change over time
  - But there are some fixed criteria
- Definition of potentially creditable hazardous waste pharmaceutical is based on manufacturers' criteria
- The VALUE in the form of manufacturer credit
  - Creates an incentive to manage the pharmaceuticals carefully
  - Allows EPA to take a lighter regulatory touch
- Remember reverse distributors are not required to have permits, so we have to limit what they can accept to ensure they do not become de facto TSDFs

WHAT PHARMACEUTICALS CAN GO TO AN RD?

From the preamble of the final rule (page 5846):

> "…we added the phrase ''reasonable expectation'' to clarify that the healthcare facility does not have to definitively know whether something will receive manufacturer credit but rather indicates that they should have a reasonable expectation that it will." (emphasis added)

WHAT PHARMACEUTICALS CAN **NOT** GO TO AN RD?

- Containers that are leaking or damaged (although secondary packaging may be damaged)
- Drugs that are dispensed to a patient but the patient refuses to take
- Free samples
- Floor sweepings ("skittles")
- Repackaged drugs (unless recalled)
- Items that you know from experience never receive credit
- Clean-up material from pharmaceutical spills
- Investigational drugs
- PPE contaminated with hazardous waste pharmaceuticals
- Medical waste & sharps
- Other hazardous wastes from your healthcare facility (e.g., lab chemicals, cleaning solutions)

Copied from DEA's list of Reverse Distributors

OHIO
- Achieva Group Returns, Inc. – (513) 474-9900
- Environmental Enterprises Inc. – (513) 541-1823 (Collector)
- Flash Returns – (334) 804-4826
- Heritage Thermal Services Inc. – (330) 385-7336
- Stericycle Inc. – (317) 860-1175 (Collector)

OKLAHOMA
- Total Returns – (580) 276-3056

PENNSYLVANIA
- Chesapeake Waste Solutions – (717) 653-8882
- Complete RX Returns DBA CRX – (570) 706-9589
- Pharmareturns – (215) 653-7400 ext. 114
- Republic Environmental Systems (Pennsylvania), LLC - Stericycle Environmental Solutions – (215) 822-8995 ext. 111
- Specialty Disposal Services Inc. SDS – (973) 402-9246

TENNESSEE
- Clean Harbors Tennessee LLC – (615) 643-3177 ext. 3177
- Pharma-Mate Inc D/B/A Returnco – (706) 250-4831 (Collector)
- Reliable Pharmaceutical Returns, LLC – (615) 361-8856 (Collector)
- Return Solutions – (865) 675-1355 (Collector)

TEXAS
- Med-Turn, Inc. – (817) 868-5300 (Collector)
- Philip Reclamation Services-Stericycle Environmental Solutions, Inc. – (713) 679-2300
- Sharps Compliance, Inc. – (903) 693-2525 (Collector)
- U.S. Ecology Texas, Inc – (361) 387-3518 ext 2257
- Veolia ES Technical Solutions, L.L.C. – (409) 736-2821 (Collector)

UTAH
- Clean Harbors Aragonite – (435) 884-8100
- National Products Sales, Pharmaceutical Division – (801) 972-4132

WASHINGTON
- P.S. Industries Inc. – (206) 749-0739

WISCONSIN
- Veolia ES Technical Solutions, L.L.C. – (262) 255-6655

January 2019

This list of reverse distributors does not constitute an endorsement by the DEA of these companies or their produ

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EPA VS DEA REVERSE DISTRIBUTOR

IF

Issuing Manufacturer Credit Only

- DEA registrant
- DEA Reverse Distributor
- EPA/RCRA Reverse Distributor

IF

Destroying (Treating) Pharmaceuticals

- DEA registrant
- DEA Reverse Distributor
- EPA/RCRA TSDF

NEW JERSEY REVERSE DISTRIBUTORS

List of Subpart P RDs in NJ – as of April 2024

NEW JERSEY	
Handler ID	**Handler Name**
NJR000084566	RX MAX RETURNS & INVENTORY SERVICES LLC
NJR000083840	ADVANCED RX RETURNS
NJR986649093	NOVARTIS PHARMACEUTICALS CORP
NJR000089805	RELIABLE HEALTHCARE LOGISTICS, LLC

List of DEA RDs in NJ – as of 2020

NEW JERSEY

Advanced RX Returns D/B/A Omega 2000 RX Returns
Sharps Assure –

REVERSE DISTRIBUTOR FAQ

Q1: I am a small reverse distributor that is a VSQG. Am I required to operate under Subpart P?

REVERSE DISTRIBUTOR FAQ

Q1: I am a small reverse distributor that is a VSQG. Am I required to operate under Subpart P?

A: Yes. All reverse distributors must operate under Subpart P for the management of their hazardous waste pharmaceuticals.

REVERSE DISTRIBUTOR FAQ

Q2: Can an OTC be sent to a reverse distributor?

REVERSE DISTRIBUTOR FAQ

Q2: Can an OTC be sent to a reverse distributor?

A: Yes. An OTC may be sent to a reverse distributor. Since there is no reasonable expectation of use/reuse, it is a solid waste. It must:

1. have a reasonable expectation of receiving manufacturer credit
2. be in original manufacture packaging
3. be undispensed
4. be unexpired or less than one year past expiration and
5. be managed as a potentially creditable hazardous waste pharmaceutical under Part 266 Subpart P

SEWER BAN

TOPIC #4

§ 266.505

SEWER PROHIBITION

- Hazardous waste pharmaceuticals may not be sewered (e.g., no disposal down the drain and no flushing)
- Will prevent **1600 - 2300 tons** of hazardous waste pharmaceuticals from being sewered annually
- The sewer prohibition applies to
  - All healthcare facilities, including healthcare facilities that are VSQGs
  - All reverse distributors

§ 266.505

SEWER PROHIBITION

- Hazardous wastes that are DEA controlled substances are also subject to the sewer prohibition
- We strongly discourage sewering of any pharmaceuticals by any entity
- NOTE: The sewer prohibition became **effective in ALL states on August 21, 2019 -** regardless of whether
  - The state is authorized to implement RCRA or
  - The state has adopted Subpart P or
  - A VSQG healthcare facility has opted into Subpart P

WHAT CAN BE SEWERED AT A HOSPITAL?

Q: EPA discourages sewering of any pharmaceuticals in any setting? Are there exceptions?

WHAT CAN BE SEWERED AT A HOSPITAL?

Q: EPA says they discourage sewering of any pharmaceuticals in any setting? Are there exceptions?

A. Yes. EPA does not object to the following being sewered

- Saline (0.9% sodium chloride)
- Lactated Ringers (sodium chloride, sodium lactate, potassium chloride, and calcium chloride)
- Sterile water

SEQUESTRATION UNITS

TOPIC #8

DRUG "TREATMENT" SYSTEMS

- There are many brands of "drug treatment" or "drug sequestration" or "drug disposal" devices in use at hospitals
- Name some brands you have heard of

DRUG "TREATMENT" SYSTEMS

- There are many brands of "drug treatment" or "drug sequestration" or "drug disposal" devices in use at hospitals
- Name some brands you have heard of
  1. Cactus sink
  2. DeTerra
  3. CsRx
  4. Rx Carbon
  5. Rx Destroyer
  6. Rx Gon
  7. NarcX
  8. SafeMedWaste

DRUG "TREATMENT" SYSTEMS

- These units are usually used to collect DEA controlled substances:
  - Use only for disposing "pharmaceutical wastage" of controlled substances
    - Pharmaceutical wastage is leftover medicine that has been dispensed but not fully administered to a patient
    - Pharmaceutical wastage does not have to meet DEA's non-retrievable standard of destruction
  - Do NOT use units for disposing **inventory** of controlled substances
- What is put into the sequestration unit will dictate how it must be managed when discarded

3 TYPES OF PHARMACEUTICAL WASTAGE

DEA Controlled Substance (e.g, codeine)	DEA + RCRA (e.g., diazepam)	RCRA Hazardous Waste (e.g., warfarin)

Inclusion of product does not constitute an endorsement

HW THAT ARE ALSO DEA CONTROLLED SUBSTANCES

Name of Drug	Other Name(s)	Medical Uses	RCRA HW Code	DEA CS Schedule
Chloral/ Chloral hydrate	Acetaldehyde, trichloro; Aquachloral Noctec, Somnote, Supprettes	Sedative	U034 Toxic	IV
Fentanyl sublingual spray	Subsys	Analgesic	D001 ignitable	II
~~Phenobarbital~~	~~Bellergal-S Donnatal Luminal~~	~~Anticonvulsant~~	~~D001 ignitable~~	~~IV~~
Testosterone gels/solutions	Androgel Axiron Fortesta, Testim	Hormone	D001 ignitable	III
Valium injectable/gel	Diazepam Diastat	Anti-anxiety	D001 ignitable	IV

3 TYPES OF PHARMACEUTICAL WASTAGE

DEA Controlled Substance (e.g, codeine)	DEA + RCRA (e.g., diazepam)	RCRA Hazardous Waste (e.g., warfarin)

- Regulated by DEA
- Not regulated as RCRA HW

3 TYPES OF PHARMACEUTICAL WASTAGE

DEA
Controlled
Substance
(e.g, codeine)

- Regulated by DEA
- Not regulated as RCRA HW

DEA
+
RCRA
(e.g., diazepam)

- Regulated by DEA
- Conditionally exempt from RCRA

RCRA
Hazardous
Waste
(e.g., warfarin)

3 TYPES OF PHARMACEUTICAL WASTAGE

DEA Controlled Substance (e.g, codeine)	DEA + RCRA (e.g., diazepam)	RCRA Hazardous Waste (e.g., warfarin)
• Regulated by DEA • Not regulated as RCRA HW	• Regulated by DEA • Conditionally exempt from RCRA	• Not regulated by DEA • Fully regulated as RCRA HW

DRUG "TREATMENT" SYSTEMS

- EPA's recommendation is to take a conservative approach
  - Odds are these units also have RCRA hazardous waste pharmaceuticals in them
  - Thus under Subpart P, these units would be considered hazardous waste pharmaceutical accumulation containers
  - The land disposal restriction (LDR) treatment standard for most hazardous waste pharmaceuticals is combustion
  - Therefore, the units must be sent to a hazardous waste combustor in order to comply with the LDRs

LEAST LIKELY SCENARIO

DEA
Controlled
Substance
(e.g, codeine)

LEAST LIKELY SCENARIO

DEA Controlled Substance (e.g, codeine)

Not regulated as RCRA hazardous waste

- Non-hazardous incineration recommended

UNLIKELY SCENARIO

DEA
Controlled
Substance
(e.g, codeine)

DEA
+
RCRA
(e.g., diazepam)

UNLIKELY SCENARIO

DEA
Controlled
Substance
(e.g, codeine)

DEA
+
RCRA
(e.g., diazepam)

Conditionally exempt from RCRA. Must be incinerated

- HW incinerator
- MW combustor
- HMIWI
- CISWI

MOST LIKELY SCENARIO

DEA
Controlled
Substance
(e.g, codeine)

DEA
+
RCRA
(e.g., diazepam)

RCRA
Hazardous
Waste
(e.g., warfarin)

MOST LIKELY SCENARIO

DEA
Controlled
Substance
(e.g, codeine)

DEA
+
RCRA
(e.g., diazepam)

RCRA
Hazardous
Waste
(e.g., warfarin)

Fully regulated hazardous waste

- Hazardous incineration required

DRUG "TREATMENT" SYSTEMS

- EPA's recommendation is to take a conservative approach
  - Odds are these units also have RCRA hazardous waste pharmaceuticals in them
  - Thus, under Subpart P, these units would be considered hazardous waste pharmaceutical accumulation containers
  - The land disposal restriction (LDR) treatment standard for most hazardous waste pharmaceuticals is combustion
  - Therefore, the units must be sent to a hazardous waste combustor in order to comply with the LDRs

10-STEP BLUEPRINT UPDATE

TOPIC #9

UPDATED IN 2022

- To help hospitals comply with RCRA
- Provides different strategies for compliance
- Updated to reflect
  - New EPA regulations
  - New DEA regulations
  - NIOSH 2020 draft list
  - DOT regulations

OVERVIEW OF 10-STEP BLUEPRINT

- Explains the RCRA Subpart P regulations in depth
- Explains differences between RCRA hazardous waste and
  - NIOSH hazardous drugs
  - DOT hazardous materials
- Recognizes that there is not one solution that will work for all healthcare facilities
- Provides options for how to comply with the RCRA regulations, depending on how the healthcare facility operates
  - Do you prefer to have different processes for pharmacy and nursing?
  - Do you prefer to have the same processes for everyone?

OTHER RESOURCES

- Final rule webpage: https://www.epa.gov/hwgenerators/final-rule-management-standards-hazardous-waste-pharmaceuticals-and-amendment-p075
- General pharms waste management webpage with resources: https://www.epa.gov/hwgenerators/management-hazardous-waste-pharmaceuticals
- Frequent Questions about the Pharms Rule: https://www.epa.gov/hwgenerators/frequent-questions-about-management-standards-hazardous-waste-pharmaceuticals-and
- Map of where the Pharms Rule is in effect: https://www.epa.gov/hwgenerators/where-are-management-standards-hazardous-waste-pharmaceuticals-and-amendment-p075

QUESTIONS?

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