

HAZARDOUS WASTE PHARMACEUTICALS FINAL RULE

NEWMOA WEBINAR

JUNE 9, 2020

Reverse Distribution & Reverse Logistics

Kristin Fitzgerald, EPA HQ
Brian Knieser, EPA HQ



OUTLINE

1. Reverse Distribution
2. Reverse Distributors in NEWMOA states
3. Reverse Logistics
4. FAQs re: Reverse Distribution
5. Unauthorized Waste Reports
6. State Adoption Maps



REVERSE DISTRIBUTION & 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

Reverse
Distribution

Rx
Pharmaceuticals

REVERSE LOGISTICS

Reverse
Logistics

Everything
Else

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

Reverse Distribution of Rx HW Pharmaceuticals

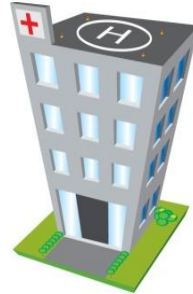
**Reasonable Expectation of
Receiving Manufacturer Credit**



**1st Reverse
Distributor**



**2nd Reverse
Distributor**



**Healthcare
Facility**

**No Reasonable Expectation of
Receiving Manufacturer Credit**



**HW
TSDF**



WHAT IS A REVERSE DISTRIBUTOR?

- Reverse distributors are middlemen that provide manufacturer credit to healthcare facilities for unsold prescription 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
 - No treatment allowed
 - 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)

DEFINITION OF REVERSE DISTRIBUTOR

Reverse Distributor means

- Any person that receives and accumulates prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer credit
- Any person, including forward distributors, third-party logistics providers, and pharmaceutical manufacturers, that processes prescription pharmaceuticals for the facilitation or verification of manufacturer credit is considered a reverse distributor

EPA VS DEA REVERSE DISTRIBUTOR

Issuing Manufacturer Credit Only

- DEA registrant
- DEA Reverse Distributor
- RCRA Reverse Distributor

Destroying (Treating) Pharmaceuticals

- DEA registrant
- DEA Reverse Distributor
- RCRA TSDF

REVERSE DISTRIBUTORS IN NEWMOA STATES

- DEA has a list of all of their registered reverse distributors
- Many, but not all, of the DEA reverse distributors are RCRA reverse distributors
- Let's look at the DEA reverse distributors in NEWMOA states and determine which are
 - RCRA reverse distributors
 - RCRA TSDFs

DEA Registered Reverse Distributors



ARIZONA

Covanta Environmental Solutions, LLC DBA Environmental Pharmaceuticals, LLC – (480) 659-9611 ext. 203 (Collector)

ARKANSAS

Arkansas Redistributors, LLC - (501)904-2929

CALIFORNIA

Aemerge Redpak Services Southern California, LLC - (760) 983-2808

Far West Returns – (916) 524-6465

Outdate RX, LLC – (916) 524-6465 or (909) 335-7071

CONNECTICUT

Clean Harbors of Connecticut Inc. – (860) 583-3696

FLORIDA

Cavu Medical Products & Services LLC DBA Pharmatech Services – (813) 749-7113

Clean Harbors Florida LLC – (863) 519-6331

Express RX Returns – (954) 589-2386

Med Safe Solutions USA LLC – (239) 849-1315

PharmaLink – (800) 257-3527

RX Return Services – (727) 754-7848

Rx Reverse Distributors Inc. – (772) 388-1212

Woodfield Distribution, LLC – (561) 998-3885

GEORGIA

Burke Horton, Inc. D/B/A The Rx Exchange – (678) 306-1866

Danox Environmental Services Inc. – (404) 671-9163

Maximum Rx Credit – (770) 985-2136

Return Logistics – (912) 748-5100

ILLINOIS

Pharma Logistics – (847) 837-1224

Pharmaceutical Returns Services – (800) 215-5878 (Collector)

Qualanex, LLC – (800) 505-9291

INDIANA

Stericycle Inc. – (317) 860-1200 (Collector)

IOWA

National Pharmaceutical – (515) 252-7722

MASSACHUSETTS

Clean Harbors of Braintree Inc – (781) 380-7154

MICHIGAN

Drug & Laboratory Disposal Inc. – (269) 685-9824 (Collector)

Nortru LLC – (313) 824-5840

U S Industrial Technologies Inc. – (734) 462-4100

MINNESOTA

3M Drug Delivery Systems – (651) 733-2073

E Z Pharmacy Returns, LLC – (800) 440-0613

NEWMOA
states
marked w/ arrows

As of January 2019

DEA Registered Reverse Distributors



NEW JERSEY

Advanced RX Returns D/B/A Omega 2000 RX Returns – (201) 222-3800

NEW YORK

Ark Business Services Inc. Ark RX Returns Solutions – (347) 590-2779

Devos Ltd. DBA Guaranteed Returns – (631) 689-0191

Maks Pharma and Diagnostics Inc – (631) 270-1528

Medwiz Solutions LLC, Returns Division – (845) 624-8080

United RX Solutions – (844) 741-9718

NORTH CAROLINA

ALMAC Clinical Services, Inc. ALMAC Clinical Services LLC – (919) 479-8850

Clean Harbors Reidsville LLC – (336) 342-6106

Pharmaceutical Dimensions – (336) 664-5287

Trilogy Medwaste Southeast, LLC – (704) 865-7550

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

NEWMOA
states
marked w/ arrows

As of January 2019

SUBPART P REVERSE DISTRIBUTORS

* also on
DEA's list of RDs

HANDLER_NAME ▾	STATE ^
PERMA-FIX OF FLORIDA INC	FL
* PHARMALINK INC	FL
STERICYCLE SPECIALTY WASTE SOLUTIONS INC	FL
USECOLOGY TAMPA INC	FL
* RETURN LOGISTICS INTERNATIONAL CORP	GA
* NATIONAL PHARMACEUTICAL RETURNS INC	IA
CAPITAL HEALTH MEDICAL CENTER - HOPEWELL	NJ
NOVARTIS PHARMACEUTICALS CORP	NJ

CAPITAL HEALTH MEDICAL CENTER

- Capital Health Medical Center
 - 1 Capital Way Pennington, NJ
 - Notified as RD on February 28, 2020 as part of their BR
 - They appear to be a hospital, not an RD



NOVARTIS

- Novartis Pharmaceutical Corp
 - 23 Farinella Dr. East Hanover, NJ
 - Notified as RD on February 25, 2020 as part of their BR
 - Novartis is a pharmaceutical manufacturer, including of controlled substances (although not at this location)
 - Some manufacturers act as a final reverse distributor to verify accuracy by the reverse distributors
 - Potential problem: Novartis can not receive controlled substances without being registered with DEA as a reverse distributor

REVERSE LOGISTICS

Reverse
Logistics

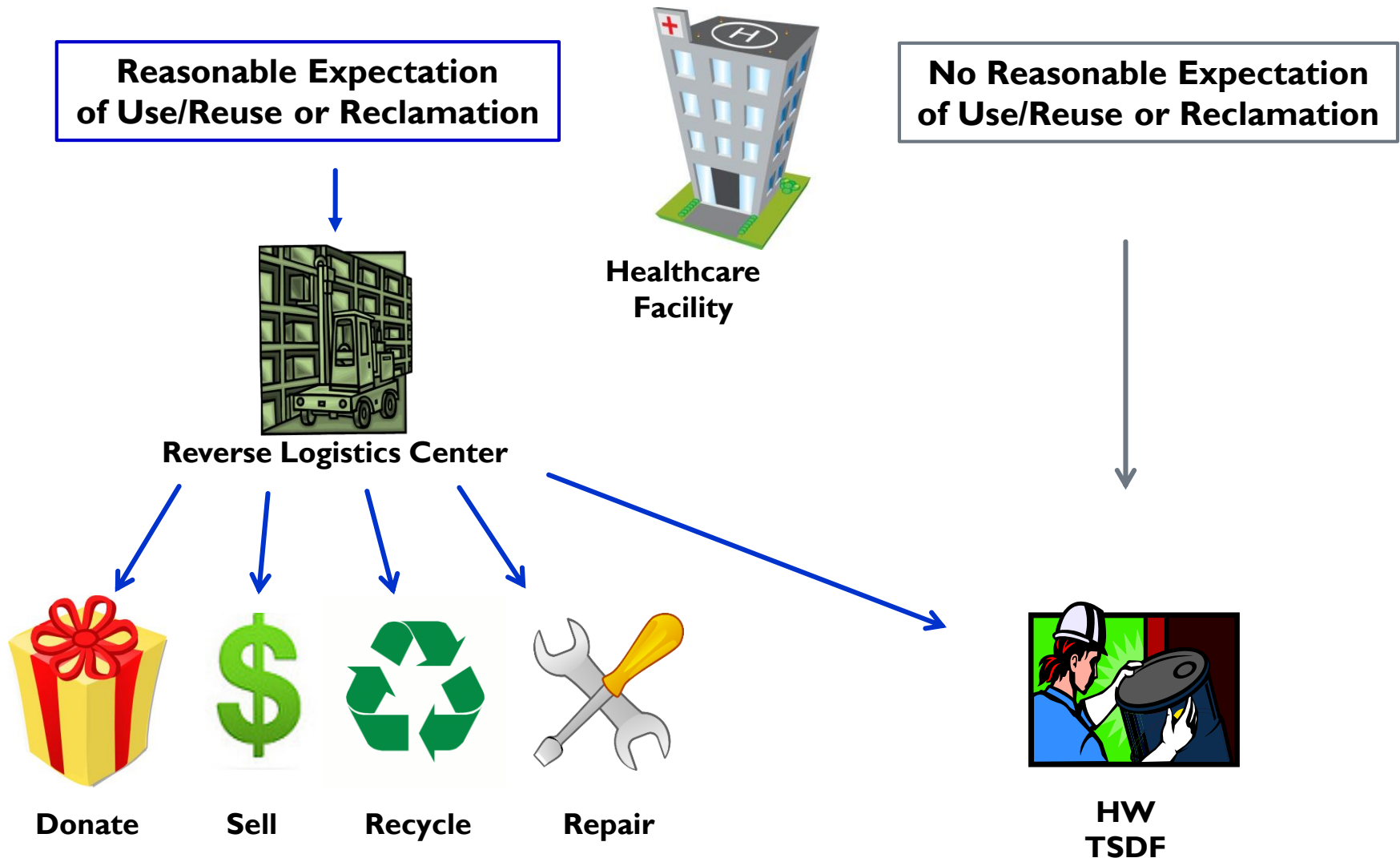
Everything
Else

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 Logistics of Unsold Retail Items & Non-Rx Pharms



REVERSE LOGISTICS POLICY: THEN AND NOW

THEN May 16, 1991 memo	NOW Pharmaceuticals Final Rule
<p>...to the extent that the materials involved are unused commercial chemical products with a <u>reasonable expectation</u> of being recycled in some way when returned, the materials are not considered as wastes...</p> <p>RCRA Online #11606</p>	<p>Nonprescription pharmaceuticals and other retail items that are sent through reverse logistics are not solid wastes at the retail store if they have a <u>reasonable expectation</u> of being legitimately use/reused (e.g., lawfully redistributed for their intended purpose) of reclaimed</p> <p>also see § 266.501(g)(2)</p>

REVERSE DISTRIBUTION v REVERSE LOGISTICS

Reverse Distribution	Reverse Logistics
Rx pharmaceuticals (OTC allowed)	
No redistribution occurs	
Rx pharmaceuticals sent to reverse distributors <u>are solid waste</u> at the healthcare facility	
In Part 266 Subpart P, which is <ul style="list-style-type: none">• Effective in non-authorized states August 21, 2019• Effective in authorized states when state adopts Subpart P	

REVERSE DISTRIBUTION v REVERSE LOGISTICS

Reverse Distribution	Reverse Logistics
Rx pharmaceuticals (OTC allowed)	Non-Rx pharmaceuticals <ul style="list-style-type: none"> e.g., OTCs & dietary supplements All other unsold retail items
No redistribution occurs	Redistribution sometimes occurs via: <ul style="list-style-type: none"> Donation Liquidation (secondary market)
Rx pharmaceuticals sent to reverse distributors <u>are solid waste</u> at the healthcare facility	Non-Rx pharmaceuticals and other unsold retail items sent to reverse logistics <u>are not solid waste</u> IF there is a reasonable expectation of legitimate use/reuse or reclamation
In Part 266 Subpart P, which is <ul style="list-style-type: none"> Effective in non-authorized states August 21, 2019 Effective in authorized states when state adopts Subpart P 	Newly codified in Part 266 Subpart P with respect to pharmaceuticals. But affirms existing policy <ul style="list-style-type: none"> Effective immediately federally Check with your state

REVERSE LOGISTICS: REGULATION VS POLICY

- Regulations: subpart P **codifies** existing policy with respect to OTC pharmaceuticals going through reverse logistics
- Reverse Logistics Policy: in the **preamble**, EPA reiterates existing policy with respect to non-pharmaceuticals going through reverse logistics
 - Not codified in the regulations
 - Excerpted Reverse Logistics Policy from preamble in a RCRA Online memo (RO # 14915)
 - Will states adopt this interpretation?



FAQS RE REVERSE DISTRIBUTION



QUESTION I

- I. Can a non-prescription pharmaceutical be sent to a reverse distributor?

QUESTION I - BACKGROUND

- EPA has become aware of two scenarios where nonprescription hazardous waste pharmaceuticals are sent to reverse distributors:
 - Retail facilities keep some nonprescription pharmaceuticals (e.g., Sudafed) behind the counter and everything behind the counter is managed together and sent to a reverse distributor even though they are not prescription pharmaceuticals
 - Some healthcare facilities (e.g., hospitals, clinics, etc.) only have contracts with reverse distributors, not with reverse logistics centers

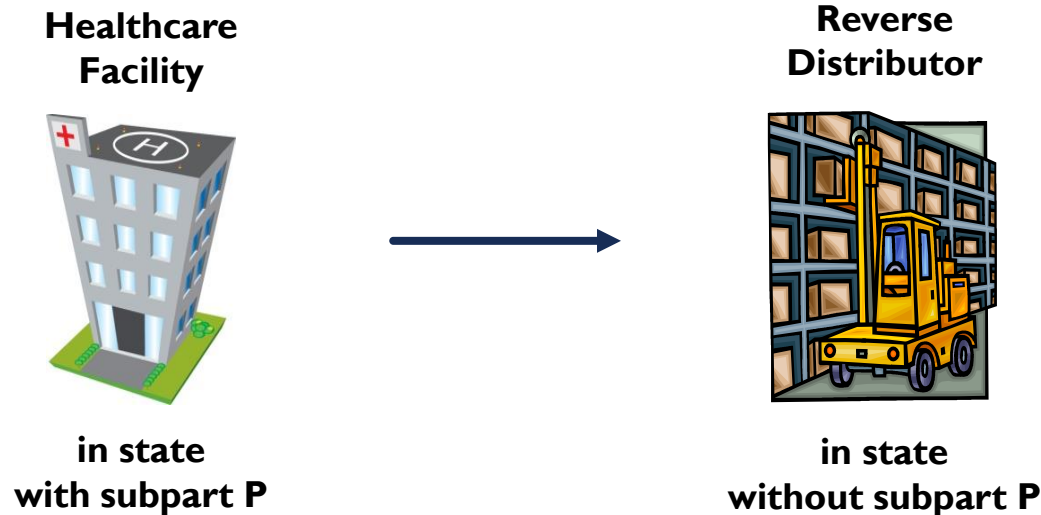
QUESTION I - ANSWER

EPA Answer: Yes. nonprescription pharmaceuticals can be sent to reverse distributors - with caveats -

- If a healthcare facility sends a nonprescription pharmaceutical to a reverse distributor, EPA considers this **over-management** as hazardous waste
- The nonprescription pharmaceuticals going to a reverse distributor must be managed as potentially creditable hazardous waste pharmaceuticals and
 - Have reasonable expectation of receiving manufacturer credit
 - Be in original manufacturer packaging
 - Be undispensed
 - Be unexpired or less than 1-yr past expiration

QUESTION 2

2. Can a healthcare facility that is in a state where part 266 subpart P is in effect send a potentially creditable hazardous waste pharmaceutical to a reverse distributor that is in a state where part 266 subpart P is not in effect?



QUESTION 2 - ANSWER

EPA Answer: Yes.

- The **healthcare facility** must comply with the applicable subpart P regulations for potentially creditable hazardous waste pharmaceuticals, including:
 - the shipping requirements in section 266.509 and
 - the recordkeeping requirements in section 266.503(e), including maintaining a record of delivery confirmation for each shipment to the reverse distributor
- The **reverse distributor** in this scenario is not subject to subpart P, but as a practical matter it would still need to comply with some portions of subpart P in order to ensure the healthcare facility can maintain compliance with subpart P, for example:
 - provide a delivery confirmation for shipments received from healthcare facilities

QUESTION 3

3. Is a reverse distributor required to issue manufacturer credit to a healthcare facility within 30 days of receiving a shipment of potentially creditable hazardous waste pharmaceuticals?

QUESTION 3 - ANSWER

EPA Answer

- No. The regulations do not specify a timeframe for issuing manufacturer credit
- The subpart P reverse distributor regulations specify a 30-day timeframe for **evaluating** the potentially creditable hazardous waste pharmaceuticals to determine whether or not they need to go to
 - another reverse distributor or
 - a TSDF



UNAUTHORIZED WASTE REPORTS



UNAUTHORIZED WASTE REPORTS

- Reverse distributors are in the business of providing manufacturer credit for unused pharmaceuticals
- Reverse distributors should be receiving only potentially creditable pharmaceuticals
- EPA was concerned that reverse distributors may receive wastes from healthcare facilities that they should not be getting
- The unauthorized waste report is intended to help minimize this practice by alerting the
 - Healthcare facility that made the mistake and
 - Regulators
- EPA developed the unauthorized waste report based on a similar provision for TSDFs that receive unmanifested hazardous waste

SHARING UNAUTHORIZED WASTE REPORTS

- Subpart P regulations require RDs to send unauthorized waste reports to
 - The healthcare facility that sent them the unauthorized waste
 - Their authorized state (or region)
- Subpart P regulations do not require the RD to send the report to the authorized state (or region) of the healthcare facility that sent the unauthorized waste
- How would the authorized state of the offending healthcare facility know that there is a potential problem?

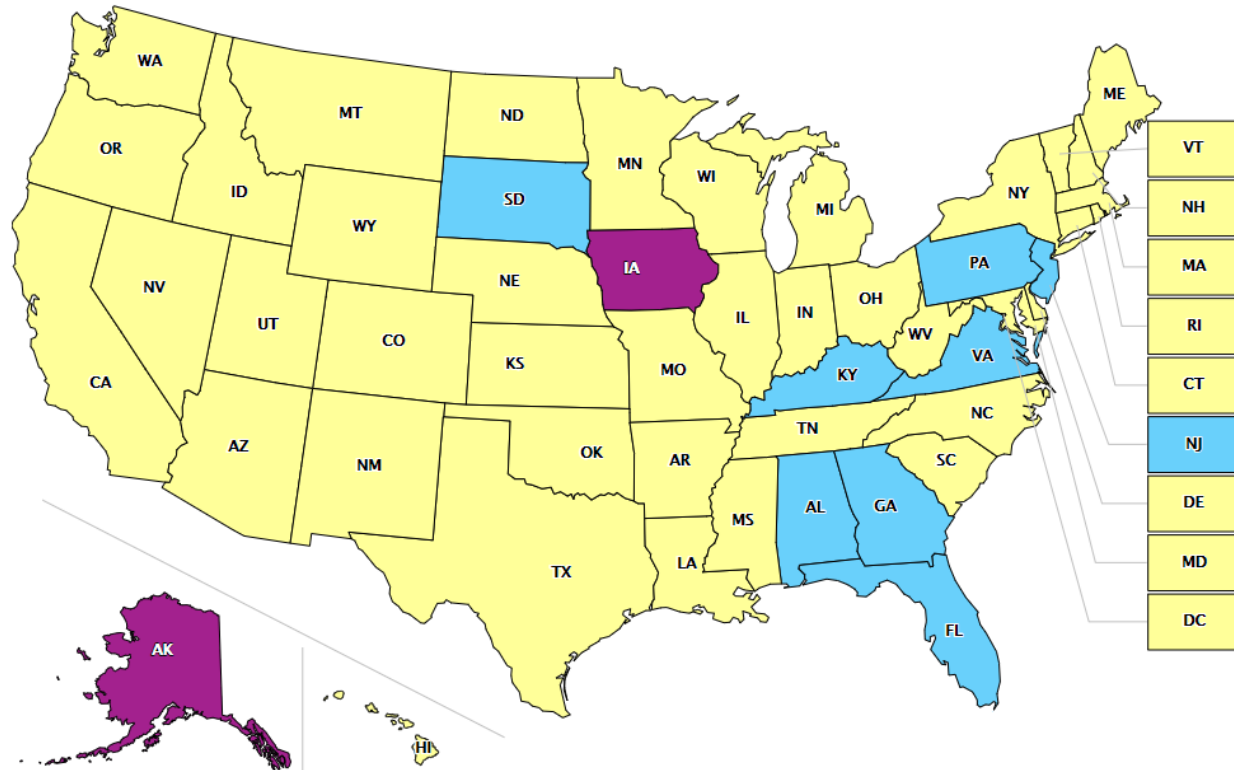
SHARING UNAUTHORIZED WASTE REPORTS

- We are developing a SharePoint site to share the unauthorized waste reports
 - RD sends unauthorized waste reports to authorized state (or region)
 - RD's authorized state emails reports to their Region
 - Region posts the reports on the SharePoint site in the state folder for the HCF that initiated the unauthorized shipment
 - Any authorized state or region can view the reports on the SharePoint site

RD → authorized state → Region → SharePoint

STATE ADOPTION OF PART 266 SUBPART P

Effective in:
Indian Country
4 Territories
11 States



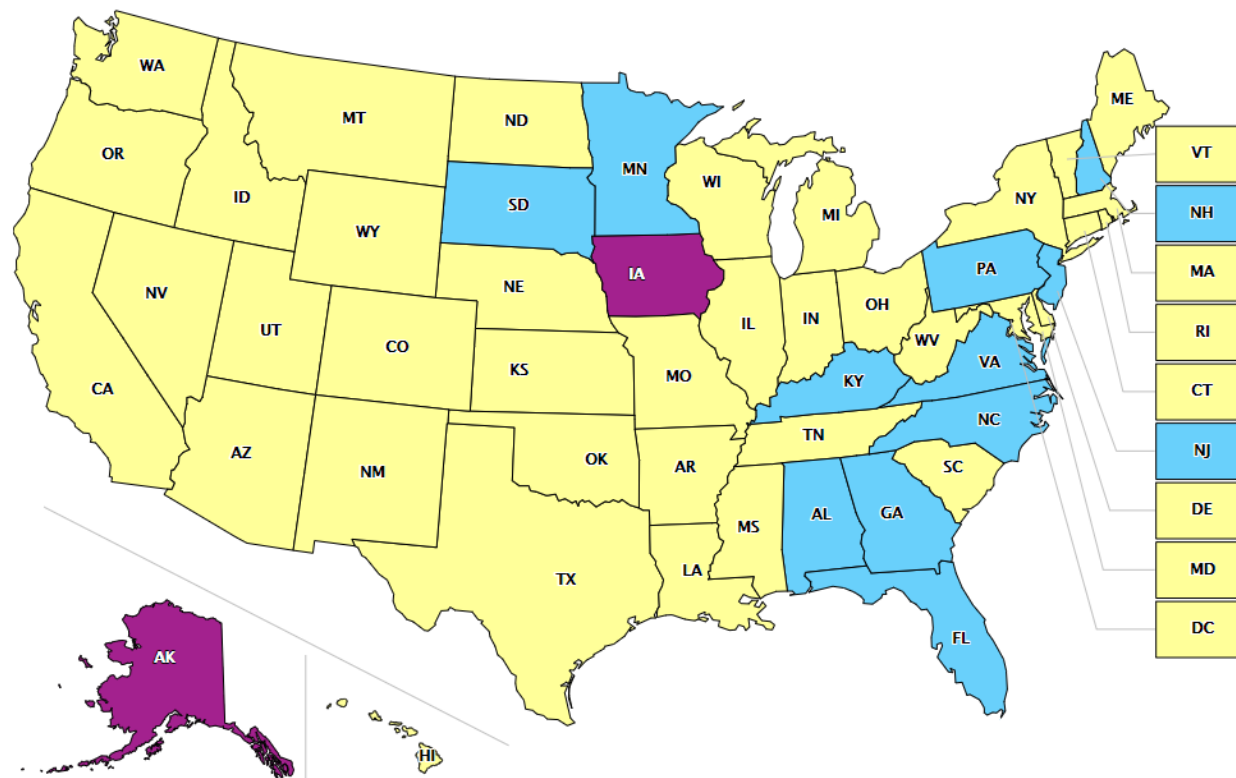
As of 5/11/20

American Samoa
Guam
Northern Mariana Islands
Puerto Rico
Virgin Islands

- Authorized
- Adopted
- Administered by EPA Region
- Neither Adopted nor Authorized

STATE ADOPTION OF NICOTINE AMENDMENT

Effective in:
Indian Country
4 Territories
15 States



As of 5/11/20

American Samoa
Guam
Northern Mariana Islands
Puerto Rico
Virgin Islands

- Authorized
- Adopted
- Administered by EPA Region
- Neither Adopted nor Authorized

RESOURCES FOR SUBPART P

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

Compliance

■ Guidance

- [EPA's Regulations on Reverse Distribution and Policy on Reverse Logistics \(RO # 14915\)](#)
- [Manifesting Non-Creditable Hazardous Waste Pharmaceuticals - New Four Character Code \(PDF\) \(2 pp, 2.09 MB, About PDF\) \(RO # 14919\)](#)
- [Memo Regarding Applicability of 40 CFR Part 266 Subpart P to Intermediate Care Facilities \(PDF\)\(8 pp, 1.29 MB, About PDF\) \(RO # 14917\)](#)
- [Frequent Questions](#)

■ Additional Resources

- [Webinar recording and presentation slides](#)
- [Where is this rule in effect?](#)
- [RCRA Retail Strategy](#)

CONTACT INFORMATION

- Kristin Fitzgerald Fitzgerald.Kristin@epa.gov
- Brian Knieser Knieser.Brian@epa.gov
- Jessica Young Young.Jessica@epa.gov