

Savvik Buying Group



Controlled Substance Mailback

Controlled Substances

DEFINITIONS

Controlled Substances

A drug or chemical whose manufacture, possession, or use is regulated by a government agency, such as the Drug Enforcement Agency (DEA)

The possession and disposal of such substances are highly regulated

Controlled Substance Schedules

Controlled substances are internationally categorized into “Schedules” (From a low of Schedule V to a high of Schedule I), which determines its potential for abuse or addiction.

- **Schedule V drugs:** low potential for abuse, such as cough suppressants w/ codeine
- **Schedule IV drugs:** less potential of abuse vs. schedule III drugs, examples are Midazolam, Ephedrine, Diazepam
- **Schedule III drugs:** low level narcotics, such as Vicodin, Tylenol w/ Codeine, Ketamine
- **Schedule II drugs:** narcotics, such as Oxycontin, Propofol, Percocet or Fentanyl
- **Schedule I drugs:** High potential for abuse & no accepted medical use, such as Heroin, LSD, Ecstasy

Consequences that generators will face for noncompliance.

The new EPA Subpart P standards have taken the US healthcare industry by storm –

- Reverse Distributors are operating under new standards that must be met. RD's can receive expired and unused pharmaceutical products. NO hazardous waste can be shipped and received.
- Effective nationally on the 21st August 2019, Subpart P regulations enacted by the Environmental Protection Agency (EPA)
- NO more disposing of pharmaceuticals in a sink. The sewer ban of controlled and hazardous waste pharmaceuticals is one of the most dramatic changes in healthcare waste regulations in this century.
- New RCRA Maximum Civil Penalty Level- RCRA hazardous waste rules, the maximum civil penalty will rise from \$37,500 per day, per violation to \$70,117 per day, per violation, a jump of over 50%.
- Landfilling of hazardous materials /wastes are a violation of regulation and subject to RCRA or DEA fines and/or imprisonment.

How does Subpart P affect Controlled Substances

Controlled Substances and RCRA hazardous controlled substances are exempt from RCRA regulations provided they meet the following criteria:

1. Not sewerred
2. Managed in compliance with DEA regulations
3. Destroyed by a method that the DEA has publicly deemed in writing to meet their non-retrievable standard, or...
4. Combusted at a permitted facility.

How does Subpart P affect Controlled Substances

- LQGs, SQGs and voluntary VSQGs must submit a one-time notification that they are operating under Subpart P on EPA form 8700-12 Site Identification Form.
- Failure to provide controlled substance and hazardous waste training for personnel both RCRA and DEA as appropriate.
- Failure to properly dispose of controlled substance and hazardous waste
- Failure to make controlled substance and hazardous waste determinations
- Failure to keep records of controlled and hazardous material determinations and formulary inventory reviews up to date.
- Failure to prepare controlled and hazardous waste manifests
- Failure to maintain records of controlled, hazardous materials & waste manifests
- Failure to properly mark controlled and hazardous waste containers for transportation as required by US DOT to TSDF's
- Failure to report controlled and hazardous waste minimization efforts on annual reports
- Failure to have a contingency plan for controlled and hazardous waste
- Specific labeling requirements for certain controlled and hazardous waste pharmaceutical containers
- DOT fines for not shipping in POPs packaging and standards.

ABOUT US



High Quality-Low Cost
Reverse Distribution
Pharmaceutical Waste Management

Founded in **2007** by Yafet Quashie and Jason Hime, Reliable Pharmaceutical Returns (RP Returns) located in **Nashville TN** was established to provide the most efficient, compliant, and cost-effective approach for reverse distribution, credit collections, and destruction of outdated and unwanted pharmaceutical drug products. RP Returns is committed to the highest standards of regulatory compliance, quality, and customer service.

RP Returns is a ...

- **Pharmaceutical reverse distribution and waste disposal company**
- **Licensed** by the Drug Enforcement Agency, multiple State Board of Pharmacies, Tennessee Department of Environment & Conservation, and US Environmental Protection Agency
- **Manage return of pharmaceuticals eligible for credit**, and properly dispose of **DEA CI-CV** controlled substances and non-hazardous and hazardous pharmaceuticals not eligible for credit.

Our customers located across the USA are ...

- Veterinarians
- Pharmacies, hospitals, clinics, doctor and dentist offices, acute care, long term care facilities
- EMTs, police and sheriff departments
- Manufacturers and contract packagers
- Wholesalers, distributors, GPO's, IDN's

RPR has capacity for small parcels to truckloads of returns while customizing services to the client's specifications

SERVICE AREA



High Quality-Low Cost
Reverse Distribution
Pharmaceutical Waste Management



Based in Nashville, TN

RP Returns maintains special permits and
licenses to service 7,000+ customers
located nationwide, including Alaska,
Hawaii, and Puerto Rico.

Pharmaceutical Waste Management

SOLUTIONS FOR OUR MEDICAL CUSTOMERS

Medical & healthcare offices need waste pharmaceutical services different from current solutions:



Higher volumes of unused and partially used pharmaceutical waste

Medical customers need access to higher volume disposal options other than what currently HealthFirst offers



Disposal of Controlled Substances

Medical and healthcare offices are more likely to have controlled substances than dental offices



Reimbursement

Credit Processing
On-site Processing
Audit Support Service
Inventory Service
Customer Portal
DEA CII-V Service
Dedicated Representative
Customer Support

Disposal Service

Waste-to-Energy
Fuel Blending
DEA CII-V Disposal
Hazardous Waste
Waste Profile Service
Witnessed Disposal
DOT Placards and Stickers
Secure Transportation

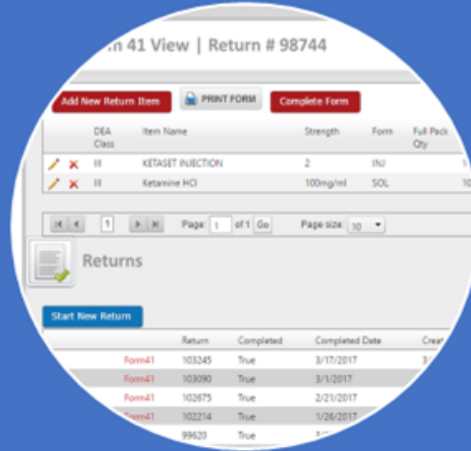
Documentation

Certificate of Destruction
Certificate of Recycle
Land Disposal Restriction
Pre-Printed BOL
Pre-Printed Manifest
Facility Specific Document
Customized Client Docs
24/7 Online Access



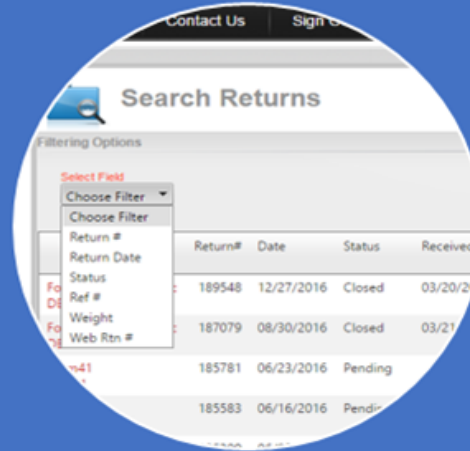
Access

Secure Portal
Multi Location
Multi User
Data Synchronization



Management

Service Request
Process Monitoring
Container Labeling
Carrier Scheduling



Reports

Audit Support
Certificate of Disposal
Waste Manifest
DEA Inventory

Controlled Substances

IDENTIFICATION

How to ID Controlled Substances

All controlled substance containers (Bottles or vials) will include a controlled substances icon (Big "C") with the schedule level within the icon.



Pharmaceutical Waste Management

REGULATORY COMPLIANCE



Drug Enforcement Administration (DEA)

21 CFR, Part 1317, Subpart A – Disposal of Controlled Substances by Registrants

“Any registered practitioner in lawful possession of a controlled substance in its inventory that desires to dispose of that substance shall”

- Destroy using an on-site method of destruction in presence of DEA agent or other authorized person
- Deliver to a reverse distributor’s registered location by common or contract carrier
- Request assistance from local DEA agent to dispose



Environmental Protection Agency (EPA)

Collecting and Disposing of Unwanted Medicines

Information for Hospitals, Pharmacies and other Businesses with Unwanted Medicines

“Healthcare facilities and healthcare-related businesses that generate pharmaceutical wastes are responsible for appropriately managing their wastes in accordance with all local, state and federal environmental regulations”

“Hospitals, pharmacies and other businesses generating pharmaceutical waste generally cannot use take-back programs or events to dispose of expired, unwanted or unused pharmaceuticals”

“EPA is currently recommending incineration as the preferred disposal method because we believe that incineration will address both environmental and diversion concerns”

Pharmaceutical Waste Management

CUSTOMER PROCESS FLOW

Easy Order Instructions

- www.boomerangpak.com
- Choose STORE, then NEW CUSTOMER
- Input company information and hit Register
- Once Registered, the system will take you to the Store to choose which Boomerang Pak and Quantity
- Include Coupon Code: Savvik2020 when checking out
- Once Boomerang Pak is ordered, you will receive a Welcome Email with Instructions, Username and Password to complete the pharmaceutical manifest.
- Customer Service – 1-888-361-8856

Product Contents

Example of the contents included in the 1 Gallon Box




- Return shipping box with UPS pre-paid shipping label
- Instructions packet
- Clear plastic bag (used for non-controlled pharmaceuticals)
- Opaque tamper proof sealable bag (used for DEA controlled substances)
- Security seal tape
- Product tracking label (RP Returns)

Pharmaceutical Recovery Services






CUSTOMER PROCESS FLOW

3 Paths to Pharmaceutical Recovery:






NON-DEA PHARMACEUTICALS

-  Fill out paper manifest (Included in box)
-  Include manifest with returned pharmaceuticals
-  Return ship in pre-paid pre-labelled return box

SCHEDULE III-V CONTROLLED SUBSTANCES

-  Access client portal with login credentials*
-  Identify and manifest all substances in interface
-  Print manifest (Form 41) and add with returned pharmaceuticals
-  Return ship in pre-paid pre-labelled return box
-  Mail (2) copies of Form 41 to local DEA Agent In Charge

SCHEDULE II CONTROLLED SUBSTANCES

-  Access client portal with login credentials*
-  ID and manifest all substances in interface. Schedule II drugs will initiate DEA 222 form.
- 
-  Return ship in pre-paid pre-labelled return box
-  Mail copy of form 41 and 222 form to local DEA Agent In Charge

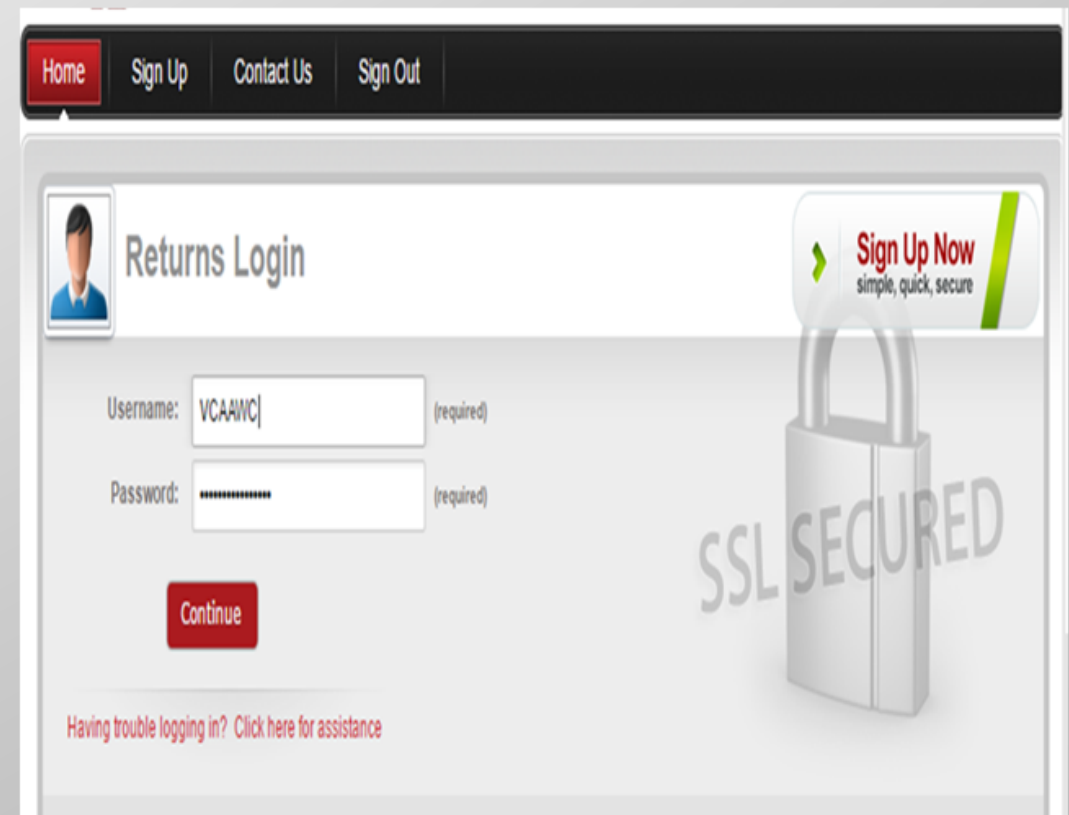
Pharmaceutical Waste Management

CUSTOMER PROCESS FLOW

Waste Processing

Customer will click on link and enter the username and password to enter the portal

- Customer will enter their DEA # to be identified in the portal
- Customer is now able to create a manifest of their pharmaceutical waste and process their return



The screenshot displays a web portal for 'Returns Login'. At the top, a navigation bar contains links for 'Home', 'Sign Up', 'Contact Us', and 'Sign Out'. The main content area features a login form with fields for 'Username' (containing 'VCAAWC') and 'Password' (masked with dots), both marked as '(required)'. A red 'Continue' button is positioned below the password field. To the right of the login form, there is a 'Sign Up Now' button with the text 'simple, quick, secure' underneath it. A large, semi-transparent 'SSL SECURED' watermark is overlaid on the right side of the page. At the bottom left, a link reads 'Having trouble logging in? Click here for assistance'.

Pharmaceutical Waste Management

CUSTOMER PROCESS FLOW


DEA Return Inventory Form


All customers must create an inventory form for all pharmaceuticals being sent to RP Returns

- DEA Form 41 must be completed for all controlled substances being returned
- NDC# or NADA# item search functionality
- Itemization of full or partial packages functionality



Schedule II Controlled Substances

A separate 222 form must be filled out for these substances. This form is physically mailed to customer prior to return shipment.

 Form 41 View | Return # 102570

 PRINT FORM Complete Form

DEA Class	Item Name	Strength	Form	Full Pack Qty	Full Pack PKG Size	P
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NDC# or NADA# Search:

NDC# or NADA#

DEA Class

Description

Strength



Form

Total Number of Full Packages

Full Package Size

Total Number of Partial Packages

Total Partial Package Piece Count

 SAVE NOW  CANCEL

Pharmaceutical Waste Management

CUSTOMER PROCESS FLOW

DEA Return Inventory Form

Customer prints out the completed forms once finished with inventory submission

- DEA Form 41 is added to the return box prior to packaging and shipping to RP Returns
- If Scheduled II drugs, customer waits to receive paperwork prior to return shipment

Customer returns shipment

- UPS return shipment label is printed from Client Returns Portal
- Customer tapes to box and gives to UPS for shipment to RP Returns



1443 Donelson Pike Nashville, TN 37217
Office: (615) 361-8856 Fax: (615) 361-8859
DEA #: RR0366422

Schedule Drug Inventory Form

COMPANY NAME:	Specialty Pharmaceutical Services			RETURN #:	182066
ADDRESS:	15 Ingram Blvd.	222 FORM #:	144367876, 144367877		
CITY:	La Vergne	STATE:	TN	ZIP:	37086
PRIMARY CONTACT:	Virginia Zamagne/Michelle Wyatt	PHONE:	(615) 287-0495	FAX:	
SHIPMENT I.D. #:	SC-1029215-CR	DEA LICENSE #:	RC0229965		

IMPORTANT! ALL SHIPMENTS MUST BE ACCOMPANIED BY A TRACKING NUMBER

# LINE	DEA CLASS	ITEM NAME	STRENGTH	FORM	FULL PACKAGE		PARTIAL PACKAGE			NDC #
					QTY	PKG SZ	QTY	COUNT	PKG SZ	
1	II	Magnacet 10mg/400mg Tablet 100ct.	10mg/400mg	TAB	0	100.00	4	100	100	59630-994-10
2	II	MAGNACET 7.5MG/400MG 100CT	7.5MG/400MG	TAB	0	100.00	1	30	100	68453-993-10
3	II	Methylin 10mg Chewable Tablet	10mg	TAB	0	100.00	1	10	100	59630-762-10
4	II	Methylin 10mg tab	10mg		0	100.00	1	40	100	68188-137-01
5	II	Methylin 10mg tab	10mg		0	100.00	1	100	100	68188-137-01
6	II	Methylin 5mg tab	5mg		0	100.00	1	40	100	68188-135-01

Savvik Buying Group– Promo Code Savvik2020

Boomerang PAK for **Non-HAZARDOUS Materials** and **DEA Controlled Substances**



Kit	Savvik Price Per Unit	Size	Weight Limit
Boomerang PAK Kit Item number: B112	\$104.05	4" x 8"	1 to 8 lbs
Boomerang Pak Kit Item number: B113	\$123.35	2 Gallon	15 lbs
Boomerang Pak Kit Item number: B114	\$239.85	5 Gallon	20 lbs
Boomerang Pak Kit Item number: B115	\$276.65	10 Gallon	30 lbs
Boomerang Pak Kit Item number: B116	\$304.10	15 Gallon	40 lbs

What is it?

The Boomerang Pak Kit returns system includes all that you'll need to confidently ship and dispose unwanted / outdated Rx and OTC pharmaceuticals compliantly, securely, and efficiently, including controlled substances (DEA Schedules II-V), ensuring their safe and secure destruction. In addition, the kit is designed for shipment of both controlled substances as well as regular (non-controlled) pharmaceutical drug products.

Who uses it?

Boomerang Pak is ideal for **VERY SMALL QUANTITY WASTE GENERATORS** of outdated or unwanted pharmaceuticals – i.e. veterinarians, pharmacies, doctor and dentist offices, long-term care and assisted living facilities, urgent care, dialysis centers, hospice care providers, EMT's, integrated delivery networks.

Boomerang PAK Kits include:

- Postage pre-paid, self-addressed, USPS approved returnable container.
- Two extra thick poly liners - one designated for controlled substances, a second for non-controlled drug products (both can be shipped in the same container).
- Tamper evident seal system
- Complete set of instructions to access to RP Returns web portal, handling of controlled substances, RP Returns contact names and phone numbers, email addresses.

Waste disposal includes:

- Tracking of and reporting of destruction via a customized landing page for customer to obtain Certificate of Destruction.
- Secure transportation.
- Reporting in compliance with DEA and EPA regulations.
- Witnessed incineration of pharmaceuticals.

Credit options:

- Boomerang Pak & Ship System through RP Returns, LLC has the capability to apply credits to your account, if eligible according to manufacturer's returns policy. The fee is 10% for all credits collected from manufacturers.

Additional 10% Discount for New Customers thru 2020

Mickey Parker
Business Development Manager
256-239-2824
Mickey.Parker@rpretains.com

Customer Service – 1-888-361- 8856



*RP Returns is a Small Business
Certified Socially and
Economically Disadvantaged (SEDB)
contractor in the 8(a) program*